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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K

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CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

Date of report (Date of earliest reported) August 30, 2019

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**BRICKELL BIOTECH, INC.**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or Other Jurisdiction  
of Incorporation)

000-21088  
(Commission File  
Number)

93-0948554  
(IRS Employer  
Identification No.)

5777 Central Avenue  
Suite 102  
Boulder, CO 80301  
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (720) 565-4755

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.01 per share	BBI	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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On August 31, 2019, the Delaware corporation formerly known as “Vical Incorporated” completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of June 2, 2019, as amended by Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated August 20, 2019, and as further amended on August 30, 2019 (the “**Merger Agreement**”), by and among Vical Incorporated (“**Vical**”), Brickell Biotech, Inc. (“**Brickell**”) and Victory Subsidiary, Inc., a wholly owned subsidiary of Vical (“**Merger Sub**”), pursuant to which Merger Sub merged with and into Brickell, with Brickell surviving the merger as a wholly owned subsidiary of Vical (the “**Merger**”). Additionally, on August 31, 2019, immediately after the completion of the Merger, the Company changed its name from “Vical Incorporated” to “Brickell Biotech, Inc.” (the “**Company**”). See Item 2.01 for additional information regarding completion of the Merger.

On August 31, 2019, in connection with, and prior to the consummation of the Merger, Vical effected a reverse stock split of its common stock, par value \$0.01 per share (“**Common Stock**”), at a ratio of 1-for-7 (the “**Reverse Stock Split**”). Unless otherwise noted herein, references to share and per-share amounts in this Current Report on Form 8-K give effect to the Reverse Stock Split. See Item 3.03 for additional information regarding the Reverse Stock Split.

## **Item 1.01 Entry into a Material Definitive Agreement**

### **Funding Agreement**

As previously announced, concurrently with the execution of the Merger Agreement, Brickell entered into a product funding agreement (the “**Funding Agreement**”) with NovaQuest Co-Investment Fund X, L.P. (“**NovaQuest**”) pursuant to which NovaQuest committed to provide up to \$25.0 million in near-term research and development funding to the Company (the “**Concurrent Financing**”). The Concurrent Financing was consummated immediately following the Merger, with \$5.6 million of the commitment to be paid to the Company on September 3, 2019 and the remaining portion of the commitment expected to be paid to the Company in quarterly reimbursements of 67% of invoiced research and development expenses incurred during the succeeding four fiscal quarters.

Upon receipt of marketing approval from the U.S. Food and Drug Administration (“**FDA**”) for sofpironium bromide, the Company will be obligated to make certain milestone payments to NovaQuest totaling \$37.5 million. Beginning in the fiscal quarter that is two years following the first commercial sale of sofpironium bromide as a registered pharmaceutical the Company will be required to make low-single digit royalty payments based on annual net sales worldwide (except for Japan, China and certain other Asian countries). If the Funding Agreement is terminated in certain circumstances, the Company will be required to pay NovaQuest \$25.0 million plus interest. However, in the event that the Company terminates its development program for sofpironium bromide for other specified reasons, including serious safety issues, a failure of the product’s Phase III studies, or the FDA’s unwillingness to approve the product, the Company will not be obligated to make any payments to NovaQuest.

In connection with the consummation of the Concurrent Financing, and as required by the Funding Agreement, the Company issued warrants to NovaQuest providing it with the right to purchase 241,225 shares of Common Stock at an exercise price of \$10.36 (the “**NovaQuest Warrants**”) and entered into a Registration Rights Agreement with NovaQuest (“**Registration Rights Agreement**”).

The foregoing descriptions of the Funding Agreement and the NovaQuest Warrants are not complete and are subject to and qualified in their entirety by reference to such agreement and warrants, copies of which are attached to this filing as Exhibit 10.1 and Exhibit 4.1, respectively, and are incorporated herein by reference.

### **License Agreements**

Brickell previously entered into various material license and collaboration agreements with universities and other research-related entities for the exclusive right to commercially develop, produce, manufacture, use and sell certain

products in certain geographies or to out-license for future development and commercialization certain of Brickell's current and future product candidates. Such material license and collaboration agreements are summarized below.

#### ***Kaken Collaboration Agreement***

In March 2015, and as later amended, Brickell entered into a license and collaboration agreement with Kaken Pharmaceutical, Co., Ltd. ("**Kaken**") (the "**Collaboration Agreement**"). Pursuant to the Collaboration Agreement, Brickell granted Kaken an exclusive right to develop, manufacture and commercialize the Company's sofipirionium bromide compound, a topical anticholinergic, in Japan and certain other designated Asian countries (the "**Territory**"). In exchange, Kaken paid Brickell an upfront, non-refundable payment.

Pursuant to the amended Collaboration Agreement, Kaken has final decision-making authority for the overall regulatory, development and commercialization strategy for sofipirionium bromide, as well as for market access activities, pricing and reimbursement activities, promotion, distribution, packaging, sales and safety and pharmacovigilance for this product in the Territory. The Collaboration Agreement further provides that Kaken will be responsible for funding all development and commercial costs for the program in the Territory and, until such time, if any, as Kaken elects to establish its own source of supply of drug product, Kaken can purchase product supply from the Company to perform all non-clinical studies, and Phase I and Phase II clinical trials in Japan at cost. Kaken is also required to enter into negotiations with the Company, to supply the Company, at cost, with clinical supplies to perform Phase III clinical trials in the United States.

The foregoing description of the Collaboration Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.2 hereto and is incorporated herein by reference.

#### ***Kaken ROFN Agreement***

In October 2017, Brickell entered into a right of first negotiation agreement (the "**ROFN Agreement**") with Kaken. Pursuant to the ROFN Agreement, if the Company conducts and completes an initial proof of concept for clinical trials for certain products in the pipeline, Kaken will have a first right, at Kaken's option, to negotiate with the Company for an exclusive license to develop, manufacture, have manufactured and commercialize the covered product(s) in Japan and to manufacture and have manufactured the Company's products outside of Japan for sale within Japan.

The foregoing description of the ROFN Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.3 hereto and is incorporated herein by reference.

#### ***Bodor License Agreement***

In December 2012, Brickell entered into a license agreement with Bodor Laboratories, Inc. ("**Bodor**") (the "**Bodor License Agreement**") for a worldwide, exclusive license to develop, manufacture, market, sell and sublicense technology products containing the proprietary compound sofipirionium bromide, based upon the patents referenced, in the agreement, with a field of use, limited to the treatment of hyperhidrosis and excessive sweating. In exchange for such rights, Brickell paid Bodor an upfront payment upon execution of the license and the Company is required to pay Bodor: (i) half of all royalties received from covered sales in Asia; (ii) a low to mid-single digit royalty on all covered sales of products anywhere outside of Asia by the Company; (iv) a low to mid-single digit royalty on all sales of products by sub-licensees, plus a percentage in the event such sub-licensee patent royalty rate exceeds a certain threshold percentage; (v) additional regulatory and sales milestone payments commencing at the completion of a Phase 2 study (completed); and (vi) certain sublicensing fees. In addition, the license agreement imposes various diligence, milestone, royalty, insurance and other obligations on the Company. If the Company fails to comply with

certain of these obligations, Bodor may have the right to terminate the license, in which event the Company may not be able to develop or market sofipironium bromide for its intended use.

The foregoing description of the Bodor License Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.4 hereto and is incorporated herein by reference.

#### ***UABRF License Agreement***

In June 2012, Brickell entered into a license agreement with the UAB Research Foundation (“**UABRF**”) (“**UABRF License Agreement**”) for a worldwide, exclusive license to manufacture, market, sell and sublicense technology products containing a novel compound for the treatment of skin conditions known to be responsive to retinoid agents based upon the patents referenced in the agreement with a field of use limited to all dermatological indications. In exchange for such rights, Brickell paid UABRF an upfront payment upon execution of the license and the Company is required to pay UABRF: (i) a low-single digit royalty on all sales of products anywhere in the world by the Company and its sub-licensees; (ii) additional regulatory and sales milestone payments commencing at the successful completion of a Phase 2 study; and (iii) certain sublicensing fees. In addition, the Company is responsible for the payment of future expenses for filing, prosecuting and maintaining licensed technologies and for any new patents that the Company intends to file, prosecute and maintain. The license agreement also imposes various diligence, milestone, royalty, insurance and other obligations on the Company. If the Company fails to comply with certain of these obligations, UABRF may have the right to terminate the license, in which event the Company may not be able to develop or market the covered compound for its intended use.

The foregoing description of the UABRF License Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.5 hereto and is incorporated herein by reference.

#### ***Manchester License Agreement***

In April 2011, Brickell entered into a license agreement with the University of Manchester (“**Manchester**”) (“**Manchester License Agreement**”) for a worldwide, exclusive license to manufacture, market, sell and sublicense a novel compound with anti-inflammatory properties derived from the human protein thioredoxin, based upon certain patents, with a field of use limited to all dermatological indications. The Manchester License Agreement imposes various diligence, milestone, royalty, payment, insurance and other obligations on the Company. If the Company fails to comply with certain of these obligations, Manchester may have the right to terminate the license, in which event the Company may not be able to develop or market the covered compound for its intended use.

The foregoing description of the Manchester License Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.6 hereto and is incorporated herein by reference.

#### ***NYU License Agreement***

In November 2015, Brickell entered into a license agreement with New York University (“**NYU**”) (“**NYU License Agreement**”) for a worldwide, exclusive worldwide license to manufacture, market, sell and sublicense certain assets for pharmaceutical development, involving a series of novel acid-related orphan nuclear receptor gamma inhibitors, initially targeting the topical treatment of psoriasis. The NYU License Agreement imposes various diligence, milestone, royalty, payment, insurance and other obligations on the Company. If the Company fails to comply with certain of these obligations, NYU may have the right to terminate the license, in which event the Company may not be able to develop or market the covered compound for its intended use.

The foregoing description of the NYU License Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.7 hereto and is incorporated herein by reference.

#### ***Orca Purchase Agreement***

In November 2015, Brickell entered an asset purchase agreement with Orca Pharmaceuticals LLC (“**Orca**”) (“**Orca Purchase Agreement**”) to acquire certain compounds, assigned technology, inventory and patent files. One of the acquired assets was a license agreement between Orca and New York University, which granted Orca an exclusive license to manufacture, market, sell and sublicense technology products based upon certain specified patents. In exchange for such rights, Brickell paid Orca an upfront payment and the Company is required to pay Orca: (i) a low-single digit royalty on net sales of products anywhere in the world by the Company and its sub-licensees; and (ii) additional regulatory and sales milestone payments. In addition, the Orca Purchase Agreement imposes various diligence, milestone, royalty, payment, insurance and other obligations on the Company. If the Company fails to comply with these obligations, Orca may have the right to terminate the agreement, in which event the Company may not be able to develop or market the covered compounds for their intended uses.

The foregoing description of the Orca Purchase Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.8 hereto and is incorporated herein by reference.

#### ***Panmira Pharmaceuticals LLC Asset Purchase Agreement***

In January 2015, Brickell executed an asset purchase agreement with Panmira Pharmaceuticals, LLC (“**Panmira**”) (“**Panmira Purchase Agreement**”). Under the Panmira Purchase Agreement, Brickell purchased all of Panmira’s inventory, patents and patent applications and files, certain technology, data and compounds for topical treatment of dermatological conditions. The Panmira Purchase Agreement imposes various obligations on the Company. If the Company fails to comply with certain of these obligations, Panmira may have the right to terminate the agreement, in which event the Company may not be able to develop or market the covered assets for their intended uses.

The foregoing description of the Panmira Purchase Agreement is not complete and is subject to and qualified in its entirety by reference to such agreement, a copy of which is attached to this filing as Exhibit 10.9 hereto and is incorporated herein by reference.

#### **Item 2.01 Completion of Acquisition**

On August 31, 2019, Vical, Brickell and the Merger Sub consummated the transaction contemplated by the Merger Agreement, and Vical issued to Brickell’s securityholders an aggregate of 4,442,692 shares of Common Stock in accordance with the terms and conditions set forth in the Merger Agreement. Following the consummation of the Merger, the business previously conducted by Brickell became the business conducted by the Company, which now is the business of being a clinical-stage pharmaceutical company focused on developing innovative and differentiated prescription therapeutics for the treatment of debilitating dermatological conditions.

The Company’s pipeline consists of potential novel therapeutics for hyperhidrosis (the targeted indication for its lead asset), cutaneous T-cell lymphoma, psoriasis, and other prevalent dermatological unmet conditions. The Company believes that its portfolio of product candidates target significant market opportunities where innovative therapies are needed. The Company’s executive management team and board of directors (described in Item 5.02 of this Current Report on Form 8-K) bring extensive experience in product development and global commercialization, having served in leadership roles at large global pharmaceutical companies and biotechs that have developed and/or launched successful products, many in areas of unmet need and achieving blockbuster status (e.g. Prozac® for depression, Cialis® for erectile dysfunction, Gemzar® for various cancers, other). The Company’s strategy is to leverage this

experience to develop, in-license, acquire and commercialize patented, innovative products that it believes can be successful in the currently underserved (and underinvested) dermatology global marketplace.

The Company's pivotal Phase 3-ready clinical-stage product candidate, sofpironium bromide, is a new, proprietary molecular entity and "soft" drug that belongs to a class of medications called anticholinergics. Brickell and its development partner for Asia, Kaken, conducted 19 Phase 1 and Phase 2 clinical studies of sofpironium bromide that encompass over 1,200 subjects. These studies have evaluated the safety, tolerability, pharmacokinetics (PK), and efficacy of sofpironium bromide formulated and delivered as a gel in adult and pediatric primary axillary hyperhidrosis patients and healthy adult subjects. In addition, Kaken reported positive pivotal Phase 3 results, achieving statistical significance on all primary and secondary endpoints, in its clinical study conducted in Japan in March 2019 to achieve a Japanese registration. Based on the positive results achieved from three completed Phase 2b clinical trials (two in the U.S. and one in Japan by Kaken), Kaken's recently completed pivotal Phase 3 clinical trial in subjects with primary axillary hyperhidrosis in Japan, as well as the Company's ongoing fully-enrolled Phase 3 long-term safety study in 300 subjects with primary axillary hyperhidrosis in the United States, the Company intends to initiate two pivotal Phase 3 clinical trials in approximately 450 subjects per study with primary axillary hyperhidrosis in the United States currently targeted for the fourth quarter of 2019 with the goal of preparing and submitting a New Drug Application to the FDA following release of the trial results.

In connection with the Merger, the name of the Company was changed to "Brickell Biotech, Inc." The Company's common stock will be listed on The Nasdaq Capital Market, on a post-split basis (giving effect to the Reverse Stock Split) under the new name on September 3, 2019. The trading symbol will also change on that date from "VICL" to "BBI." The Common Stock will be represented by a new CUSIP number: 10802T 105.

Immediately following the consummation of the Merger, there were 7,810,773 shares of Common Stock issued and outstanding, with Brickell's former securityholders beneficially owning approximately 57% of the outstanding shares of Common Stock and Vical's former securityholders beneficially owning approximately 43% of the outstanding shares of Common Stock.

### **Item 3.02 Unregistered Sales of Securities**

Pursuant to the Merger Agreement, Vical issued 4,442,692 shares of Common Stock to Brickell's former securityholders on August 31, 2019. The nature of the transaction and the nature and amount of consideration received by Brickell's securityholders are described in Item 2.01 of this Form 8-K, which is incorporated by reference into this Item 3.02. Such issuances were exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, and the rules promulgated thereunder.

On August 31, 2019, in connection with the consummation of the Funding Agreement, the Company issued the NovaQuest Warrants. Such issuance was exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, and the rules promulgated thereunder.

### **Item 3.03 Material Modification to Rights of Security Holders**

On August 30, 2019, Vical's stockholders approved the Reverse Stock Split. As a result of the Reverse Stock Split, the number of issued and outstanding shares of Common Stock was reduced to a smaller number of shares, such that every 7 shares of Common Stock held by a stockholder immediately prior to the Reverse Stock Split were combined and reclassified into one share of Common Stock after the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split.

The Reverse Stock Split had no effect on the par value of the Common Stock or authorized but unissued shares of preferred stock. Immediately after the Reverse Stock Split, each stockholder's percentage ownership interest in Vical and proportional voting power remained unchanged.

A summary of the changes made to the Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws is included in Item 5.03 of this Current Report on Form 8-K, which is incorporated by reference into this Item 3.03.

#### **Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangement of Certain Officers**

In connection with the consummation of the Merger, each of Dr. R. Gordon Douglas, Richard Beleson, Robert Merton, George Morrow and Thomas Shenk resigned from the Company's board of directors and any respective committee membership of the Company's board of directors. The resignations of such directors were not the result of any disagreement with the Company relating to the Company's operations, policies or practices.

In accordance with the Merger Agreement, the Company's board of directors (and its committees) and executive officers were reconstituted to include the following directors and executive officers:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Reginald L. Hardy	62	Co-Founder and Chairman of the Board (Class III)
George Abercrombie	64	Director (Class I)
William Ju, M.D.	62	Director (Class II)
Dennison T. Veru	58	Director (Class II)
Vijay B. Samant	66	Director (Class I)
Gary A. Lyons	67	Director (Class III)
Robert B. Brown	58	Chief Executive Officer and Director (Class III)
Andrew D. Sklawer	36	Co-Founder, Chief Operating Officer and Secretary
R. Michael Carruthers	62	Chief Financial Officer
Adam Levy	41	Chief Business Officer
Deepak Chadha	49	Chief Research & Development Officer
Jose Breton	30	Controller and Chief Accounting Officer
David R. McAvoy	57	General Counsel, Chief Compliance Officer and Assistant Secretary

Class III directors have a term expiring in 2019, Class I directors have a term expiring in 2020 and Class II directors have a term expiring in 2021.

Dennison Veru is chairperson of the Audit Committee, and George Abercrombie and Vijay Samant are members. Reginald Hardy is chairperson of the Compensation Committee, and Dennison Veru and Gary Lyons are members. George Abercrombie is chairperson of the Nominating and Corporate Governance Committee, and Gary Lyons and William Ju are members.

#### **Board of Directors**

##### ***Reginald L. Hardy, Co-Founder and Chairman of the Board***

Mr. Hardy has over 30 years of experience in serving as the Chief Executive Officer and/or the President for publicly-traded and privately-held pharmaceutical companies. Prior to co-founding Brickell and serving as its Chief Executive Officer from inception in 2009 through 2018, Mr. Hardy was the co-founder and President of Concordia Pharmaceuticals, Inc., an oncology drug development company acquired by Kadmon Corporation in 2011. Mr. Hardy was co-founder and served as president of SANO Corporation, a pharmaceutical company focused on the development of novel transdermal drug delivery systems that was acquired by Elan Corporation in 1998, from 1992 to 1998. Prior to SANO, Mr. Hardy served as the president of the generics group at IVAX Corporation, a pharmaceutical

company focused on the development and manufacture of medicines for pain, respiratory disease, oncology and women's health. Mr. Hardy has also held various corporate roles with Hoechst-Roussel Pharmaceuticals, Inc. and Key Pharmaceuticals, Inc. Mr. Hardy earned his B.S. degree in pharmacy from the University of North Carolina–Chapel Hill and M.B.A. from UNC–Greensboro.

***George B. Abercrombie, Director***

Mr. Abercrombie served as Senior Vice President and Chief Commercial Officer of Innoviva, Inc., a royalty management company focused on respiratory assets partnered with Glaxo Group Limited from 2014 to 2018. Mr. Abercrombie joined the Brickell Board of Directors in 2010. Mr. Abercrombie served as the President and Chief Executive Officer of Hoffmann-La Roche, Inc. from 2001 to 2009 where he was responsible leading Roche's North American Pharmaceutical Operations including the United States and Canada. Prior to joining Roche, Mr. Abercrombie served as Senior Vice President of U.S. Commercial Operations at Glaxo Wellcome Inc, with responsibilities encompassing pharmaceutical sales and marketing, electronic commerce, the U.S. managed care system, disease management, business planning and development, and late-stage clinical drug studies. He joined Glaxo Wellcome as Vice President and General Manager of the Glaxo Pharmaceuticals Division in 1993 following 10 years at Merck & Co., Inc., where he held a broad range of positions in sales, marketing, executive sales management and business development. Mr. Abercrombie serves on the Boards of Directors of Biocryst Pharmaceuticals, Hessian Pharmaceuticals, and the North Carolina GlaxoSmithKline Foundation. As an Adjunct Professor at Duke University's Fuqua School of Business, he teaches second year MBA candidates in Fuqua's Health Sector Curriculum. Mr. Abercrombie received a B.S. degree in Pharmacy from the University of North Carolina–Chapel Hill. He also earned an M.B.A. from Harvard University.

***William Ju, Director***

Dr. Ju is a board-certified dermatologist and has over 20 years of biopharmaceutical experience in a wide variety of therapeutic areas, including dermatology. Since 2012, Dr. Ju has served as the President and a Founding Trustee of Advancing Innovation in Dermatology, Inc., a not-for-profit organization focused on the development of new dermatologic solutions for patients and healthcare providers. Dr. Ju joined the Brickell Board of Directors in 2014. Dr. Ju has served as President and Chief Executive Officer of Follica, Inc., a biotechnology company that develops a treatment system for hair loss in adults, from 2009 to 2012 and Chief Operating Officer at PTC Therapeutics, Inc, a pharmaceutical company focused on the discovery, development and commercialization of medicines for the treatment of rare disorders from 2003 to 2009. In addition, he has held executive positions at Pharmacia Corporation/Pfizer, Inc. Merck & Co., Inc., and Hoffmann-La Roche, Inc. in a broad spectrum of product development functions. Dr. Ju served as project leader for SUTENT<sup>®</sup>, introduced CANCIDAS<sup>®</sup> into humans, and was part of the product development teams for CRIXIVAN<sup>®</sup> and TRANSLARNA<sup>™</sup>. Dr. Ju began his pharmaceutical career at Hoffmann-La Roche where he was a clinical leader for the development of dermatology compounds. Dr. Ju received his M.D. from the University of Pennsylvania School of Medicine and his A.B. from Princeton University.

***Dennison (Dan) T. Veru, Director***

Mr. Veru has served as Chief Investment Officer and Co-Chairman of Palisade Capital Management, an independent asset management firm, since 2000. Mr. Veru has oversight responsibilities for all the investment strategies at Palisade Capital Management involving publicly traded securities. Mr. Veru joined the Brickell Board of Directors in 2014. From 1992 through 1999, Mr. Veru was the President and Director of Research at Awad Asset Management and helped oversee the firm's growth. Prior to Awad Asset Management, Mr. Veru worked at Drexel Burnham Lambert and later at Smith Barney Harris Upham where he held a variety of analytical roles. In addition to his professional responsibilities, Mr. Veru is a member of the Board of Overseers of the St. Lukes and Roosevelt Hospital, a member of the finance committee of the Dwight-Englewood School, and a member of the board of directors of the McCarton School for Autistic Children. Mr. Veru graduated from Franklin & Marshall College. Mr. Veru's public company investment experience provides him with the qualification and skill to serve on the Company's board of directors.

***Vijay B. Samant, Director***

Mr. Samant served as President and Chief Executive Officer of Vical since November 2000. Prior to joining Vical, he had 23 years of diverse U.S. and international sales, marketing, operations, and business development experience with Merck. From 1998 to 2000, he was Chief Operating Officer of the Merck Vaccine Division. From 1990 to 1998, he served in the Merck Manufacturing Division as Vice President of Vaccine Operations, Vice President of Business Affairs and Executive Director of Materials Management. Mr. Samant holds a master's degree in management studies from the Sloan School of Management at MIT, a master's degree in chemical engineering from Columbia University, and a bachelor's degree in chemical engineering from the University of Bombay, University Department of Chemical Technology. Mr. Samant was a member of the board of directors of AmpliPhi Biosciences Corporation from 2015 to 2019, a member of the board of directors of Raptor Pharmaceutical Corporation from 2011 to 2014, and a member of the board of directors for BioMarin Pharmaceutical Inc. from 2002 to 2004. Mr. Samant was a Director of the Aeras Global TB Vaccine Foundation from 2001 to 2010, a member of the Board of Trustees for the National Foundation for Infectious Diseases from 2003 to 2012, and a member of the Board of Trustees for the International Vaccine Institute in Seoul, Korea from 2008 to 2012.

***Gary A. Lyons, Director***

Mr. Lyons held various positions with Neurocrine Biosciences, Inc., a biopharmaceutical company, for 16 years through January 2008, including President, Chief Executive Officer and member of the board of directors. From 1983 to 1993, Mr. Lyons held various executive positions at Genentech, Inc., a biotechnology company, including Vice President of Business Development, Vice President of Sales, and Director of Sales and Marketing. Mr. Lyons presently serves as a member of the board of directors of Neurocrine Biosciences, Inc. and Novus Therapeutics, Inc. (Nasdaq: NVUS) and is chairman of the board of directors of Rigel Pharmaceuticals, Inc. and Retrophin, Inc., all of which are publicly held biotechnology companies. In addition, Mr. Lyons served previously on the board of directors of PDL BioPharma, Facet Biotech Corporation, KaloBios Pharmaceuticals, Inc. and NeurogesX, Inc. Mr. Lyons holds a bachelor's degree in marine biology from the University of New Hampshire and an M.B.A. degree from Northwestern University, J.L. Kellogg Graduate School of Management.

***Robert B. Brown, Chief Executive Officer and Director***

Mr. Brown joined Brickell as its Chief Executive Officer and Director in January 2019 after having spent over 30 years at Eli Lilly and Company, where he most recently served as the Chief Marketing Officer and Senior Vice President of marketing from 2009 through 2018. As Chief Marketing Officer, Mr. Brown was responsible for building and leading marketing capabilities across Eli Lilly and Company's pharmaceutical business units, including diabetes, oncology, emerging markets and Lilly-BioMedicines, a business area focused on treatments for debilitating diseases. Prior to his role as Chief Marketing Officer, Mr. Brown held the position of Vice President and Chief Marketing Officer for Lilly USA from 2007 to 2009, in which he partnered with the business units to ensure Eli Lilly and Company continued to develop industry leading marketing capabilities, streamline and improve marketing processes, and transform marketing by building a consumer marketing center of excellence. From 2003 to 2007, Mr. Brown was the executive director of marketing for the Intercontinental region, including responsibility for Europe. As the head marketer for Eli Lilly and Company's international operations, Mr. Brown was responsible for the marketing of all Eli Lilly and Company's products outside the United States. Mr. Brown joined Eli Lilly and Company in 1985, after receiving a B.S. in economics from DePauw University and a M.S. in business administration from Indiana University. Mr. Brown currently serves on the board of trustees of Franklin College.

**Executive Officers**

***Andrew D. Sklawer, Co-Founder, Chief Operating Officer and Secretary***

Mr. Sklawer has served as Brickell's Chief Operating Officer and Secretary since its inception in 2009 and is one of its founders. Prior to co-founding Brickell, Mr. Sklawer served as the Head of Operations at Concordia

Pharmaceuticals, Inc., an oncology drug development company that was acquired by Kadmon Corporation in 2011. Prior to joining Concordia, Mr. Sklawer held various positions at Verid, Inc., a developer of security technology prior to its acquisition by EMC Corporation. Mr. Sklawer holds a B.A. in marketing from the University of Florida and earned his M.B.A. from the University of Miami. Mr. Sklawer currently serves as a board member for StartUp FIU, a Florida International University platform that supports researchers, inventors, innovators, and entrepreneurs to conceive, launch, and scale solutions, is a member of the Advisory Committee of Advancing Innovation in Dermatology Accelerator Fund and is a board member of the Colorado BioScience Association.

***R. Michael Carruthers, Chief Financial Officer***

Mr. Carruthers has served as Brickell's Chief Financial Officer since 2017. He has over 20 years of experience serving as the Chief Financial Officer for publicly-traded pharmaceutical companies. Mr. Carruthers previously served as Interim President of Nivalis Therapeutics (Nasdaq: NVLS), a pharmaceutical company that focuses on the discovery and development of product candidates for cystic fibrosis, beginning in January 2017 until August 2017 and Chief Financial Officer and Secretary since February 2015. From 1998 to 2015, he served as Chief Financial Officer for Array BioPharma (Nasdaq: ARRY), a biopharmaceutical company that focuses on the discovery, development, and commercialization of small molecule drugs to treat patients with cancer and other diseases. Prior to this, his professional experience included serving as Chief Financial Officer of Sievers Instrument, treasurer and controller for the Waukesha division of Dover Corporation and accountant with Coopers & Lybrand. Mr. Carruthers received a B.S. in accounting from the University of Colorado and a M.B.A. from the University of Chicago.

***Adam Levy, Chief Business Officer***

Mr. Levy has served as Brickell's Chief Business Officer since 2019. Prior to joining Brickell, Mr. Levy served as Chief Business Officer at miRagen Therapeutics, a clinical-stage biopharmaceutical company discovering and developing proprietary RNA-targeted therapies with a specific focus on microRNAs and their role in diseases where there is a high unmet medical need, from 2016 through 2019. Between 2000 through 2016, Mr. Levy held multiple Investment Banking positions at Merrill Lynch, Pierce, Fenner & Smith Incorporated, Jefferies Group and Wedbush Securities Inc. Mr. Levy received a B.S. in applied economics from Cornell University.

***Deepak Chadha, Chief Research & Development Officer***

Mr. Chadha has served as Brickell's Chief Research & Development Officer since 2018 and previously served as Brickell's Chief Regulatory, Pre-clinical and Quality Compliance Officer from 2016 to 2018. Prior to joining Brickell, Mr. Chadha served as Vice President, Global Regulatory Affairs at Suneva Medical, a medical technology company that develops, manufactures, and commercializes aesthetic products for the dermatology, plastic, and cosmetic surgery markets, from 2014 to 2016. During his time at Suneva Medical, Mr. Chadha led the regulatory approval for BELLAFILL® dermal filler for acne scar correction and supported the company's commercial products life cycle management. Prior to joining Suneva, Mr. Chadha worked at Allergan (f.k.a. KYTHERA) from 2007 to 2014, where Mr. Chadha led the development of their product, KYBELLA®, from an early clinical phase to an NDA stage, and also supported the ex-U.S. regulatory activities. Mr. Chadha also served as Vice President of Global Regulatory Affairs at Allergan Medical (f.k.a. Inamed Corporation) from 2004 to 2007, where he assisted in building the organization's Global Regulatory Affairs department, and was involved with the approval for JUVEDERM®, Bioenterics®, LAP-BAND® and Silicone gel-filled breast implants. Mr. Chadha holds a B.S. in pharmaceutical sciences from Berhampur University in Orissa, India, an M.S. in pharmaceuticals from Hamdard University in New Delhi, India, and an M.B.A. in international business from California State University, Dominguez Hills.

***Jose Breton, Controller and Chief Accounting Officer***

Mr. Breton has served as Brickell's Controller and Chief Accounting Officer since 2013. Previously, Mr. Breton was an auditor from 2014 to 2015 at Deloitte LLP. Mr. Breton began his career in 2012 as a Client Manager at Global Resource Partners, Inc., an accounting and business advisory firm. In this role, Mr. Breton had overall responsibility

for clients' financial reporting, planning and budgeting, systems of internal controls, corporate and benefits accounting and administration of stock option activity. Mr. Breton holds a B.B.A. degree in Accounting and Finance and a Master's Degree in Taxation from the University of Miami.

***David R. McAvoy, General Counsel, Chief Compliance Officer and Assistant Secretary***

Mr. McAvoy has served as Brickell's General Counsel, Chief Compliance Officer and Assistant Secretary since 2019. He previously served as General Counsel, Vice President and Chief Compliance Officer for Endocyte, Inc., a nuclear medicine and oncology biotech, from 2017 to 2018. Prior to joining Endocyte Inc., Mr. McAvoy was at Eli Lilly and Company for 27 years serving in various leadership positions, including as General Counsel of Lilly Emerging Markets, and most recently, in an executive management business role running strategic alliances for the food animal production group at Lilly's former Elanco Animal Health subsidiary. While at Eli Lilly and Company, Mr. McAvoy was lead FDA counsel launching several medicines, including Prozac<sup>®</sup> for depression, Gemzar<sup>®</sup> for pancreatic and lung cancers, and ReoPro<sup>®</sup>, one of the first interventional cardiology agents. Mr. McAvoy earned a J.D. and M.S. in environmental science from Indiana University and a B.A. in political science from the University of Notre Dame. He serves on the board of directors for The Villages of Indiana, Inc., championing families for abandoned and abused children.

**Employment and Consultancy Agreements**

Brickell had entered into employment or consultancy agreements with each of the executive officers named in this Current Report on Form 8-K. Such agreements remained effective following the consummation of the Merger.

Under the terms of the employment agreement entered into between Brickell and Robert B. Brown, Mr. Brown is entitled to an annual base salary of \$450,000, and is eligible for the Company's benefit programs, vacation benefits and medical benefits. In addition, Mr. Brown is entitled to a discretionary bonus of \$225,000. The agreement provides that upon written notice, either party may terminate the employment arrangement with or without cause, but 90 days' notice is required if the agreement is terminated by Mr. Brown.

Under the terms of the employment agreement entered into between Brickell and Andrew D. Sklawer, Mr. Sklawer is entitled to an annual base salary of \$350,000, and is eligible for the Company's benefit programs, vacation benefits and medical benefits. In addition, Mr. Sklawer is entitled to a discretionary bonus of \$122,500. The agreement provides that upon written notice, either party may terminate the employment arrangement with or without cause, but 90 days' notice is required if the agreement is terminated by Mr. Sklawer.

Under the terms of the consultancy agreement entered into between Brickell and R. Michael Carruthers, Mr. Carruthers is entitled to a monthly retainer of \$20,000 per month for the provision of approximately 80 hours of services per month with no annual salary or bonus. In addition, if Mr. Carruthers is directed to perform services or other functions in his capacity as consultant in locations other than the Company's headquarters in Boulder, Colorado, he is entitled to receive an additional compensation of \$2,000 per day. Mr. Carruthers is not entitled to participate in any benefit programs that the Company may make available to employees. The agreement provides that either party may terminate the consultancy agreement for any reason or no reason upon 30 days' prior written notice.

The foregoing descriptions of the employment and consultancy agreements are not complete and are subject to and qualified in its entirety by reference to such agreements, copies of which are attached to this filing as Exhibits 10.11, 10.12, 10.13, 10.14, 10.15 and 10.16 hereto and are incorporated herein by reference.

### Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year

#### Amended and Restated Certificate of Incorporation

On August 31, 2019, immediately following the consummation of the Merger, the Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to give effect to corporate changes made as a result of and in connection with the Merger, including changing the Company's name from "Vical Incorporated" to "Brickell Biotech, Inc." The foregoing description of the Company's Amended and Restated Certificate of Incorporation is not complete and is subject to and qualified in its entirety by reference to such certificate of incorporation, a copy of which is attached to this filing as Exhibit 3.2 hereto and is incorporated herein by reference.

#### Amended and Restated Bylaws

On August 31, 2019, immediately following the consummation of the Merger, the Company adopted Amended and Restated Bylaws to give effect to corporate changes made as a result of and in connection with the Merger. The foregoing description of the Company's Amended and Restated Bylaws is not complete and is subject to and qualified in its entirety by reference to such bylaws, a copy of which is attached to this filing as Exhibit 3.3 hereto and is incorporated herein by reference.

A summary of the changes made to Vical's Certificate of Amendment (Reverse Stock Split) to the Restated Certificate of Incorporation as a result of the Reverse Stock Split is included in Item 3.03 of this Current Report on Form 8-K, which is incorporated by reference into this Item 5.03.

### Item 5.07 Submission of Matters to a Vote of Security Holders.

On August 30, 2019, Vical held a special meeting of its stockholders (the "**Special Meeting**") to vote on the three proposals described in the definitive proxy statement and proxy card filed with the Securities and Exchange Commission on July 12, 2019, which was amended on August 8, 2019 and again on August 20, 2019. At the close of business on the record date (July 2, 2019), Vical had 22,841,278 shares of common stock outstanding and entitled to vote. At the Special Meeting, 18,420,336 shares of Common Stock were present in person or represented by proxy and entitled to vote. The number of votes cast for and against each proposal, as well as the number of abstentions and broker non-votes with respect to each matter voted upon are set forth below:

1. To approve an amendment to Vical's restated certificate of incorporation, as amended, to effect a reverse split of Vical's common stock at a ratio in the range of between 1-for-5 to 1-for-15, inclusive, with such ratio to be mutually agreed by Vical and Brickell and to be effected by Vical immediately prior to the effective time of the Merger:

For	Against	Abstain
14,190,590	4,155,454	74,292

2. To approve the consummation of a change of control of Vical resulting from the Merger and the other transactions and actions contemplated by the Merger Agreement, including the Concurrent Financing and the reverse split of Vical's common stock pursuant to the rules of The Nasdaq Capital Market, as contemplated by the Merger Agreement:

For	Against	Abstain
7,971,060	4,605,625	33,721

3. To adjourn the Special Meeting, if needed, to solicit additional votes to approve the foregoing proposals:

For	Against	Abstain
12,073,458	6,012,431	334,447

## Item 8.01. Other Events

### Closing of Novaquest Funding Agreement

Pursuant to the Funding Agreement, the Concurrent Financing was consummated immediately following the closing of the Merger on August 31, 2019. A summary of the Funding Agreement is included in Item 1.01 of this Current Report on Form 8-K, which is incorporated by reference into this Item 8.01.

### Press Release

On September 3, 2019, the Company issued a press release announcing the closing of the Merger and the Concurrent Financing. The press release contains statements intended as “forward-looking statements” which are subject to the cautionary statements about forward-looking statements set forth therein. The press release is attached to this filing as Exhibit 99.1.

## Item 9.01 Financial Statements and Exhibits

### *(a) Financial Statements of Business Acquired*

Brickell’s audited financial statements for the years ended December 31, 2018 and 2017 are filed herewith and incorporated by reference herein as Exhibit 99.2.

Brickell’s unaudited financial statements for the three and six months ended June 30, 2019 are filed herewith and incorporated by reference herein as Exhibit 99.3.

### *(b) Pro Forma Financial Information*

The Company’s unaudited pro forma combined financial statements are filed herewith and incorporated by reference herein as Exhibit 99.4.

The unaudited pro forma combined financial data was prepared based on the historical financial results reported by Vical and Brickell and is intended to show how the Merger might have affected historical financial statements. The unaudited pro forma combined financial statements give effect to the Reverse Stock Split.

The unaudited pro forma combined balance sheet as of June 30, 2019 is presented as if the Merger had been completed on that date. The unaudited pro forma combined statements of operations and comprehensive loss for the year ended December 31, 2018 and the six months ended June 30, 2019 combines the historical statements of operations of Vical and Brickell and gives pro forma effect to the Merger as if it had been completed on January 1, 2018.

The historical financial data has been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. The pro forma adjustments are based on management's estimates of the fair value of the assets acquired and liabilities assumed and have been prepared to illustrate the estimated effect of the Merger and certain other adjustments.

**(d) Exhibits**

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>3.1</u></a>	Certificate of Amendment (Reverse Stock Split) to the Restated Certificate of Incorporation
<a href="#"><u>3.2</u></a>	Amended and Restated Certificate of Incorporation, as currently in effect
<a href="#"><u>3.3</u></a>	Amended and Restated Bylaws
<a href="#"><u>3.4</u></a>	Certificate of Merger
<a href="#"><u>4.1</u></a>	Form of Warrant Certificate
<a href="#"><u>10.1*</u></a>	Funding Agreement, as amended, dated June 2, 2019, by and between Brickell Biotech, Inc. and NovaQuest Co-Investment Fund X, L.P.
<a href="#"><u>10.2*</u></a>	License, Development and Commercialization Agreement, as amended, dated March 31, 2015, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.
<a href="#"><u>10.3*</u></a>	Right of First Negotiation Agreement, as amended, dated March 31, 2015, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd.
<a href="#"><u>10.4*</u></a>	License Agreement, as amended, dated December 15, 2012, by and among Brickell Biotech, Inc., Bodor Laboratories, Inc. and Nicholas S. Bodor
<a href="#"><u>10.5*</u></a>	UAB Research Foundation License Agreement, as amended, dated June 26, 2012, by and between Brickell Biotech, Inc. and the UAB Research Foundation
<a href="#"><u>10.6*</u></a>	License Agreement, dated May 20, 2011, by and between Brickell Biotech, Inc. and the University of Manchester
<a href="#"><u>10.7*</u></a>	License Agreement, as amended, dated June 6, 2013, by and among Brickell Biotech, Inc, Orca Pharmaceuticals LLC and the New York University
<a href="#"><u>10.8*</u></a>	Orca Pharmaceuticals LLC Asset Purchase Agreement, dated June 6, 2013, by and between Brickell Biotech, Inc. and Orca Pharmaceutics
<a href="#"><u>10.9*</u></a>	Panmira Pharmaceuticals LLC Purchase Agreement, dated January 30, 2015, by and between Brickell Biotech, Inc. and Panmira Pharmaceuticals
<a href="#"><u>10.10</u></a>	Boulder Lease Agreement, as amended, dated August 4, 2016, by and between Brickell Biotech, Inc. and BMC Properties, LLC
<a href="#"><u>10.11**</u></a>	Employment Agreement, dated November 16, 2018, by and between Brickell Biotech, Inc. and Robert Brown
<a href="#"><u>10.12**</u></a>	Second Amended and Restated Employment Agreement, dated November 27, 2018, by and between Brickell Biotech, Inc. and Andy Sklawer
<a href="#"><u>10.13</u></a>	Amended and Restated Employment Agreement, dated August 28, 2019, by and between Brickell Biotech, Inc. and Deepak Chadha
<a href="#"><u>10.14</u></a>	Brickell Biotech, Inc. Letter Agreement, dated July 10, 2018 by and between Brickell Biotech Inc. and Jose Breton
<a href="#"><u>10.15</u></a>	Employment Agreement, dated July 1, 2019, by and between Brickell Biotech Inc. and David R. McAvoy
<a href="#"><u>10.16</u></a>	Employment Agreement, dated August 1, 2019, by and between Brickell Biotech Inc. and Adam Levy
<a href="#"><u>10.17</u></a>	Registration Rights Agreement, dated August 31, 2019, by and between Brickell Biotech, Inc. and NovaQuest Co-Investment Fund X, L.P.
<a href="#"><u>10.18*</u></a>	U.S. Security Agreement, dated August 31, 2019, by and between Brickell Biotech, Inc. and NovaQuest Co-Investment Fund X, L.P.
<a href="#"><u>23.1</u></a>	Consent of Ernst & Young LLP

<a href="#">99.1</a>	Press Release, dated September 3, 2019
<a href="#">99.2</a>	Audited Financial Statements of Brickell Biotech, Inc. for the years ended December 31, 2018 and 2017
<a href="#">99.3</a>	Unaudited Interim Financial Statements of Brickell Biotech, Inc. for the three and six months ended June 30, 2018 and 2019
<a href="#">99.4</a>	Unaudited Pro Forma Combined Financial Statements

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\* Portions of Exhibit have been omitted due to confidentiality considerations.

\*\* Compensatory Agreements.



**CERTIFICATE OF AMENDMENT OF THE RESTATED CERTIFICATE OF  
INCORPORATION OF VICAL INCORPORATED**

Vical Incorporated (the "Corporation"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "General Corporation Law"), does hereby certify as follows:

1. The current name of the Corporation is Vical Incorporated.
2. The original certificate of incorporation of the Corporation was filed with the Secretary of State of the State of Delaware on April 30, 1987.
3. The Board of Directors of the Corporation duly adopted resolutions pursuant to Section 242 of the General Corporation Law approving an amendment of the Corporation's Restated Certificate of Incorporation, as amended, as follows:

Paragraph A of Article IV of the Restated Certificate of Incorporation of the Corporation, as amended, is hereby amended to add the following paragraph immediately following the second paragraph of Paragraph A of Article IV, as follows:

"Effective as of 12:01 a.m. on September 3, 2019 (the "Effective Time"), each seven shares of Common Stock issued or outstanding (including treasury shares) immediately prior to the Effective Time shall be reclassified and combined into one validly issued, fully paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Effective Time and shall represent one share of Common Stock from and after the Effective Time (such reclassification and combination of shares, the "Second Reverse Stock Split"). The par value of the Common Stock following the Second Reverse Stock Split shall remain at \$0.01 par value per share. No fractional shares of Common Stock shall be issued as a result of the Second Reverse Stock Split and, in lieu thereof, upon surrender after the Effective Time of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time, any person who would otherwise be entitled to a fractional share of Common Stock as a result of the Second Reverse Stock Split, following the Effective Time, shall be entitled to receive, with respect to each such fractional share, a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled multiplied by the fair value per share of the Common Stock immediately prior to the Effective Time as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Effective Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Effective Time into which the shares formerly represented by such certificate have been reclassified (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Effective Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified."

4. Thereafter, pursuant to a resolution of the Board of Directors of the Corporation, the amendment was submitted to the stockholders of the Corporation for their approval at a special meeting of stockholders which was duly called and held upon notice in accordance with Section 222 of the General Corporation Law, at which meeting the necessary number of shares required by statute were voted in favor of the amendment. Accordingly, said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law.
  5. On August 30, 2019, the Board of Directors of the Corporation determined that each seven shares of the Corporation's Common Stock, par value \$0.01 per share ("Common Stock"), issued and outstanding immediately prior to the Effective Time shall automatically be combined into one validly issued, fully paid and non-assessable share of Common Stock. The Corporation publicly announced this ratio on August 30, 2019.
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**IN WITNESS WHEREOF**, this Corporation has caused this Certificate of Amendment of the Restated Certificate of Incorporation, as amended to be signed by its President and Chief Executive Officer this 30th day of August, 2019.

/s/ Vijay Samant

Vijay Samant  
President and Chief Executive Officer

**RESTATED CERTIFICATE OF INCORPORATION  
OF  
VICAL INCORPORATED**

Vical Incorporated, a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

**FIRST.** The name of the corporation is Vical Incorporated.

**SECOND.** The date of filing of its original Certificate of Incorporation with the Secretary of State of Delaware was April 30, 1987.

**THIRD.** At a meeting of the Board of Directors of Vical Incorporated, resolutions were duly adopted providing that the first provision of the preamble of the Restated Certificate of Incorporation of Vical Incorporated, as amended, shall be amended further and restated to read in its entirety as follows:

“**FIRST.** The name of the Corporation is Brickell Biotech, Inc.”

**FOURTH.** Effective as of 12:10 a.m. on August 31, 2019 (the “Effective Time”), the Restated Certificate of Incorporation of said corporation shall be amended and restated to read in full as follows:

**ARTICLE I**

The name of the corporation is Brickell Biotech, Inc.

**ARTICLE II**

The address of its registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

**ARTICLE III**

The corporation is organized for the purposes of transacting any or all lawful business for which corporations may be organized under the laws of the United States and the laws of the State of Delaware. The corporation shall have all of the corporate powers enumerated under Delaware law.

**ARTICLE IV**

**A. Classes of Stock.** The total number of shares of all classes of capital stock which the corporation shall have authority to issue is Fifty-Five Million (55,000,000) shares, of which Fifty Million (50,000,000) shares of the par value of One Cent (\$0.01) each shall be Common

Stock (the "Common Stock") and Five Million (5,000,000) shares of the par value of One Cent (\$0.01) each shall be Preferred Stock (the "Preferred Stock").

The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is authorized to fix the number of shares of any series of Preferred Stock and to determine the designation of any such shares. The Board of Directors also is authorized to determine or alter the rights (including but not limited to voting rights), preferences, privileges and restrictions granted to or imposed upon any wholly unissued series of Preferred Stock, and within the limits and restrictions stated in any resolution or resolutions of the Board of Directors originally fixing the number of shares constituting any series, to increase or decrease (but not below the number of shares of such series outstanding) the number of shares of such series subsequent to the issue of shares of that series by filing a certificate pursuant to the applicable laws of the State of Delaware.

**B. Common Stock.**

**1. Relative Rights of Preferred Stock and Common Stock.** All preferences, voting powers, and relative, participating, optional or other special rights and privileges, and qualifications, limitations, or restrictions of the Common Stock are made expressly subject and subordinate to those that may be fixed with respect to any shares of the Preferred Stock.

**2. Voting Rights.** Except as otherwise required by law or this Restated Certificate of Incorporation, each holder of Common Stock shall have one vote in respect of each share of stock held by such holder of record on the books of the corporation for the election of directors and on all matters submitted by the Board of Directors to a vote of stockholders of the corporation.

**3. Dividends.** Subject to the preferential rights of the Preferred Stock, the holders of shares of Common Stock shall be entitled to receive, when and if declared by the Board of Directors, out of the assets of the corporation which are by law available therefor, dividends payable either in cash, in property or in shares of capital stock.

**4. Dissolution, Liquidation or Winding Up.** In the event of any dissolution, liquidation or winding up of the affairs of the corporation, after distribution in full of the preferential amounts, if any, to be distributed to the holders of shares of the Preferred Stock, holders of Common Stock shall be entitled, unless otherwise provided by law or this Restated Certificate of Incorporation, to receive all of the remaining assets of the corporation of whatever kind available for distribution to stockholders ratably in proportion to the number of shares of Common Stock held by each of them respectively.

**ARTICLE V**

**A. Board Size.** The number of directors that constitutes the entire Board shall be fixed by, or in the manner provided in, the Amended and Restated Bylaws of the Corporation. At each annual meeting of stockholders, directors of the Corporation shall be elected to hold office until the expiration of the term for which they are elected and until their successors have been

duly elected and qualified or until their earlier death, resignation or removal; except that if any such election shall not be so held, such election shall take place at a stockholders' meeting called and held in accordance with the Delaware General Corporation Law

**B. Board Structure.** From and after the Effective Time, the directors shall be divided into three (3) classes as nearly equal in size as is practicable, hereby designated Class I, Class II and Class III. The Board may assign members of the Board already in office to such classes at the time such classification becomes effective. The term of office of the initial Class III directors shall expire at the annual meeting of the stockholders in 2019, the term of office of the initial Class I directors shall expire at the annual meeting of the stockholders in 2020, and the term of office of the initial Class II directors shall expire at the annual meeting of the stockholders in 2021. At each annual meeting of stockholders, commencing with the first regularly scheduled annual meeting of stockholders in 2019, each of the successors elected to replace the directors of a Class whose term shall have expired at such annual meeting shall be elected to hold office for a three year term and until the third annual meeting next succeeding his or her election and until his or her respective successor shall have been duly elected and qualified. Notwithstanding the foregoing provisions of this Article V, each director shall serve until his or her successor is duly elected and qualified or until his or her death, resignation, or removal. If the number of directors is thereafter changed, any newly created directorships or decrease in directorships shall be so apportioned among the classes as to make all classes as nearly equal in number as is practicable. No decrease in the number of directors constituting the Board shall shorten the term of any incumbent director.

**C. Removal; Vacancies.** Any director may be removed from office by the stockholders of the Corporation as provided in Section 141(k) of the Delaware General Corporation Law. Vacancies occurring on the Board for any reason and newly created directorships resulting from an increase in the authorized number of directors may be filled only by vote of a majority of the remaining members of the Board, although less than a quorum, or by a sole remaining director, and not by stockholders. A person elected to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall be duly elected and qualified.

#### **ARTICLE VI**

Special meetings of the stockholders of the corporation, unless otherwise prescribed by applicable law or by this certificate, may be called only by the Chief Executive Officer of the corporation or by a resolution adopted by the affirmative vote of a majority of a quorum of the Board of Directors.

#### **ARTICLE VII**

Election of directors need not be by written ballot unless the Bylaws so provide.

#### **ARTICLE VIII**

The Board of Directors is empowered expressly to adopt, amend or repeal the Bylaws of the corporation; provided, however, that any adoption, amendment or repeal of the Bylaws of the corporation by the Board of Directors shall require the approval of at least sixty-six and two-thirds percent (66 2/3%) of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any resolution providing for adoption, amendment or repeal is presented to the Board of Directors). The stockholders also shall have power to adopt, amend or repeal the Bylaws of the corporation; provided, however, that in addition to any vote of the holders of any class or series of stock of the corporation required by law or by this Restated Certificate of Incorporation the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of the stock of the corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for such adoption, amendment or repeal by the stockholders of any provision(s) of the Bylaws of the corporation.

#### **ARTICLE IX**

One third (1/3) of the shares entitled to be cast on any matter by a voting group, or in case of the Board, the number of directors shall constitute a quorum of that voting group, or the Board, for action on that matter.

#### **ARTICLE X**

No contract or other transaction between the corporation and one or more of its directors, or between the corporation and any other corporation, firm, association or other entity in which one or more of the directors are directors or officers, or are financially interested, shall be either void or voidable because of such relationship or interest or because such director or directors are present at the meeting of the Board of Directors or a committee thereof which authorizes, approves or ratifies such contract or transaction or because his or her votes are counted for such purpose, if:

- A. The material facts of such relationship or interest are disclosed or known to the Board of Directors, or a duly empowered committee thereof, which in good faith authorizes, approves or ratifies the contract or transaction by a majority vote or written consent sufficient for such purpose without counting the vote or votes of such interested director or directors, even though the disinterested directors comprise less than a quorum; or
- B. The material facts of such relationship or interest are disclosed or known to the shareholders entitled to vote and they in good faith by majority vote of a quorum of the shareholders or written consent authorize, approve or ratify such contract or transaction; or
- C. The contract or transaction is fair and reasonable as to the corporation at the time it is authorized by the Board of Directors, a committee thereof, or the shareholders.

A director of the corporation may transact business, borrow, lend, or otherwise deal or contract with the corporation to the full extent and subject only to the limitations and provisions of the applicable laws of the State of Delaware and the laws of the United States.

Interested directors may be counted in determining the presence of a quorum at a meeting of the Board of Directors or a committee thereof which authorizes, approves or ratifies such contract or transaction.

## ARTICLE XI

**A. No Personal Liability.** The liability of a director of the corporation for monetary damages shall be eliminated to the fullest extent under applicable law.

**B. Indemnification.** To the fullest extent permitted by applicable law, the corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the corporation (and any other persons to which applicable law permits the corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise in excess of the indemnification and advancement otherwise permitted by such applicable law. If applicable law is amended after approval by the stockholders of this Article XI to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to the corporation shall be eliminated or limited to the fullest extent permitted by applicable law as so amended.

Any repeal or modification of this Article shall only be prospective and shall not affect the rights or protections or increase the liability of any director under this Article in effect at the time of the alleged occurrence of any act or omission to act giving rise to liability or indemnification.

## ARTICLE XII

Notwithstanding any other provision of this Restated Certificate of Incorporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of the stock of the corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend in any respect or repeal Article XI, or Articles V, VI, VIII and X, hereof.

**FIFTH.** This Restated Certificate of Incorporation duly was adopted by the Board of Directors of this corporation.

**SIXTH:** This Restated Certificate of Incorporation duly was adopted by the stockholders in accordance with sections 242 and 245 of the General Corporation Law of the State of Delaware.

**IN WITNESS WHEREOF**, said Vical Incorporated has caused its corporate seal to be hereunto affixed and this certificate to be signed by its Chief Executive Officer, Robert B. Brown, and its Secretary, Andrew D. Sklawer, this 30<sup>th</sup> day of August, 2019

**VICAL INCORPORATED**

By: /s/ Robert B. Brown  
Robert B. Brown  
Chief Executive Officer

**Attest:**

/s/ Andrew D. Sklawer  
Andrew D. Sklawer  
Secretary

**AMENDED AND RESTATED  
BYLAWS  
OF  
BRICKELL BIOTECH, INC.**

**ARTICLE I**

**MEETINGS OF STOCKHOLDERS**

**Section 1. Place of Meetings.** All meetings of the stockholders shall be held at such place within or outside the State of Delaware as may be fixed from time to time by the Board of Directors or the chief executive officer, or if not so designated, at the registered office of the corporation.

**Section 2. Annual Meeting.** An annual meeting of stockholders shall be held at such date, time and place as designated by the Board of Directors or the chief executive officer and stated in the notice of meeting. At the annual meeting the stockholders shall elect by a plurality vote those directors to hold office based on the number of directors in the class whose terms are expiring and do so for a term of three (3) years until the annual meeting of stockholders coinciding with the end of such term.

At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business either (i) must be specified in a written notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors or the chief executive officer or secretary of the corporation, (ii) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (iii) otherwise properly brought before the meeting by a stockholder. In addition to any other applicable requirements, for business to be properly brought before an annual meeting by a stockholder, the stockholder must have given timely notice thereof in writing to the secretary of the corporation. To be timely, a stockholder's notice must be delivered to or mailed and received at one of the principal executive office(s) of the corporation, not less than ninety (90) calendar days nor more than one-hundred and twenty (120) calendar days prior to the annual meeting; provided, however, that in the event that less than forty-five (45) calendar days' notice or prior public disclosure of the date of the annual meeting is given or made to stockholders, notice by the stockholder to be timely must be so received not later than the close of business on the tenth (10<sup>th</sup>) business day following the day on which such notice of the date of the annual meeting was mailed or such public disclosure was made. A stockholder's notice to the secretary of the corporation shall set forth as to each matter the stockholder proposes to bring before the annual meeting (i) a brief description of the business desired to be brought before the annual meeting and the reasons for conducting such business at the annual meeting, (ii) the name and record address of the stockholder proposing such business, (iii) the class and number of shares of the corporation which are beneficially owned by the stockholder and (iv) any material interest of the stockholder in such business. In no event shall the adjournment or postponement of an annual meeting commence a new notice time period (or extend any notice time period).

Notwithstanding anything in these bylaws to the contrary, no business shall be conducted at the annual meeting except in accordance with the procedures set forth in this Section 2 by any stockholder of any business properly brought before the annual meeting in accordance with said procedure.

The chairperson of an annual meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the provisions of this Section 2, or is otherwise not compliant with these bylaws, and if the chairperson should so determine, the chairperson shall so declare to the meeting and any such business not properly brought before the meeting shall not be transacted.

**Section 3. Special Meetings.** Special meetings of the stockholders, for any purpose or purposes, unless otherwise prescribed by statute or by the corporation's certificate of incorporation, may be called only by the chief executive officer at his or her discretion, or by a resolution adopted by the affirmative vote of a majority of the Board of Directors. Business transacted at any special meeting shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

**Section 4. Notice of Meetings.** Except as otherwise provided by law, written notice of each meeting of stockholders, annual or special, stating the place, date and hour of the meeting and, in the case of a special meeting, the purpose or purposes for which the meeting is called, shall be given not less than ten (10) nor more than sixty (60) calendar days before the date of the meeting, to each stockholder entitled to vote at such meeting. Without limiting the manner by which notices of meetings otherwise may be given to stockholders, any such notice may be given by electronic transmission in the manner provided in Section 232 of the Delaware General Corporation Law and as that statute may be amended. Notice of any meeting need not be given to any stockholder who, either before or after the meeting, shall submit a waiver of notice or who shall attend such meeting, except when the stockholder attends for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of the meeting shall be bound by the proceedings of the meeting in all respects as if due notice thereof had been given.

**Section 5. Voting List.** The officer responsible for the stock ledger of the corporation shall prepare and make, at least ten (10) calendar days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder limited to any purpose germane to the meeting for a period of at least ten (10) calendar days before the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list was provided with the notice of the meeting; (b) during ordinary business hours, at the principal place of business of the corporation; or (c) either at a place within the city or town where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list also shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. Except as provided by

applicable law, the stock ledger of the corporation shall be the only evidence as to who are the stockholders entitled to examine the stock ledger and the list of stockholders or to vote in person or by proxy at any meeting of stockholders.

**Section 6. Quorum.** The holders of one-third (1/3) of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of stockholders for transaction of business, except as otherwise provided by statute, the certificate of incorporation or these bylaws. A quorum, once established, shall not be broken by subsequent withdrawal of enough votes to leave less than a quorum.

**Section 7. Adjournments.** Any meeting of stockholders may be adjourned from time to time to any other time and/or any other place at which a meeting of stockholders may be held under these bylaws, which time and place shall be announced at the meeting, by a majority of the stockholders present in person or represented by proxy at the meeting and entitled to vote, though less than a quorum, or, if no stockholder is present or represented by proxy, by any officer entitled to preside at or to act as corporate secretary of such meeting, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) calendar days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

**Section 8. Action at Meetings.** When a quorum is present at any meeting, the vote of the holders of a majority of the stock present in person or represented by proxy and entitled to vote on the question shall decide any question brought before such meeting, unless the question is one upon which by express provision of law, the corporation's certificate of incorporation or these bylaws, a different vote is required, in which case such express provision shall govern and control the decision of such question.

**Section 9. Voting and Proxies.** Unless otherwise provided in the corporation's certificate of incorporation, each stockholder shall at every meeting of the stockholders be entitled to one vote, in person or by proxy, for each share of capital stock having voting power held of record by such stockholder. Each stockholder entitled to vote at a meeting of stockholders, or to express consent or dissent to corporate action in writing without a meeting, may authorize another person or persons to act for such stockholder by proxy; provided that the instrument authorizing such proxy to act shall have been executed in writing (which shall include telegraphing, cabling or other means of electronically transmitted written copy) and signed and dated by the stockholder personally or by the stockholder's duly authorized attorney in fact. No such proxy shall be voted or acted upon after three (3) years from its effective date, unless the proxy expressly provides for a longer period.

**Section 10. Action by Consent.** Unless otherwise restricted by the corporation's certificate of incorporation or these bylaws, any action required or permitted to be taken at any annual or special meeting of the stockholders of the corporation may be taken without a meeting,

if a majority of the stockholders of the corporation consent thereto in writing or by electronic transmission.

## ARTICLE II

### DIRECTORS

**Section 1. Number, Election, Tenure and Qualification.** The number of directors which shall constitute the whole board shall not be less than five (5) nor more than nine (9); provided, however, the board shall be comprised of an odd number of directors. Within and according to such limit, the actual number of directors shall be determined by resolution of the Board of Directors, or by the stockholders at the annual , or at any special meeting of stockholders. The directors shall be elected at the annual meeting or at any special meeting of the stockholders, except as provided in Section 3 of this Article, and each director elected shall hold office until such director's successor is elected and qualified or until the director's earlier death, resignation, disqualification, or removal. Directors need not be stockholders. Directors shall serve according to a set of staggered terms such that in any given year there is no more than twenty-five percent (25%) turnover of the Board.

**Section 2. Enlargement.** The number of the Board of Directors may be increased at any time by vote of a majority of the directors then in office, subject to maintaining an odd number for the Board.

**Section 3. Nominations.** Subject to the rights of holders of any class or series of stock having a preference over the common stock as to dividends or upon liquidation, nominations for election to the Board of Directors of the corporation at a meeting of stockholders may be made on behalf of the board by the nominating committee appointed by the board, or by any stockholder of the corporation entitled to vote for the election of directors at such meeting. Such nominations, other than those made by the nominating committee on behalf of the board, shall be made by notice in writing delivered or mailed by first class United States mail or a nationally recognized courier service, postage prepaid, to the secretary or assistant secretary of the corporation, and received by such officer not less than one hundred-twenty (120) calendar days prior to any meeting of stockholders called for the election of directors; provided, however, that if less than ninety (90) calendar days' notice of the meeting is given to stockholders, such nomination shall have been mailed or delivered to the secretary or the assistant secretary of the corporation not later than the close of business on the seventh (7<sup>th</sup>) calendar day following the day on which the notice of meeting was mailed. Such notice shall set forth as to each proposed nominee who is not an incumbent director (i) the name, age, business address and, if known, residence address of each nominee proposed in such notice, (ii) the principal occupation or employment of each such nominee, (iii) the number of shares of stock of the corporation which are owned beneficially by each such nominee and by the nominating stockholder, (iv) any other information concerning the nominee that must be disclosed of nominees in proxy solicitations regulated by Regulation 14A of the Securities Exchange Act of 1934, as amended, and (v) a written questionnaire with respect to the background and qualification of such nominee (which questionnaire shall be provided by the corporate secretary upon written request) and a written statement and agreement executed by each such nominee acknowledging that such person

consents to being named in the corporation's proxy statement as a nominee and to serving as a director if elected.

The chairperson of the meeting, if the facts warrant, may determine and declare to the meeting that a nomination was not made in accordance with the foregoing procedure, and if the chairperson should so determine, the chairperson shall so declare the meeting and the defective nomination shall be disregarded.

**Section 4. Vacancies.** Vacancies and newly created directorships resulting from any increase in the authorized number of directors may be filled by a majority of the directors then in office, though less than a quorum, or by a sole remaining director, and the directors so chosen shall hold office until the next annual election at which the term of the class to which they have been elected expires and until their successors are duly elected and shall qualify or until the director's earlier death, resignation, disqualification, or removal. If there are no directors in office, then an election of directors may be held in the manner provided by statute. In the event of a vacancy in the Board of Directors, the remaining directors, except as otherwise provided by law or these bylaws, may exercise the powers of the full board until the vacancy is filled.

**Section 5. Resignation and Removal.** Any director may resign at any time for any reason upon giving written or electronic notice to the corporation at its principal place of business or to the chief executive officer or the secretary of the corporation. Such resignation shall be effective upon receipt of such notice by any of the foregoing unless the notice specifies such resignation to be effective at some other time or upon the happening of some other event. Any director or the entire Board of Directors may be removed, but only for cause, by the holders of a majority of the shares then entitled to vote at an election of directors, unless otherwise specified by law or the certificate of incorporation of the corporation.

**Section 6. General Powers.** The business and affairs of the corporation shall be managed by its Board of Directors, which may exercise all powers of the corporation and do all such lawful acts and things as are not by statute or by the certificate of incorporation or by these bylaws directed or required to be exercised or done solely by the stockholders.

**Section 7. Chairperson of the Board.** If the Board of Directors appoints a chairperson of the board, such chairperson, when present, shall preside at all meetings of the stockholders and the Board of Directors. The chairperson shall perform such duties and possess such powers as are customarily vested in the office of the chairperson of the board or as may be vested in the chairperson by the Board of Directors.

**Section 8. Place of Meetings.** The Board of Directors may hold meetings, both regular and special, either within or outside the State of Delaware to the extent held in the United States of America.

**Section 9. Regular Meetings.** Regular meetings of the Board of Directors may be held without notice at such time and at such place as shall from time to time be determined by the board; provided that any director who is absent when such a determination is made shall be given prompt written notice of such determination. A regular meeting of the Board of Directors

may be held without notice immediately after and at the same place as the annual meeting of stockholders. Notwithstanding the foregoing, the board shall meet at a minimum frequency of quarterly.

**Section 10. Special Meetings.** Special meetings of the board may be called by the chief executive officer, secretary of the corporation, or on the written request of three (3) or more directors, or by one (1) director in the event that there is only one (1) director in office. Four (4) hours' notice to each director, either personally or by e-mail or other electronic transmission, commercial delivery service or similar means sent to such director's business or home address, or three (3) calendar days' notice by written notice deposited in the mail or delivered by a nationally recognized courier service, shall be given to each director by the secretary of the corporation or by the officer or one of the directors calling the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

**Section 11. Quorum, Action at Meeting, Adjournments.** At all meetings of the board, a majority of directors then in office, but in no event less than one third (1/3) of the entire board, shall constitute a quorum for the transaction of business and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board of Directors, except as may be provided otherwise specifically by law or by the corporation's certificate of incorporation. For purposes of this Section 11, the term "entire board" shall mean the number of directors last fixed by the stockholders or directors, as the case may be, in accordance with law and these bylaws; provided, however, that if less than all the number so fixed of directors were elected, the "entire board" shall mean the greatest number of directors so elected to hold office at any one time pursuant to such authorization. If a quorum shall not be present at any meeting of the Board of Directors, a majority of the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present.

**Section 12. Action by Consent.** Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the board or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or transmission or transmissions are filed with the minutes of proceedings of the board or committee.

**Section 13. Telephonic Meetings.** Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board of Directors or of any committee thereof may participate in a meeting of the Board of Directors or of any committee, as the case may be, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

**Section 14. Committees.** The Board of Directors, by resolution passed by a majority of the whole board, may designate one or more committees of the board, each committee to consist of one or more of the directors of the corporation; provided, however, the total number of Committee members shall be an odd number. The board may designate one or more directors as

alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. Any such committee, to the extent provided in the resolution of the Board of Directors, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to amending the certificate of incorporation of the corporation or these bylaws, adopting an agreement of merger, acquisition or consolidation of the corporation in its entirety, recommending to the stockholders the sale, lease or exchange of all or substantially all of the corporation's property and assets, recommending to the stockholders a dissolution of the corporation or a revocation of a dissolution; and, unless the resolution designating such committee or the corporation's certificate of incorporation expressly so provide, no such committee shall have the power or authority to declare a dividend or to authorize the issuance of stock or stock options or warrants. Such committee or committees shall have such name or names as may be determined from time to time by resolution adopted by the Board of Directors. Each committee shall keep regular minutes of its meetings and make such reports to the Board of Directors as the Board of Directors may request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business in compliance with applicable laws and these bylaws and the corporation's certificate of incorporation, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these bylaws for the conduct of its business by the Board of Directors.

**Section 15. Compensation.** Unless otherwise restricted by the certificate of incorporation of this corporation or these bylaws, the Board of Directors shall have the authority to fix from time to time the compensation of directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board of Directors and the performance of their responsibilities as directors and may be paid a fixed sum for attendance at each meeting of the Board of Directors and/or a stated salary as director. Payment may be by cash or by stock or stock option or warrant, as determined by the Board of Directors otherwise in accordance with these bylaws. No such payment shall preclude any director from serving the corporation or its parent or subsidiary corporations in any other capacity and receiving compensation therefor. The Board of Directors may also allow compensation for members of special or standing committees for service on such committees.

### ARTICLE III

#### OFFICERS

**Section 1. Enumeration.** The officers of the corporation shall be chosen by the Board of Directors and shall be a president, a secretary and a treasurer and such other officers with such titles, terms of office and duties as the Board of Directors may from time to time determine, including one or more vice-presidents, and one or more assistant secretaries and assistant treasurers. If authorized by resolution of the Board of Directors, the chief executive officer may be empowered to appoint from time to time assistant secretaries and assistant

treasurers. Any number of offices may be held by the same person, unless the certificate of incorporation or these bylaws otherwise provide.

**Section 2. Election.** The Board of Directors at its first meeting after each annual meeting of stockholders shall choose a president, a secretary and a treasurer. Other officers may be appointed by the Board of Directors at such meeting, at any other meeting, or by written consent.

**Section 3. Tenure.** The officers of the corporation shall hold office until their successors are chosen and qualify, unless a different term is specified in the vote choosing or appointing such officer, or until such officer's earlier death, resignation or removal. Any officer elected or appointed by the Board of Directors or by the chief executive officer may be removed at any time by the affirmative vote of a majority of the Board of Directors or a committee of the board duly authorized to do so, except that any officer appointed by the chief executive officer also may be removed at any time by the chief executive officer. Any vacancy occurring in any office of the corporation may be filled by the Board of Directors, at its discretion. Any officer may resign by delivering such officer's written or electronic resignation to the corporation at its principal place of business or to the chief executive officer or the secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

**Section 4. President.** The president shall be the chief executive officer unless the Board of Directors otherwise provides. The president, unless the Board of Directors provides otherwise in a specific instance or generally, shall (i) preside at all meetings of the stockholders and the Board of Directors, (ii) conduct general and active management of the business of the corporation, and (iii) be responsible that all orders and resolutions of the Board of Directors are implemented. The president further shall execute bonds, mortgages, and other contracts requiring a seal, under the seal of the corporation, except where required or permitted by law to be otherwise signed and executed and except where the signing and execution thereof shall be expressly delegated by the Board of Directors to some other officer or agent of the corporation.

**Section 5. Vice-Presidents.** In the absence of the president or in the event of the president's inability or refusal to act, the vice-president, or if there be more than one vice-president, the vice-presidents in the order designated by the Board of Directors or the chief executive officer (or in the absence of any designation, then in the order determined by their tenure in office) shall perform the duties of the president, and when so acting, shall have all the powers of and be subject to all the restrictions upon the president. The vice-presidents shall perform such other duties and have such other powers as the Board of Directors or the chief executive officer may from time to time prescribe.

**Section 6. Secretary.** The secretary shall have such powers and perform such duties as are incident to the office of secretary. The secretary shall maintain a stock ledger and prepare lists of stockholders and their addresses as required and shall be the custodian of corporate records. The secretary shall attend all meetings of the Board of Directors and all meetings of the stockholders and record all the proceedings of the meetings of the corporation and of the Board of Directors in a book to be kept for that purpose and shall perform like duties for the standing

committees when required. The secretary shall give, or cause to be given, notice of all meetings of the stockholders and special meetings of the Board of Directors, and shall perform such other duties as may be from time to time prescribed by the Board of Directors or chief executive officer, under whose supervision the secretary shall be. The secretary shall have custody of the corporate seal of the corporation and the secretary, or an assistant secretary, shall have authority to affix the same to any instrument requiring it and when so affixed, it may be attested by the secretary's signature or by the signature of such assistant secretary. The Board of Directors may give general authority to any other officer to affix the seal of the corporation and to attest the affixing by such officer's signature.

**Section 7. Chief Financial Officer.** The chief financial officer shall be the principal financial officer of the corporation and shall have such powers and perform such duties as may be assigned by the Board of Directors or the chief executive officer.

**Section 8. Other Officers.** Such other officers as the Board of Directors may choose shall perform such duties and have such powers as from time to time may be assigned to them by the Board of Directors.

**Section 9. Bond.** If required by the Board of Directors, any officer shall give the corporation a bond in such sum and with such surety or sureties and upon such terms and conditions as shall be satisfactory to the Board of Directors, including without limitation a bond for the faithful performance of the duties of such officer's office and for the restoration to the corporation of all books, papers, vouchers, money and other property of whatever kind in such officer's possession or under such officer's control and belonging to the corporation.

**Section 10. Delegation of Authority.** The Board of Directors may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding any provision hereof.

## ARTICLE IV

### NOTICES

**Section 1. Delivery.** Whenever, under the provisions of law, or of the certificate of incorporation or these bylaws, written notice is required to be given by the corporation to any director, officer or stockholder, such notice may be given by mail, addressed to such director, officer or stockholder, at such person's address as it appears on the records of the corporation, with postage thereon prepaid, and such notice shall be deemed to be given at the time when the same shall be deposited by the corporation in the United States mail or delivered to a nationally recognized courier service. Unless written notice by mail is required by law, written notice may also be given by e-mail or electronic transmission, commercial delivery services or similar means, addressed to such director, officer or stockholder at such person's e-mail or address as it appears on the records of the corporation, in which case such notice shall be deemed to be given when delivered by the corporation into the control of the persons charged with effecting such transmission, the transmission charge to be paid by the corporation or the person sending such

notice and not by the addressee. Oral notice or other in-hand delivery, in person or by telephone, shall be deemed given at the time it actually is given.

**Section 2. Waiver of Notice.** Whenever any notice is required to be given by the corporation under the provisions of law or of the certificate of incorporation or of these bylaws, a waiver thereof in writing, signed and dated by the person or persons entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent thereto.

## ARTICLE V

### INDEMNIFICATION

**Section 1. Actions Other than by or in the Right of the Corporation.** The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, investigative or otherwise (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceedings, had no reasonable cause to believe such person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

**Section 2. Actions by or in the Right of the Corporation.** The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, investigative or otherwise, by or in the right of the corporation to procure a judgment or legally binding decision in its favor by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable for negligence, fraud or misconduct in the performance of such person's duty or obligations to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the

case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery of the State of Delaware or such other court shall deem proper.

**Section 3. Success on the Merits.** To the extent that any person described in Section 1 or 2 of this Article V has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in said Sections, or in defense of any claim, issue or matter therein, such person shall be indemnified by the corporation against their expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

**Section 4. Specific Authorization.** Any indemnification under Section 1 or 2 of this Article V (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of any person described in said Sections is proper in the circumstances because such person has met the applicable standards of conduct set forth in said Sections. Such determination shall be made (1) by the Board of Directors by a majority vote of a quorum consisting of directors who were not parties to such action, suit or proceeding, or (2) if such a quorum is not obtainable, or even if obtainable a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (3) by a majority vote of a quorum of the stockholders of the corporation.

**Section 5. Advance Payment.** Expenses incurred in defending a civil, criminal, administrative, investigative or other action, suit or proceeding for which indemnification is appropriate under these bylaws may be paid by the corporation in advance of the final disposition of such action, suit or proceeding as authorized by the Board of Directors in the manner provided for in Section 4 of this Article V upon receipt of an undertaking by or on behalf of any person described in said Section to repay such amount unless it ultimately is determined that such person is entitled to indemnification by the corporation as authorized in this Article V.

**Section 6. Non-Exclusivity.** The indemnification provided by this Article V shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise, both as to action in such person's official capacity and as to action in any other capacity while holding such office, and shall continue as to a person who has ceased to be director, officer, employee or agent of the corporation and shall inure to the benefit of the heirs, executors and administrators of such a person.

**Section 7. Insurance.** The Board of Directors may authorize, by a vote of the majority of the full board, the corporation to purchase and maintain insurance of any type and amount on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of this Article V or applicable law.

**Section 8. Severability.** If any word, clause or provision of this Article V or any award made hereunder shall for any reason be determined to be invalid, the provisions hereof shall not be affected otherwise thereby but shall remain in full force and effect.

**Section 9. Intent of Article.** The intent of this Article V is to provide for indemnification to the fullest extent permitted by section 145 of the General Corporation Law of Delaware or any other applicable law. To the extent that such Section or any successor section, or other applicable law, may be amended or supplemented from time to time, this Article V shall be amended automatically and construed so as to permit indemnification to the fullest extent from time to time permitted by the law.

## ARTICLE VI

### CAPITAL STOCK

**Section 1. Certificates of Stock.** Every holder of stock in the corporation shall be entitled to have a certificate, signed by, or in the name of the corporation by, the chairperson or vice-chairperson of the Board of Directors, or the president or a vice-president and the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the corporation, certifying the number of shares owned by such stockholder in the corporation. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. Certificates may be issued for partly paid shares and in such case upon the face or back of the certificates issued to represent any such partly paid shares, the total amount of the consideration to be paid therefor, and the amount paid thereon shall be specified.

**Section 2. Lost Certificates.** The Board of Directors may direct a new stock certificate or certificates to be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen or destroyed. When authorizing such issue of a new certificate or certificates, the Board of Directors may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed stock certificate or certificates, or such owner's legal representative, to give reasonable evidence of such loss, theft or destruction, to advertise the same in such manner as it shall require and/or to give the corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen or destroyed or the issuance of such new certificate.

**Section 3. Transfer of Stock.** Upon surrender to the corporation or the transfer agent of the corporation of a certificate for shares, duly endorsed or accompanied by proper evidence of succession, assignment, or authority to transfer, and proper evidence of compliance with other conditions to rightful transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate, and record the transaction upon its books.

**Section 4. Record Date for Action at a Meeting or for Other Purposes.** In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not be more than sixty (60) calendar days nor less than ten (10) calendar days before the date of such meeting, nor more than sixty (60) calendar days prior to any other action to which such record date relates. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting. If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. The record date for determining stockholders for any other purpose within this Section 4 of Article VI shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

**Section 5. Registered Stockholders.** The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and any other rights related to ownership of these shares, and to vote as such owner, and to hold liable for calls and assessments a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

## ARTICLE VII

### CERTAIN TRANSACTIONS

**Section 1. Transactions with Interested Parties.** No contract or transaction between the corporation and one or more of its directors or officers, or between the corporation and any other corporation, partnership, association or other organization in which one or more of the corporation's directors or officers also are directors or have a financial interest, shall be void or voidable solely for these reasons, or solely because the director or officer is present at or participates in the meeting of the board or committee thereof which authorizes the contract or transaction, or solely because the vote or votes of such director or officer are counted for such purpose, if:

(a) the material facts as to such person's relationship or interest and as to the contract or transaction are disclosed or are known to the Board of Directors or the committee of the board, and the board or committee in good faith authorizes the contract or transaction by written consent or the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum; or

(b) the material facts as to such person's relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction specifically is approved in good faith by written consent or a majority vote of a quorum of the stockholders; or

(c) the contract or transaction is fair and reasonable as to the corporation as of the time it is authorized, approved or ratified, by the Board of Directors, a committee thereof, or the stockholders.

**Section 2. Quorum.** Common or interested directors may be counted in determining the presence of a quorum at a meeting of the Board of Directors or of a committee which authorizes the contract or transaction.

## ARTICLE VIII

### GENERAL PROVISIONS

**Section 1. Dividends.** Dividends upon the capital stock of the corporation, if any, may be declared by the Board of Directors at any regular or special meeting of the board or stockholders, or by written consent, pursuant to applicable law. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the certificate of incorporation.

**Section 2. Reserves.** The directors may set apart out of any funds of the corporation available for dividends a reserve or reserves for any proper purpose and, separately, may abolish any such reserve.

**Section 3. Checks.** All checks or demands for money and notes of the corporation shall be signed either by the corporation's chief financial officer, chief accounting officer, or such officer or officers, or such other person or persons, as the Board of Directors may from time to time designate in writing.

**Section 4. Fiscal Year.** The fiscal year of the corporation shall be fixed by resolution of the Board of Directors and may change at the discretion of the board.

**Section 5. Seal.** The Board of Directors, by resolution, may adopt a corporate seal but is not required to do so. The corporate seal shall have inscribed thereon the name of the corporation, the year of its organization, and the word "Delaware". The seal may be used by causing it or a facsimile thereof to be impressed or affixed or otherwise reproduced. The seal may be altered from time to time by the Board of Directors.

## ARTICLE IX

### AMENDMENTS

The Board of Directors is expressly empowered to adopt, amend or repeal these bylaws, provided, however, that any adoption, amendment or repeal of these bylaws by the Board of

Directors shall require the approval of at least sixty-six and two-thirds percent ( $66\frac{2}{3}\%$ ) of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any resolution providing for adoption, amendment or repeal is presented to the board). The stockholders also shall have power to adopt, amend or repeal these bylaws, provided, however, that in addition to any vote of the holders of any class or series of stock of this corporation required by law or by the certificate of incorporation of this corporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent ( $66\frac{2}{3}\%$ ) of the voting power of all of the then outstanding shares of the stock of the corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for such adoption, amendment or repeal by the stockholders of any provisions of these bylaws.

**CERTIFICATE OF MERGER**  
**OF**  
**VICTORY SUBSIDIARY, INC.**  
**WITH AND INTO**  
**BRICKELL BIOTECH, INC.**

Pursuant to Section 251(c) of the General Corporation Law of the State of Delaware (the “DGCL”), Brickell Biotech, Inc., a Delaware corporation, does hereby certify the following information in connection with the merger of Victory Subsidiary, Inc., a Delaware corporation, with and into Brickell Biotech, Inc. (the “Merger”):

**FIRST:** The name and state of incorporation of each of the constituent corporations in the Merger (the “Constituent Corporations”) are as follows:

<u>Name</u>	<u>State of Incorporation</u>
Brickell Biotech, Inc.	Delaware
Victory Subsidiary, Inc.	Delaware

**SECOND:** The Agreement and Plan of Merger and Reorganization, dated as of June 2, 2019, by and among Vical Incorporated, Victory Subsidiary, Inc. and Brickell Biotech, Inc. (as amended on August 20, 2019 and as may be amended, modified, and supplemented from time to time, the “Merger Agreement”), setting forth the terms and conditions of the Merger, has been approved, adopted, executed and acknowledged by each of the Constituent Corporations pursuant to and in accordance with the requirements of Section 251(c) of the DGCL (and, with respect to Victory Subsidiary, Inc., by the written consent of its sole stockholder in accordance with Section 228 of the DGCL).

**THIRD:** The name of the surviving corporation in the Merger is BRICKELL BIOTECH, INC. (the “Surviving Corporation”), and shall be changed to “BRICKELL SUBSIDIARY, INC.”.

**FOURTH:** The certificate of incorporation of Brickell Biotech, Inc. as in effect immediately prior to the Merger shall be amended and restated in its entirety at the effective time of the Merger as set forth in **ANNEX A** attached hereto and, as so amended and restated, shall be the certificate of incorporation of the Surviving Corporation until thereafter amended as provided therein or by applicable law.

**FIFTH:** The executed Merger Agreement is on file at the principal place of business of the Surviving Corporation, the address of which is 5777 Central Avenue, Suite 102, Boulder, CO 80301.

**SIXTH:** A copy of the Merger Agreement will be furnished by the Surviving Corporation, on request and without cost, to any stockholder of either Constituent Corporation.

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**SEVENTH:** The Merger shall become effective as of 12:05 a.m. Eastern time on Tuesday, September 3, 2019.

*(Remainder of page intentionally left blank)*

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IN WITNESS WHEREOF, the undersigned has executed this Certificate of Merger on the 30<sup>th</sup> day of August, 2019.

**BRICKELL BIOTECH, INC.**

By: /s/ Robert Brown

Name: Robert Brown

Title: Chief Executive  
Officer

*[Signature Page to Delaware Certificate of Merger]*

THIS WARRANT AND THE SECURITIES UNDERLYING THIS WARRANT HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR THE SECURITIES LAWS OF ANY STATE, AND MAY NOT BE SOLD, TRANSFERRED, ASSIGNED OR HYPOTHECATED UNLESS (A) THERE IS AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT COVERING SUCH SECURITIES AND THERE IS FULL COMPLIANCE WITH THE APPLICABLE STATE SECURITIES LAWS, (B) THE SALE IS MADE IN ACCORDANCE WITH RULE 144 UNDER THE SECURITIES ACT OR (C) BRICKELL BIOTECH, INC. (THE "COMPANY") RECEIVES AN OPINION OF COUNSEL FOR THE HOLDER OF THE SECURITIES REASONABLY SATISFACTORY TO THE COMPANY STATING THAT SUCH SALE IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF THE SECURITIES ACT AND COMPLIES WITH APPLICABLE STATE SECURITIES LAWS.

THIS WARRANT MAY NOT BE TRANSFERRED OR ASSIGNED BY THE REGISTERED HOLDER TO A NON-AFFILIATE OF THE HOLDER WITHOUT THE PRIOR WRITTEN CONSENT OF THE COMPANY.

COMMON STOCK PURCHASE WARRANT

Brickell Biotech, Inc.

Date of Issuance:

August 31, 2019

Warrant No. W-1

FOR VALUE RECEIVED, Brickell Biotech, Inc., a Delaware corporation (the "Company"), hereby grants to NovaQuest Co-Investment Fund X, L.P. ("NovaQuest") or its registered assigns (the "Holder") the right to purchase from the Company Two Hundred Forty-One Thousand Two Hundred Twenty-Five (241,225) shares of common stock, par value \$0.01 per share ("Common Stock"), of the Company (the "Warrant Stock") at a price per share equal to \$10.36 (the "Exercise Price") to such Holder. This Common Stock Purchase Warrant (this "Warrant") is issued pursuant to the terms and conditions of the Funding Agreement, dated as of June 2, 2019 (the "Funding Agreement"), between Brickell Subsidiary, Inc. (formerly known as Brickell Biotech, Inc.) and NovaQuest. Capitalized terms used herein but not otherwise defined herein shall have the meanings set forth for such terms in the Funding Agreement.

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This Warrant is subject to the following provisions:

**1. Exercise of Warrant.**

(a) Number of Shares. Subject to the terms and conditions hereinafter set forth, the Holder is entitled, upon surrender of this Warrant, to purchase from the Company Two Hundred Forty-One Thousand Two Hundred Twenty-Five (241,225) shares of Warrant Stock (subject to adjustment as provided herein).

(b) Exercise Period. The Holder may exercise, in whole or in part, the purchase rights represented by this Warrant at any time and from time to time after the Date of Issuance through and including 5:30 p.m., New York City time, on the date that is the tenth (10th) anniversary of the issuance of this Warrant (the "Expiration Date"). At 5:30 p.m., New York City time, on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value, and this Warrant shall be terminated and no longer outstanding.

(c) Exercise Procedure.

(i) This Warrant or any part hereof specified by the Holder shall be deemed to have been exercised at the time the Company receives all of the following items (the "Exercise Time"):

(a) a completed Exercise Notice, as described in **Section 1(f)** below, executed by the Person exercising all or part of the rights represented by this Warrant (the "Purchaser");

(b) this Warrant; and

(c) the aggregate Exercise Price for the number of shares of Warrant Stock being purchased through such exercise, such aggregate Exercise Price to be payable by check or a wire transfer in immediately available funds to the Company in an amount equal to the product of the Exercise Price multiplied by the number of shares of Warrant Stock being purchased with the proceeds of such check or wire transfer.

(ii) Certificates for shares of Warrant Stock purchased upon exercise of all or part of this Warrant shall be promptly delivered by the Company to the Purchaser. Unless this Warrant has expired or all of the purchase rights represented hereby have been fully exercised, the Company shall prepare a new warrant certificate, substantially identical hereto, representing the rights formerly represented by this Warrant which have not expired or been exercised and shall promptly deliver such new Warrant to the Person designated for delivery in the Exercise Notice.

(iii) The Warrant Stock issuable upon the exercise of all or part of this Warrant shall be deemed to have been issued to the Purchaser at the Exercise Time, and the Purchaser shall be deemed for all purposes to have become the record holder of such Warrant Stock at the Exercise Time.

(iv) Upon payment in full of the Exercise Price, each share of Warrant Stock issuable upon exercise of all or part of this Warrant shall be, and the Company shall take all such actions as may be necessary or appropriate such that each such share of such Warrant Stock shall be, validly issued, fully paid and nonassessable, issued without violation of preemptive or similar rights of any stockholder of the Company, and free from all liens and charges with respect to the issuance thereof.

(v) The Company shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock such number of shares of Common Stock as are from time to time issuable upon the exercise of this Warrant.

(vi) The Company shall use its commercially reasonable efforts to cause all of the shares of the Warrant Stock, immediately upon such exercise, to be listed on any domestic securities exchange upon which shares of Common Stock or other securities constituting Warrant Stock are listed at the time of such exercise. The Company shall take all such actions as may be necessary to ensure that all such shares of Warrant Stock are issued without violation by the Company of any applicable law or governmental regulation or any requirements of any domestic securities exchange upon which shares of Common Stock or other securities constituting Warrant Stock may be listed at the time of such exercise (except for official notice of issuance which shall be immediately delivered by the Company upon each such issuance).

(d) Conditional Exercise. Notwithstanding any other provision hereof, if an exercise of any portion of this Warrant is to be made in connection with a public offering or a sale of the Company (pursuant to a merger, sale of stock, or otherwise), then such exercise may at the election of the Holder be conditioned upon the consummation of such transaction, in which case such exercise shall not be deemed to be effective until immediately prior to the consummation of such transaction.

(e) Cashless Exercise. Notwithstanding any provisions herein to the contrary, if the fair market value of one share of Warrant Stock is greater than the Exercise Price, in lieu of exercising this Warrant for cash, the Holder may elect to receive Warrant Stock equal to the value (as determined below) of this Warrant (or the portion thereof being canceled) by surrender of this Warrant at the principal office of the Company together with the properly executed subscription form and notice of such election in which event the Company shall issue to the Holder a number of shares of Warrant Stock computed using the following formula:

$$X = \frac{Y (A-B)}{A}$$

Where X = the number of shares of Warrant Stock to be issued to the Holder.

Y = the number of shares of Warrant Stock purchasable under the Warrant or, if only a portion of the Warrant is being exercised, the portion of the Warrant being canceled (at the date of such calculation).

A = the fair market value of one share of Common Stock of the Company (at the date of such calculation).

B = Exercise  
Price.

For purposes of the above calculation, the fair market value of one share of Common Stock shall be (i) the last reported sale price of the Common Stock or the closing price quoted on the Nasdaq National Market, the New York Stock Exchange, or the NYSE American, as published in The Wall Street Journal for the five (5) trading days prior to the date of determination of fair market value, or, if no such closing sale price is reported, the last reported sale price on the principal U.S. national or regional securities exchange on which the Common Stock (or other relevant capital stock) is so listed or quoted, or if the Common Stock (or other relevant capital stock) is not so listed or quoted on a U.S. national or regional securities exchange, the last quoted bid price for the Common Stock (or other relevant capital stock) in the over-the-counter market as reported on the OTC Bulletin Board or by Pink Sheets LLC or similar organization. If at any time the Common Stock is not listed on any domestic securities exchange or quoted on the OTC Bulletin Board, the Pink OTC Markets or similar quotation system or association, then the "fair market value" of the Common Stock shall be the fair market value per share as determined in good faith by the Company's Board of Directors.

(f) Exercise Notice. Upon any exercise of all or part of this Warrant, the Exercise Notice shall be substantially in the form set forth in **Warrant Exhibit A** hereto. Such Exercise Notice shall be dated the actual date of execution thereof.

**2. Definitions.** The following terms have meanings set forth below:

(a) "Date of Issuance" means the date of initial issuance of this Warrant (as of immediately after such issuance) regardless of the number of times new certificates representing the unexpired and unexercised rights formerly represented by this Warrant shall be issued.

(b) "Holder" with respect to this Warrant means the Person who is reflected as the holder thereof on the register maintained by the Company.

(c) "Person" means an individual, a partnership, a joint venture, a corporation, a trust, an unincorporated organization and a government or any department or agency thereof.

**3. No Rights; Limitations of Liability.** Prior to the exercise of this Warrant and except as otherwise specifically provided herein or in the Funding Agreement, this Warrant shall not entitle the Holder hereof to any rights as a stockholder of the Company.

**4. Replacement.** Upon receipt of evidence reasonably satisfactory to the Company (an affidavit of the Holder shall be satisfactory) of the loss, theft, destruction or mutilation of any certificate evidencing this Warrant, and in the case of any such loss, theft or destruction, upon receipt of an indemnity reasonably satisfactory to the Company, or in the case of any such mutilation, upon surrender and cancellation of such certificate, the Company shall (at its expense) execute and deliver in lieu of such certificate a new certificate of like tenor and dated the date of such lost, stolen, destroyed or mutilated certificate.

**5 . Legend.** The certificates representing shares of Warrant Stock issued upon exercise of the Warrants shall bear a legend substantially as follows:

“THESE SECURITIES HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE “SECURITIES ACT”), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS ESTABLISHED BY EVIDENCE TO SUCH EFFECT, THE FORM AND SUBSTANCE OF WHICH SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.”

**6. Charges, Taxes and Expenses.** Issuance and delivery of certificates for representing shares of Warrant Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided, however*, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any certificates for shares of Warrant Stock or the Warrant in a name other than that of the Holder or its affiliates. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving shares of Warrant Stock upon exercise hereof.

**7 . Certain Adjustments.** The Exercise Price and number of shares of Warrant Stock issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this **Section 7**.

(a) **Stock Dividends and Splits.** If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares, or (iii) combines its outstanding shares of Common Stock into a smaller number of shares, then in each such case the Exercise Price shall be adjusted to a price determined by multiplying the Exercise Price in effect immediately prior to the effective date of such event by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding on such effective date immediately before giving effect to such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after giving effect to such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, and any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision, combination or reclassification.

(b) **Fundamental Transactions.** If, at any time while this Warrant is outstanding (i) the Company effects (A) any merger of the Company with (but not into) another Person, in which

stockholders of the Company immediately prior to such transaction own less than a majority of the outstanding stock of the surviving entity, or (B) any merger or consolidation of the Company into another Person, (ii) the Company effects any sale of all or substantially all of its assets in one or a series of related transactions, (iii) any tender offer or exchange offer approved or authorized by the Company's Board of Directors is completed pursuant to which holders of at least a majority of the outstanding Common Stock tender or exchange their shares for other securities, cash or property, or (iv) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (other than as a result of a subdivision or combination of shares of Common Stock covered by **Section 7(a)** above) (in any such case, a "Fundamental Transaction"), then the Holder shall have the right thereafter to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of shares of Warrant Stock then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the "Alternate Consideration"), and the Holder shall no longer have the right to receive shares of Warrant Stock upon exercise of this Warrant. The Company shall not effect any such Fundamental Transaction unless prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or the corporation purchasing or otherwise acquiring such assets or other appropriate corporation or Person shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this **Section 7(b)** shall similarly apply to subsequent transactions of an analogous type to any Fundamental Transaction.

(c) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to **Section 7(a)**, the number of shares of Warrant Stock that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the increased or decreased number of shares of Warrant Stock shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(d) Calculations. All calculations under this **Section 7** shall be made to the nearest cent or the nearest share, as applicable. The number of shares of Common Stock outstanding at any given time shall not include shares owned or held by or for the account of the Company.

(e) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this **Section 7**, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of shares of Warrant Stock or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in reasonable detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

( f ) **Notice of Corporate Events.** If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company, (ii) authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) business days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction; *provided, however*, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

**8. No Fractional Shares.** No fractional shares of Warrant Stock will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of shares of Warrant Stock to be issued shall be rounded up to the next whole number.

**9. Registration Rights.** The Holder and its assignees are entitled to the benefit of such registration rights in respect of the Warrant Stock as are set forth in the Registration Rights Agreement, dated as of the date hereof, between the Company and Holder, including the right to assign such rights as set forth therein. The form of the Registration Rights Agreement is set forth on Warrant Exhibit B.

**10. Notices.** Except as otherwise expressly provided herein, all notices referred to in this Warrant shall be in writing and shall be delivered personally, sent by reputable express courier service (charges prepaid), sent by registered or certified mail, return receipt requested, postage prepaid or sent by facsimile or email of a PDF document (with confirmation of transmission) and shall be deemed to have been given when so delivered, sent or deposited in the U.S. Mail (i) to the Company, at its principal executive offices and (ii) to the Holder of this Warrant, at such holder's address as it appears in the records of the Company (unless otherwise indicated by any such holder).

**11. Restrictions on Transfer.**

(a) The Holder represents, by accepting this Warrant that it understands that this Warrant and any securities obtainable upon exercise of this Warrant have not been registered for sale under Federal or state securities laws and are being offered and sold to the Holder pursuant to one or more exemptions from the registration requirements of such securities laws. Certificates representing Warrant Stock must bear the restrictive legend set forth herein. The Holder understands that the Holder must bear the economic risk of such Holder's investment in this Warrant and any Warrant Stock or other securities obtainable upon exercise of this Warrant for an indefinite period of time, as this Warrant and such Warrant Stock or other securities have not been registered under Federal or state securities laws and therefore cannot be sold unless subsequently registered under such laws, or an exemption from such registration is available.

(b) The Holder, by such Holder's acceptance of this Warrant, represents to the Company that such Holder is acquiring this Warrant and will acquire any Warrant Stock or other securities obtainable upon exercise of this Warrant for such Holder's own account for investment and not with a view to, or for sale in connection with, any distribution thereof in violation of the Securities Act. The Holder agrees that this Warrant will not be sold or otherwise transferred unless (i) a registration statement with respect to such transfer is effective under the Securities Act or (ii) such sale or transfer is made pursuant to one or more exemptions from the Securities Act, and (iii) such sale or transfer to a non-affiliate of the Holder is approved by the prior written consent of the Company. The Holder agrees the Warrant Stock will not be sold or otherwise transferred unless (i) a registration statement with respect to such transfer is effective under the Securities Act or (ii) such sale or transfer is made pursuant to one or more exemptions from the Securities Act, and (iii) such sale or transfer is made in accordance with the rights and restrictions set forth in the Investors' Rights Agreement.

**12. Amendment.** Except as expressly provided herein, neither this Warrant nor any term hereof may be amended, waived, discharged or terminated other than by a written instrument approved by the Board of Directors of the Company and signed by an authorized officer the Company and the Holder.

**13. Successors and Assigns.** Subject to the restrictions on transfer set forth in this Warrant, and compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and permitted assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant.

**14. Descriptive Headings; Governing Law.** The descriptive headings of the several Sections and paragraphs of this Warrant are inserted for convenience only and do not constitute a part of this Warrant. All questions concerning the construction, validity and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to any choice of law or conflict provision or rule that would cause the application of the laws of any jurisdiction other than the State of New York.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the Company executed this Warrant as of the Date of Issuance hereof.

**BRICKELL BIOTECH, INC.**

By: /s/ Robert Brown

Name: Robert Brown

Title: Chief Executive Officer

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*[Signature Page to NovaQuest Warrant]*

**Warrant Exhibit A**

**EXERCISE NOTICE**

The undersigned, pursuant to the provisions set forth in the attached Warrant (Warrant No. W-\_\_\_\_), hereby agrees to subscribe for the purchase of \_\_\_\_\_ shares of the Warrant Stock covered by such Warrant and makes payment in full at the price per share provided by such Warrant.

The undersigned requests that certificates for such shares be issued in the name of, and delivered to:

(Name)

\_\_\_\_\_

(Address)

\_\_\_\_\_  
\_\_\_\_\_

(Signature and Date)

\_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant)

(Insert Social Security Number or EIN)

\_\_\_\_\_

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**Warrant Exhibit B**

**BRICKELL BIOTECH, INC.  
REGISTRATION RIGHTS AGREEMENT**

[See Exhibit 10.17]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**FUNDING AGREEMENT**

This Funding Agreement (this “*Agreement*”) is entered into as of June 2, 2019 (the “*Effective Date*”), between Brickell Biotech, Inc., a Delaware corporation with a principal place of business at 5777 Central Avenue, Suite 102, Boulder, Colorado 80301 (“*Company*”) and NovaQuest Co-Investment Fund X, L.P., a Delaware limited partnership, with a place of business at 4208 Six Forks Road, Suite 920 Raleigh, NC 27609 (“*NovaQuest*”). Company and NovaQuest are each referred to herein by name or, individually, as a “*Party*” or, collectively, as “*Parties*.”

**INTRODUCTION**

A. Company is dedicated to the research, development, and commercialization of products for the treatment of human diseases, disorders, and conditions.

B. Company currently has certain pharmaceutical products under development and desires to enter into an agreement to receive funding to develop and commercialize the Product (as defined below).

C. NovaQuest and Company desire for NovaQuest to provide funding for Company’s development of the Product (as defined below) up to the maximum amount specified herein and for Company to make certain payments to NovaQuest as set forth herein, all subject to the terms and conditions of this Agreement.

D. As a condition to Closing and as a material inducement for NovaQuest’s entry into this Agreement, NovaQuest and Company will enter into a security agreement pursuant to which Company will grant to NovaQuest a first priority security interest in the Product Assets and the proceeds thereof in the form and substance as set forth on Exhibit A (the “*Security Agreement*”).

E. As a condition to Closing and as a material inducement for NovaQuest’s entry into this Agreement, Company will cause Vical to execute and deliver a warrant in the form and substance as set forth on Exhibit B (the “*Warrant Agreement*”).

NOW, THEREFORE, in consideration of the premises and mutual covenants herein below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

**ARTICLE I**

**DEFINITIONS**

1.1 When used and capitalized in this Agreement (other than the headings of the Articles and Sections), including the foregoing recitals, exhibits and schedules hereto, the following terms shall have the meanings assigned to them in this Article and include the plural as well as the singular and include all participles of each such term, as applicable.

“*AAA*” has the meaning set forth in Section 11.2(b).

“*AAA Rules*” has the meaning set forth in Section 11.2(b).

“*Act*” shall mean, collectively, the United States Federal Food, Drug, and Cosmetic Act of 1938, including any amendments thereto, and all regulations promulgated thereunder and any successor laws.

“*Affiliate*” means, with respect to an entity, any business entity controlling, controlled by, or under common control with, such entity, but only for so long as such control exists. For the purposes of this definition, “controlling,” “controlled,” and “control” mean the possession, directly (or indirectly through one or more intermediary entities), of the power to direct the management or policies of an entity, including through ownership of fifty percent (50%) or more of the voting securities of such entity (or, in the case of an entity that is not a corporation, ownership of fifty percent (50%) or more of the corresponding interest for the election of the entity’s managing authority).

“*Agreement*” has the meaning set forth in the preamble hereto.

“*Anticipated Closing Date*” has the meaning set forth in Section 3.1(c)(i).

“*Applicable Law*” means any applicable law, rule, or regulation of any Governmental Authority, or judgment, order, writ, decree, permit, or license of any Governmental Authority.

“*Arbitration*” has the meaning set forth in Section 11.2(b).

“*Arbitrator*” has the meaning set forth in Section 11.2(c).

“*Business Day*” means any day other than Saturday, Sunday, or any day on which banking institutions located in the State of New York are permitted or obligated by law to close.

“*Closing*” has the meaning set forth in Section 2.3.

“*Closing Date*” means the date on which the Closing actually occurs.

“*Commercially Reasonable Efforts*” means, with respect to the Product, (i) before receipt of U.S. Approval, the level of effort and resources commonly dedicated in the pharmaceutical industry by a Permitted Company to the development of a product of similar commercial potential at a similar stage in its lifecycle to the Product, taking into account the CRE Considerations and (ii) after receipt of U.S. Approval, the level of effort and resources commonly dedicated in the pharmaceutical industry by a Permitted Company to manufacturing and commercialization of a product of similar commercial potential as determined on a market-by-market basis, taking into account the CRE Considerations but without regard to the particular circumstances of Company or any other Responsible Party, any other product opportunities of Company or any other Responsible Party, or any payments due to NovaQuest. Without limiting or derogating from the generality of the foregoing, Commercially Reasonable Efforts requires Company and each other Responsible Party to, as applicable: (a) timely assign responsibility for all Development and Commercialization activities to specific employees who are held accountable for progress; (b) monitor the progress of such employees on an on-going basis; (c) set and consistently seek to achieve specific and meaningful

objectives and timelines for carrying out such Development (including in accordance with the Development Plan) and Commercialization activities; (d) consistently make and implement decisions and allocate and spend sufficient resources designed to advance progress with respect to such objectives and timelines; (e) employ compensation systems for its sales representatives and other employees and agents that are not materially less favorable than the compensation systems that Company and its Affiliates apply to their other comparable development and commercialization programs, in order to reasonably incentivize such sales representatives and other employees and agents to achieve such objectives and timelines; and (f) use reasonable care in (A) selecting any Third Party to whom it may grant any rights (by license or otherwise) to Develop or Commercialize the Product and (B) negotiating and enforcing the terms of any agreement entered into with respect thereto. **“Commercially Reasonable”** shall have a corresponding meaning.

**“Commercialize”** or **“Commercialization”** means any and all activities directed to marketing, promoting, distributing, importing, exporting, offering to sell, or selling the Product, including commercial manufacturing activities.

**“Company”** has the meaning set forth in the preamble hereto.

**“Competing Product”** means any anticholinergic for the topical treatment of axillary hyperhidrosis.

**“Confidential Information”** has the meaning set forth in Section 6.1.

**“Cover”** means that the use, manufacture, sale, offer for sale, development, commercialization, or importation of the subject matter in question by an unlicensed entity would infringe a claim of a Patent.

**“CRE Considerations”** means issues, considerations, and matters relating to safety, efficacy, the regulatory environment, and other relevant scientific and technical factors, all without regard to any payments owed to NovaQuest.

**“Develop”** or **“Developing”** means engaging in manufacturing, preclinical, clinical, or other research and development activities (including manufacturing activities related thereto) directed towards obtaining U.S. Approval. **“Development”** means the process of Developing.

**“Development Budget”** means the budget included in the Development Plan for the performance of the Development Plan setting forth the estimated expenses associated with Developing the Product, as amended from time to time in accordance with the terms of this Agreement.

**“Development Invoice”** means, with respect to a particular Fiscal Quarter during the Product Funding Period, an invoice that sets forth: (i) the Development Payment invoiced to NovaQuest for such Fiscal Quarter; (ii) Company’s reasonable and good faith estimate of anticipated expenses to carry out the Product Development Activities for such Fiscal Quarter; (iii) the Eligible Expenses for the preceding Fiscal Quarter; and (iv) a calculation made in accordance with the requirements set forth in Section 3.1(c) to support the Development Payment invoiced to NovaQuest for such Fiscal Quarter.

**“Development Obligations”** has the meaning set forth in Section 3.2(a)(i).

**“Development Payment”** has the meaning set forth in Section 3.1(a).

**“Development Plan”** means the plan attached hereto as Exhibit C, setting forth, in reasonable detail, the Product Development Activities, as amended from time to time in accordance with the terms of this Agreement.

**“Dispute”** has the meaning set forth in Section 11.2(a).

**“Dispute Notice”** has the meaning set forth in Section 11.2(a).

**“Effective Date”** has the meaning set forth in the preamble hereto.

**“Eligible Expenses”** means the reasonable and documented expenses actually incurred by Company on or after the Effective Date solely in connection with the Product Development Activities during the Product Funding Period.

**“Encumbrance”** means any lien, charge, security interest, mortgage, option, privilege, pledge, right of first refusal, hypothecation, adverse ownership interest, charge, trust or deemed trust (whether contractual, statutory, or otherwise arising), or any other encumbrance, or similar right, or claim of any other Person of any kind whatsoever whether choate or inchoate. **“Encumber”** means to impose, suffer, or otherwise create any Encumbrance.

**“Excluded Taxes”** means federal withholding Taxes imposed by the U.S. federal government pursuant to the U.S. Internal Revenue Code of 1986, as amended, on amounts payable to or for the account of NovaQuest.

**“FDA”** means the United States Food and Drug Administration, or any successor agency thereto.

**“First Commercial Sale”** means the first commercial sale of the Product by a Responsible Party in the Territory in exchange for cash, or another form of consideration to which value can be ascribed and ascertained, that falls within the meaning of Net Sales herein.

**“Fiscal Quarter”** means each of the following three (3) month periods during each Fiscal Year: January 1 through March 31; April 1 through June 30; July 1 through September 30; and October 1 through December 31.

**“Fiscal Year”** means the twelve (12) month period from January 1 through December 31.

**“GAAP”** means U.S. generally accepted accounting principles, as in effect on the date or for the period with respect to which such standards are applied.

**“Governmental Authority”** means any national, supra-national (e.g., the European Commission or the Council of the European Union), federal, state, local, or foreign court or governmental agency, authority, instrumentality, regulatory body, department, bureau, political subdivision, or other governmental entity (including the FDA) or any arbitral tribunal, in each case of a competent jurisdiction, including any such authority that is responsible for issuing approvals, licenses, registrations, or authorizations necessary for the manufacture, import, sale, pricing, and/or use of the Product for human therapeutic use in any applicable regulatory jurisdiction.

“**Hercules**” means Hercules Technology Growth Capital, Inc.

“**Hercules Loan**” means that certain Loan and Security Agreement entered into by Company and Hercules, dated as of February 18, 2016 and as amended from time to time, including pursuant to that certain First Amendment to Loan and Security Agreement dated as of December 14, 2017, that certain Second Amendment to Loan and Security Agreement dated as of March 30, 2018 and that certain Third Amendment to Loan and Security Agreement dated as of July 30, 2018.

“**Indemnified Party**” has the meaning set forth in Section 10.2(a).

“**Indemnifying Party**” has the meaning set forth in Section 10.2(a).

“**Investment Schedule**” means the anticipated schedule of Development Payments, listed on a Fiscal Quarter-by-Fiscal Quarter basis on Exhibit D.

“**Joint Steering Committee**” has the meaning set forth in Section 5.3(a).

“**JSC Member**” has the meaning set forth in Section 5.3(b).

“**Liabilities**” means any and all indebtedness, liabilities, and obligations, whether accrued, fixed, or contingent, mature or inchoate, known or unknown, reflected on a balance sheet or otherwise, including those arising under any law or judgment of any court of any kind or any award of any arbitrator of any kind, and those arising under any contract, commitment, or undertaking.

“**License**” means a grant of any rights in, to, or under any Product IP Rights or Regulatory Approvals associated with or Covering the Product in the Territory, including a grant of rights to market, sell, distribute, or otherwise Commercialize the Product in the Territory; provided, however, that none of the following, alone, shall constitute a “License” within the meaning hereof: (i) any implied license granted to a Person by virtue of a sale of a product to such Person or by virtue of any service performed by such Person at the request of another Person; or (ii) any license granted to any Person in connection with such Person’s performance of contract research services or contract manufacturing services.

“**Licensee**” means a Third Party or an Affiliate of Company that is granted a License, regardless of whether such License is granted by Company, an Affiliate of Company, or another Licensee.

“**Loss**” has the meaning set forth in Section 10.1.

“**Material Adverse Effect**” means any of the following: (a) a material adverse effect on the validity or enforceability of this Agreement; (b) a material adverse effect on the ability of Company or any other Responsible Party to perform any of Company’s material obligations under this Agreement; (c) a material adverse effect on Development or Commercialization; (d) the inability of Company to make a payment required by this Agreement, or (e) a material adverse effect on the sales or potential sales of the Product; provided, however, that in determining whether there has been a Material Adverse Effect or whether a Material Adverse Effect could or would reasonably be expected to occur pursuant to any of clause (a), (b), or (c) of this definition, any change, event, circumstance, or occurrence solely attributable to an Uncured NovaQuest Funding Breach shall be disregarded.

**“Material Adverse Event”** means any of the following: (a) any Governmental Authority has imposed, or communicated its intent to, impose a suspension, clinical hold, or other adverse regulatory action regarding the Development Plan or the Product where such action has had or would reasonably be expected to have a Material Adverse Effect; (b) Company or any other Responsible Party terminates a material clinical study involving the Product; (c) the occurrence of any event that would reasonably be expected to result in at least a [\*\*\*]-month delay of either (i) a Responsible Party’s receipt of U.S. Approval for the Product by the Target U.S. Approval Date or (ii) the anticipated date of First Commercial Sale set forth in the Development Plan; (d) the occurrence of any of the events set forth in subsections (a), (b), or (c) of the definition of **“Technical Failure”**; (e) Company materially amends the Phase III Study Protocol without the prior written consent of NovaQuest, which consent may not be unreasonably withheld; (f) either (i) [\*\*\*] or (ii) any [\*\*\*] members of Company’s senior executives (other than [\*\*\*]) cease to provide the same or substantially similar services to Company as of the Effective Date through the end of the Product Funding Period for any reason, provided, however, that (x) if [\*\*\*]’s cessation of services is a result of either his disability that substantially adversely affects his ability to work or his death, then such cessation of services shall not be deemed a Material Adverse Event and (y) if the Company hires a replacement for [\*\*\*], or such [\*\*\*] other senior executives, as applicable, within [\*\*\*] calendar days after such individual(s)’ employment with the Company terminates, or as otherwise agreed to with NovaQuest, and such replacement(s) are reasonably acceptable to NovaQuest, then such cessation of services shall not be deemed a Material Adverse Event; or (g) the existence or occurrence of a Material Adverse Effect.

**“Material Contract”** means (a) any agreement related to the Development, marketing, promotion, manufacture, Commercialization, or distribution of the Product or (b) any other agreement for which breach, non-performance, or failure to renew by Company could reasonably be expected to result in a Material Adverse Event.

**“Milestone Date”** means the date on which a Responsible Party receives U.S. Approval. For the sake of clarity, the Milestone Date shall occur only once.

**“Milestone Installment Payments”** means installments of the Milestone Payment Obligation pursuant to Section 4.1(a).

**“Milestone Payment Obligation”** means Thirty-Seven Million, Five Hundred Thousand Dollars (\$37,500,000).

**“NDA”** means a new drug application (as defined in Title 21 of the U.S. Code of Federal Regulations, as amended from time to time) submitted to the FDA seeking approval to introduce, distribute, sell, or market a drug product for human therapeutic use in the U.S. (including a new drug application submitted under Section 505(b)(2) of the Act).

**“Net Sales”** means the gross amount invoiced by Company, its Affiliates, and any Licensees, to Third Parties for sales or other dispositions of the Product in the Territory, less the sum of the following items to the extent such deductions are commercially reasonable and directly and solely related to the sale of the Product in the Territory:

- (a) Trade, quantity, and cash discounts or rebates, credits or refunds allowed and actually taken or accrued for sales of the Product;

(b) Discounts, refunds, rebates (including wholesaler inventory management fees), credits, cost of samples and free goods, returns, chargebacks, and retroactive price adjustments actually taken or accrued for sales of the Product, which effectively reduce the net selling price;

(c) Price reductions, chargebacks or rebates, retroactive or otherwise, imposed by or negotiated with any Governmental Authority in a jurisdiction with regard to sales of the Product in such jurisdiction;

(d) Transportation, importation, shipping, insurance, and other handling expenses directly chargeable to sales of the Product, but only to the extent set forth separately in the invoice, and in no event shall a reduction under this clause (d) exceed [\*\*\*] of the applicable Fiscal Quarter gross amount invoiced for sales of the Product;

(e) Taxes imposed on the production, sale, or delivery of the Product in a jurisdiction, including sales, use, excise, turnover, inventory, or value added Taxes (but excluding income Taxes and similar Taxes), but only to the extent set forth separately in the applicable invoices; and

(f) Bad debts, but in no event shall a reduction under this clause (f) exceed [\*\*\*] of the applicable Fiscal Quarter gross amount invoiced for sales of the Product; provided that the amount of any bad debts deducted pursuant to this exception and actually collected in a subsequent Fiscal Quarter shall be included in Net Sales for such subsequent Fiscal Quarter.

Net Sales shall not include sales or other dispositions of the Product by Company, an Affiliate thereof, or a Licensee to Company, an Affiliate thereof, or a Licensee for purposes of resale thereby; provided, however, that such Person's commercial resale of such Product shall be counted in determining Net Sales subject to Revenue Share Payments pursuant to this Agreement. Further, use, supply or donation of the Product by Company, its Affiliates or any Licensee for no profit (i) in connection with patient assistance programs, (ii) for charitable or promotional purposes, (iii) for preclinical, clinical, regulatory or governmental purposes, or compassionate use or other similar programs, or (iv) for tests or studies reasonably necessary to comply with any Applicable Law, or request by a Governmental Authority shall not, in each case, be deemed sales of such Product for purposes of this definition of "Net Sales."

With respect to any sale of the Product for consideration other than monetary consideration on arm's length terms, which non-monetary or non-arm's length consideration has the effect of reducing the invoiced amount below what it would have been in the absence of such non-monetary or non-arm's length consideration, for purposes of calculating the Net Sales under this Agreement, the Product in such sale shall be deemed to be sold for cash exclusively and at the average Net Sales price charged to Third Parties for cash sales in arm's length transactions during the applicable reporting period (or if there were only *de minimus* cash sales, then at the fair market value as determined by comparable markets).

Any recovery, damages, or amounts in settlement received by any Responsible Party with respect to the alleged, actual, or potential infringement of the Product IP Rights in the Territory or any settlement agreement entered into with respect thereto shall be deemed to be Net Sales.

Net Sales shall be determined from the books and records of Company, its Affiliates, and Licensees, as applicable, maintained in accordance with GAAP as regularly and consistently employed by Company, its Affiliates, and Licensees, as applicable.

“**Non-Technical Termination Payment**” means a payment to NovaQuest in an amount equal to Twenty-Five Million Dollars (\$25,000,000), plus [\*\*\*].

“**NovaQuest Indemnities**” has the meaning set forth in Section 10.1.

“**NovaQuest**” has the meaning set forth in the preamble hereto.

“**Party**” has the meaning set forth in the preamble hereto.

“**Patents**” means all patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, revalidations, supplementary protection certificates, and patents of addition) and patent applications (including all provisional applications, continuations, continuations-in-part, and divisions) and all counterparts and equivalents of any of the foregoing in any country or jurisdiction.

“**Payment Report**” has the meaning set forth in Section 4.1(c).

“**Permitted Company**” means a pharmaceutical and/or biologics company with either (a) global annual revenue for its most recently completed Fiscal Year that is equal to or greater than [\*\*\*], based on most recent data collected or compiled by Evaluate Pharma (or a similar company to the extent Evaluate Pharma’s data is not available) or (b) a market capitalization that is equal to or greater than [\*\*\*].

“**Person**” means any natural person, corporation, trust, joint venture, association, unincorporated organization, cooperative, company, partnership, trust, limited liability company, government (domestic or foreign), and any agency or instrumentality thereof, or any other entity recognized by law.

“**Phase III Studies**” means the human clinical trials of the Product described in the Development Plan that are designed to ascertain efficacy and safety of the Product, for the purpose of enabling the preparation and submission of a NDA or a foreign equivalent thereof in the Territory.

“**Phase III Study Protocol**” means that certain protocol for the Phase III Studies attached hereto as Exhibit E.

“**Post-Phase III Termination Payment**” means a payment to NovaQuest in an amount equal to Twenty-Five Million Dollars (\$25,000,000), plus [\*\*\*].

“**Prime Rate**” has the meaning set forth in Section 4.4.

“**Prior-Quarter Development Payment Excess**” means, for a particular Fiscal Quarter, an amount equal to the difference of (a) the Scheduled Payment for the immediately preceding Fiscal Quarter *minus* (b) [\*\*\*] of the Eligible Expenses actually incurred for such immediately preceding Fiscal Quarter. If the foregoing calculation results in a number that is less than zero (0), then the Prior-Quarter Development Payment Excess shall be deemed to be zero (0).

“**Product**” means any product that contains Solfipironium Bromide.

“**Product Assets**” means all assets (i) of the Company and any of Company’s Affiliates that are engaged in the Development or Commercialization of the Product in the Territory or (ii) of a

Licensee, excluding, for the purpose of clause (ii), assets owned or controlled by such Licensee prior to the date on which it is granted a License, that are, in the case of clause (i) and clause (ii), material to, or reasonably necessary for, the Commercialization or Development of the Product in the Territory, including, for the avoidance of doubt, the following assets: Product IP Rights, Product IP Agreements, all Regulatory Filings, product packaging, product inserts, product labels, Regulatory Approval applications, Regulatory Approvals, regulatory exclusivity, copies of correspondence with regulatory authorities, copies of pre-clinical and clinical data, pharmacology and biology data, Material Contracts, and inventory.

**“Product Development Activities”** means all activities conducted by or on behalf of Company or any other Responsible Party, including efforts undertaken, services performed, and goods purchased, in connection with the Development of the Product, in each case that are included in the Development Plan.

**“Product Funding Period”** means, with respect to the Program, the period commencing on the Closing Date and ending on the earliest to occur of (a) the last day of the Fiscal Quarter in which the Total Funding Commitment is met; (b) U.S. Approval; (c) termination of the Program; or (d) [\*\*\*].

**“Product IP Agreement”** means any contract pursuant to which a Responsible Party has been granted, assigned or otherwise conveyed any right, title or interest in or to any Product IP Rights by a Third Party.

**“Product IP Rights”** means all intellectual property relating to the Product owned or licensed (i) by the Company or by any of Company’s Affiliates that are engaged in the Development or Commercialization of the Product in the Territory or (ii) by a Licensee, excluding, for the purpose of clause (ii), intellectual property rights owned or controlled by such Licensee prior to the date on which it is granted a License, that are, in the case of clause (i) and clause (ii), reasonably necessary for the Commercialization or Development of the Product in the Territory, including, for the avoidance of doubt, the following intellectual property: (a) the Product Know-How; (b) all Patents Covering the Product (including, without limitation, its composition, formulation, delivery, manufacture, or use); (c) all trademarks, service marks, trade names, and works protectable under copyright laws, relating to the Product; and (d) all copies and tangible embodiments of any of the foregoing (in whatever form or medium); provided, that trademarks, service marks, and trade names that relate generally to the Company or the Company’s Affiliates, and not to the Product, shall not be included in clauses (c) or (d) of this definition.

**“Product Know-How”** means, with respect to the Product, all conceptions, ideas, reductions-to-practice, innovations, inventions, trade secrets, technology, processes, practices, formulae, instructions, procedures, assembly procedures, results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data, including study designs and protocols), machines, equipment, compositions of matter, compounds, formulations, genetic material, improvements, enhancements, modifications, technological developments, know-how, methods, treatments, techniques, systems, designs, artwork, drawings, plans, specifications, documentation, data and information, customer lists, lists and identities of key opinion leaders in each case whether or not confidential, proprietary, patentable, copyrightable, or susceptible to any other form of legal protection, in written, electronic or any other form.

“**Program**” means Developing the Product in compliance in all respects with the Development Plan and the Development Budget and in a manner that ensures that a Responsible Party is reasonably likely to receive U.S. Approval on or before the Target U.S. Approval Date.

“**Quarterly Report**” means a report submitted by Company to NovaQuest in accordance with the provisions of Section 3.1(b), in the form and substance as set forth on Exhibit F and that contains the following information with respect to the applicable Fiscal Quarter: (a) a reasonably detailed clinical update, regulatory update, and commercial update regarding the Product; (b) a reasonably detailed summary of any legal action brought by Company during the most recently completed Fiscal Quarter against a Third Party for such Third Party’s infringement of any Patents Covering the Product; (c) a complete, accurate and detailed list of all Eligible Expenses incurred during the most recently completed Fiscal Quarter and a comparison of such Eligible Expenses to the Development Budget, and any applicable Quarterly Invoice for such recently completed Fiscal Quarter; and (d) Company’s reasonable and good faith estimate of the anticipated expenses to carry out the Product Development Activities for the current Fiscal Quarter and for each subsequent Fiscal Quarter of the Program. All amounts in each Quarterly Report shall be denominated in U.S. Dollars.

“**Recordkeeping Period**” has the meaning set forth in Section 5.2(a).

“**Regulatory Approval**” means, with respect to the Product, in respect of a particular jurisdiction, all approvals (including supplements, amendments, pre- and post-approvals), licenses, registrations, or authorizations of any Governmental Authority that are necessary for the manufacture, distribution, use, sale, marketing, or other Commercialization of the Product for human therapeutics purposes in such jurisdiction.

“**Regulatory Filing**” means any applications, filings, or submission required by or provided to a Governmental Authority relating to the Development, manufacture, Commercialization, pricing, or other exploitation of the Product, including any supporting documentation, correspondence, meeting minutes, amendments, supplements, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, and manufacturing, shipping, or storage records with respect to any of the foregoing, including an NDA, drug master filing, clinical trial application, and any counterparts or equivalents of any of the foregoing.

“**Report Update**” has the meaning set forth in Section 3.3(d).

“**Responsible Party**” means (a) each of Company and its Affiliates and (b) each Licensee.

“**Resumption Notice**” has the meaning set forth in Section 3.3(d).

“**Revenue Share Payment**” has the meaning set forth in Section 4.1(b).

“**Revenue Share Rate**” has the meaning set forth in Section 4.1(b).

“**Scheduled Payment**” means, for a particular Fiscal Quarter, the Development Payment set forth in the Investment Schedule for such Fiscal Quarter.

“**Security Agreement**” has the meaning set forth in the Introduction hereto.

“**Senior Officer**” means (a) in the case of NovaQuest, its managing partner and (b) in the case of Company, its chief executive officer.

“**Sofpironium Bromide**” means that certain molecule that is more particularly described in Exhibit G.

“**Successful Completion**” means, with respect to the Phase III Studies, the achievement of any primary clinical endpoint identified in Phase III Study Protocol.

“**Target U.S. Approval Date**” means June 30, 2022.

“**Tax**” means any present or future tax, levy, impost, duty, assessment, charge, fee, deduction, or withholding of any nature and whatever called (including interest and penalties thereon) by any Governmental Authority, on whomever and wherever imposed, levied, collected, withheld, or assessed.

“**Technical Failure**” means any of the following:

(a) a reasonable and good faith determination by Company that the Product presents risk of death, a life-threatening condition, or a serious safety or health concern to patients such that, based on then-available data, no Responsible Party can ethically and in good faith administer the Product to patients;

(b) the Product fails to achieve each of the primary endpoints for the Phase III Studies conducted in compliance with Phase III Study Protocol (as may be amended in accordance with this Agreement), as reviewed by FDA, such that the Product is not reasonably likely to receive U.S. Approval; or

(c) Company receives either (i) a final unconditional non-approval letter from the FDA with respect to the Product or (ii) an equivalent notice from the European Medicines Agency that, in either the case of (i) or (ii), renders the receipt of U.S. Approval not reasonably likely.

For the avoidance of doubt, if any of the foregoing (a) through (c) of this definition is caused in whole or in part by the gross negligence or willful misconduct by a Responsible Party, then a “Technical Failure” shall be deemed not to have occurred.

“**Technical Failure Termination Notice**” has the meaning set forth in Section 3.3(a).

“**Term**” has the meaning set forth in Section 9.1.

“**Territory**” means worldwide, but not the following countries: Japan, China (including Hong Kong), South Korea, Taiwan, Malaysia, Cambodia, Singapore, Thailand, Indonesia, or Vietnam. “**Territory**” also does not include any country in which Regulatory Approval is obtained without use of, or reference to, any data obtained in the Phase III Studies.

“**Third Party**” means any Person, including a Governmental Authority, other than Company, NovaQuest, and each of their respective Affiliates.

“**Third Party Claim**” has the meaning set forth in Section 10.1.

“**Total Funding Commitment**” means Twenty-Five Million Dollars (\$25,000,000).

“**Uncured NovaQuest Funding Breach**” means NovaQuest’s breach of its obligation to pay any Development Payment in accordance with this Agreement and NovaQuest’s subsequent failure to cure such breach within sixty (60) calendar days after receiving written notice of such breach from Company.

“**United States**” or “**U.S.**” means the United States of America, including its territories and possessions.

“**U.S. Approval**” means the receipt of Regulatory Approval in the United States from the FDA.

“**Vical Transaction**” means that certain transaction pursuant to which Merger Sub merges with and into Company pursuant to the Vical Merger Agreement.

“**Vical Merger Agreement**” means, (i) that certain Agreement and Plan of Merger and Reorganization by and among Vical Incorporated, a Delaware corporation (“**Vical**”), Victory Subsidiary, Inc., a Delaware corporation and wholly owned subsidiary of Vical (“**Merger Sub**”), and Company, dated as of June 2, 2019.

“**Warrant Agreement**” has the meaning set forth in the Introduction hereto.

## ARTICLE II

### SCOPE OF AGREEMENT

2.1 **General Agreement.** Subject to the terms and conditions hereof, and provided that Company is Developing the Product in accordance with this Agreement (including, for the avoidance of doubt, in accordance with the Development Plan and the Development Budget), NovaQuest shall make the payments as set forth in Section 3.1 up to an aggregate maximum amount equal to the Total Funding Commitment in exchange for the right to receive payments from Company as set forth in, and subject to, ARTICLE IV.

2.2 **Limitations.** Company accepts, acknowledges, and agrees that NovaQuest is agreeing, on the terms and conditions set forth in this Agreement, only to satisfy the funding obligations set forth in Section 3.1 and its other obligations expressly set forth herein and is not assuming any Liability of Company, of whatever nature, whether presently in existence or arising or asserted hereafter.

2.3 **Closing.** The effectiveness of the transactions contemplated by this Agreement (the “**Closing**”) will occur immediately following the closing of the Vical Transaction, subject to the satisfaction of the conditions set forth in Section 2.4. For clarity, NovaQuest will have no obligations to fund any Development Payments until the Closing Date, and Company shall have no obligations under ARTICLE IV until the Closing Date.

## 2.4 Effectiveness Conditions.

(a) Company Effectiveness Conditions. Company's obligation to consummate the transactions under this Agreement as contemplated shall be subject to the satisfaction or waiver by Company of the following conditions:

(i) NovaQuest shall have delivered a certificate, executed by an authorized officer of NovaQuest, certifying that the representations and warranties set forth in Section 7.2 are true and correct in all material respects as of the Closing Date (except with respect to representations and warranties qualified by the term "material," which representations and warranties shall be true and correct in all respects as of the Closing Date);

(ii) NovaQuest shall have executed and delivered the Security Agreement; and

(iii) The "Closing" of the Vical Transaction (as defined in Section 1.3 of the Vical Merger Agreement) shall have occurred.

( b ) NovaQuest Effectiveness Conditions. NovaQuest's obligation to consummate the transactions under this Agreement as contemplated at Closing shall be subject to the satisfaction or waiver by NovaQuest of the following conditions:

(i) Company shall have delivered a certificate, executed by an authorized officer of Company, certifying that (A) the representations and warranties set forth in Section 7.1 are true and correct in all respects as of the Closing Date except, in each case, or in the aggregate, where the failure to be true and correct would not reasonably be expected to have a Company Material Adverse Effect or a Parent Material Adverse Effect (both as defined in the Vical Merger Agreement and taken together, as a whole) (without giving effect to any Material Adverse Effect or other materiality qualifiers therein) and (B) Company has complied in all material respects with the covenants set forth in Section 8.5;

(ii) Company shall have executed and delivered the Security Agreement;

(iii) Company shall have delivered a duly executed payoff letter in a form and substance reasonably acceptable to NovaQuest ("**Payoff Letter**") setting forth the payoff amount and a per diem amount, and which confirms that upon repayment in full of all outstanding amounts under the Hercules Loan, all commitments under the Hercules Loan will be terminated and all Encumbrances upon any of the property of the Company constituting collateral under the Hercules Loan will be released;

(iv) Company shall have caused Vical to execute and deliver the Warrant Agreement to become effective at the Closing Date.

(v) The "Closing" (as defined in Section 1.3 of the Vical Merger Agreement) of the Vical Transaction shall have occurred in accordance with the terms thereof; and

(vi) Company shall have delivered a copy of its bank statements and a closing certificate, executed by an authorized officer of the Company and certifying that (A) the bank statement copy delivered to NovaQuest is true, complete, and correct and (B) the Parent Net Cash (as defined in the Vical Merger Agreement) is at least [\*\*\*].

## ARTICLE III

### DEVELOPMENT AND COMMERCIALIZATION

#### 3.1 Product Development Funding.

(a) General Commitments. For each Fiscal Quarter during the Product Funding Period in which Company submits a Development Invoice and a Quarterly Report to NovaQuest, NovaQuest shall, subject to the Total Funding Commitment and the other terms of this Agreement, advance funds to Company as invoiced for up to [\*\*\*] of the expenses to carry out the Product Development Activities for each such Fiscal Quarter (each such payment a “*Development Payment*”). Company shall use Development Payments solely to fund Product Development Activities.

(b) Quarterly Reports. Beginning with the first Fiscal Quarter that commences after the Effective Date and for each subsequent Fiscal Quarter during the Product Funding Period, Company shall submit a complete and correct Quarterly Report to NovaQuest within ten (10) Business Days following the first Business Day of each such Fiscal Quarter.

(c) Development Invoices and Development Payments.

(i) Company shall provide NovaQuest with at least fifteen (15) Business Days’ prior written notice of the date on which the Closing is reasonably anticipated to occur (such date, the “*Anticipated Closing Date*”). On the later of (A) the Anticipated Closing Date or (B) the Closing Date, NovaQuest shall pay Company a Development Payment equal to the Scheduled Payment for the period from the Closing Date through the end of the Fiscal Quarter in which the Closing Date occurs, which, for the avoidance of doubt, is the Scheduled Payment shown in the column titled “Q3 2019” in the Investment Schedule. Thereafter, beginning with the first Fiscal Quarter that commences after the Effective Date and for each subsequent Fiscal Quarter during the Product Funding Period, Company shall submit a complete and correct Development Invoice to NovaQuest within ten (10) Business Days following the first Business Day of each such Fiscal Quarter. The first Development Invoice shall require NovaQuest to pay Company an amount equal to the Scheduled Payment for such Fiscal Quarter. All subsequent Development Invoices shall calculate the Development Payment for a given Fiscal Quarter as follows:

$$\text{Development Payment} = \text{Scheduled Payment} - \text{Prior Quarter Development Payment Excess.}$$

(ii) If, with respect to a particular Fiscal Quarter, NovaQuest receives a Quarterly Report within the timeframe set forth in Section 3.1(b) and a Development Invoice within the timeframe set forth in this Section 3.1(c) and such Quarterly Report and Development Invoice are complete and accurate in all material respects, then, subject to the Total Funding Commitment, NovaQuest shall pay Company a Development Payment in an amount equal to the amount set forth on the Development Invoice for such Fiscal Quarter within thirty (30) Business Days following NovaQuest’s receipt of the aforementioned Quarterly Report and Development Invoice.

(d) Miscellaneous. Each payment under this Section 3.1 will be made in U.S. Dollars by electronic wire transfer in immediately available funds to the bank account set forth in Exhibit H or such other account designated by Company in writing. Notwithstanding anything to the contrary

herein, NovaQuest's aggregate payment obligations under this Section 3.1 shall not exceed the Total Funding Commitment.

### 3.2 **Diligence.**

#### (a) Development.

(i) Company shall, and shall ensure that each applicable Responsible Party shall (A) use Commercially Reasonable Efforts to perform all activities described in the Development Plan in accordance with the timelines set forth in the Development Plan and in compliance in all respects with the Development Budget and (B) otherwise Develop the Product in a manner that is reasonably likely to result in U.S. Approval no later than the Target U.S. Approval Date (the "**Development Obligations**"). Company agrees to timely and promptly pay and fund all Product Development Activities that exceed NovaQuest's payment obligations set forth in Section 3.1.

(ii) The Development Plan shall not be amended in any material respect without the prior written consent of NovaQuest, which consent shall be not unreasonably withheld, conditioned or delayed.

(iii) Upon and following Successful Completion, Company shall (A) within nine (9) months after Successful Completion, prepare, complete, and submit to the FDA all Regulatory Filings necessary to obtain U.S. Approval and (B) use Commercially Reasonable Efforts to obtain U.S. Approval on or before the Target U.S. Approval Date.

(b) Commercialization Diligence. Company shall, and shall ensure that each applicable Responsible Party shall, use Commercially Reasonable Efforts to launch, market, promote, sell, and otherwise Commercialize the Product in the United States from and after the receipt of U.S. Approval for each indication that is a subject of such U.S. Approval and in each jurisdiction in the Territory for which Regulatory Approval is received. Company shall, and shall ensure that each applicable Responsible Party shall, use Commercially Reasonable Efforts to manufacture or have manufactured the Product in sufficient quantities and of adequate quality to satisfy forecasted wholesaler and direct buyer demand in the Territory after the receipt of Regulatory Approval in any jurisdiction in the Territory.

### 3.3 **Program Termination.**

( a ) Right to Terminate for Technical Failure. Company shall not, and shall ensure that no Responsible Party shall, suspend or terminate the Program prior to U.S. Approval for any reason (even a Commercially Reasonable reason), except that (i) Company may terminate the Program in its entirety upon the occurrence of a Technical Failure and then only in accordance with this Section 3.3(a) and (ii) Company may terminate the Program in accordance with Section 3.3(b) or in accordance with Article IX termination provisions. If Company reasonably and in good faith determines that a Technical Failure may have occurred, then Company shall provide NovaQuest, within three (3) Business Days of such determination, written notice thereof and the details and evidence of such failure (a "**Technical Failure Termination Notice**"). The Parties (including each Party's Senior Officer and JSC Members) shall meet in person as promptly as possible to review and discuss the purported Technical Failure and the possible termination of the Program. Company will reasonably consider NovaQuest's feedback with respect to the purported Technical Failure and keep NovaQuest fully informed on a timely basis regarding the details of any discussions or

correspondence with Third Parties regarding any termination of the Program for Technical Failure. If Company decides, after reasonably considering NovaQuest's feedback, to terminate the Program for Technical Failure, then Company shall immediately deliver written notice of the same to NovaQuest. Company shall not delay its decision to terminate the Program for Technical Failure to obtain additional payments from NovaQuest under Section 3.1.

( b ) Post-Phase III Termination. If, after the completion of the Phase III Studies, the FDA requires, as a condition of receiving its Regulatory Approval, an additional study or additional Development work beyond that which is contained in the Development Plan that would, in the reasonable determination of Company, be reasonably expected to either (i) take Company, using Commercially Reasonable Efforts, longer than [\*\*\*]months to complete or (ii) cost, in the aggregate, more than [\*\*\*], then Company may terminate the Program by providing to NovaQuest: (A) written notice of such termination; (B) a true and complete copy of FDA correspondence relating to the additional Development requirements; and (C) the Post-Phase III Termination Payment. Company shall not be permitted to effect a termination of the Program pursuant to this Section 3.3(b) unless it provides NovaQuest with the items described in (A), (B), and (C) of this Section 3.3(b) within thirty (30) Business Days of Company's receipt of notice from the FDA of the additional Development requirements.

( c ) Non-Technical Termination. Company shall become obligated to pay NovaQuest the Non-Technical Termination Payment if either of the following events occur:

(i) a Responsible Party terminates the Program in any material respect for any reason other than (A) Technical Failure pursuant to Section 3.3(a), or (B) pursuant to Section 3.3(b); or

(ii) the Responsible Parties fail, for three (3) consecutive months or longer, to actively and materially engage in the Development of the Product in a manner that is reasonably likely to result in U.S. Approval on or before the Target U.S. Approval Date; provided, however, that such failure by the Responsible Parties is not a direct result of an Uncured NovaQuest Funding Breach.

For the avoidance of doubt, NovaQuest's exercise of its rights under Section 3.3(e) does not, and will not, constitute an Uncured NovaQuest Funding Breach.

( d ) Consequences of Program Termination. If Company terminates the Program for any reason, then (in addition to any other applicable terms and provisions of this Section 3.3):

(i) Company's obligations set forth in Section 3.2 of this Agreement shall terminate;

(ii) NovaQuest's obligations under this Agreement to make any additional Development Payments will terminate immediately;

(iii) Company shall refund to NovaQuest any unspent or uncommitted portion of any Development Payment paid by NovaQuest within ten (10) Business Days of the termination of the Program;

(iv) Company shall remain obligated to make payments to NovaQuest pursuant and subject to ARTICLE IV, with any Post-Phase III Termination Payment or Non-Technical Termination Payment paid to NovaQuest to be credited against Company's future payment obligations under ARTICLE IV; and

(v) if Company or any other Responsible Party subsequently resumes conduct of the Program (or is be deemed to have resumed conduct of the Program as set forth below), then Company shall provide NovaQuest with (A) prompt written notice thereof (but in any event within thirty (30) Business Days of such resumption) (a "**Resumption Notice**") and (B) as promptly as practicable thereafter, a complete and accurate report summarizing the information that is new or material to the Program as of the date such report is provided (the "**Report Update**"). Within thirty (30) Business Days of Company providing the Report Update to NovaQuest, NovaQuest shall have the right (but not the obligation), upon written notice to Company, to resume making any remaining Development Payments in accordance with Section 3.1 hereof. For the purposes of this Agreement, Company will be deemed to have resumed conduct of the Program if Company or any other Responsible Party engages in any material Development or Commercialization of the Product. For the avoidance of doubt, Company's obligations to make payments to NovaQuest pursuant and subject to ARTICLE IV shall survive termination of the Program for Technical Failure under Section 3.3(a) or otherwise pursuant to Section 3.3(b) or Section 3.3(c).

(e) NovaQuest's Right to Suspend Payments. Without limiting any of NovaQuest's rights or remedies, if NovaQuest reasonably and in good faith determines that a Material Adverse Event has occurred, then, anything to the contrary in this Agreement notwithstanding, NovaQuest shall have the right, in its sole discretion, to suspend paying any further Development Payments. NovaQuest shall provide Company with written notice thereof within three (3) Business Days of such determination. NovaQuest's obligation to pay any further Development Payments shall resume upon Company's receipt of written notice from NovaQuest that the Material Adverse Event has been resolved or cured to NovaQuest's reasonable satisfaction. Concurrently with any such notice, NovaQuest shall pay the Company an amount equal to the aggregate amount of Scheduled Payments that were not paid during such suspension. If NovaQuest elects to suspend its obligation to pay Development Payments and the applicable Material Adverse Event is not resolved or cured to NovaQuest's reasonable satisfaction within twelve (12) months, then NovaQuest may, in its sole discretion, terminate its obligation to pay any further Development Payments.

## ARTICLE I

### PAYMENTS TO NOVAQUEST

#### 4.1 Payments and Reports.

(a) **Milestone Payment Obligation.** Company's obligation to pay the Milestone Payment Obligation shall accrue, and be irrevocably earned by NovaQuest, on the Milestone Date, and Company shall pay the Milestone Payment Obligation in two installments as described in the remainder of this Section 4.1(a).

(i) Company shall pay NovaQuest [\*\*\*] within five (5) Business Days after the Milestone Date.

(ii) Company shall pay NovaQuest [\*\*\*] on or before the second (2<sup>nd</sup>) anniversary of the Milestone Date.

(b) **Revenue Share Payments.** Commencing with the Fiscal Quarter that begins immediately following the second (2<sup>nd</sup>) anniversary of the date on which the First Commercial Sale occurs and continuing for each subsequent Fiscal Quarter during the Term, Company shall pay to NovaQuest a payment in an amount equal to the product of (i) the applicable percentage in the column labeled "Revenue Share Rate" in the table set forth below (each such percentage, a "**Revenue Share Rate**") multiplied by (ii) the aggregate total of the Net Sales for such Fiscal Quarter (each such payment, a "**Revenue Share Payment**"). Company shall pay NovaQuest a Revenue Share Payment within forty-five (45) calendar days after the end of each Fiscal Quarter during which any Net Sales occur.

Tier	Revenue Share Rate	Net Sales Range
1	[***]	Net Sales in a Fiscal Year are less than or equal to [***].
2	[***]	Net Sales in a Fiscal Year are greater than [***] and less than or equal to [***].
3	[***]	Net Sales in a Fiscal Year are greater than [***].

Revenue Share Payments for a Fiscal Quarter are due and payable within forty-five (45) calendar days after the end of each Fiscal Quarter. Company shall submit a Payment Report simultaneously with its payment of each Revenue Share Payment.

(c) **Payment Reports.** Commencing with the Fiscal Quarter during which the First Commercial Sale occurs and for each Fiscal Quarter thereafter, within forty-five (45) calendar days after the end of each such Fiscal Quarter, Company shall prepare and deliver a written report to NovaQuest showing an accurate calculation of Net Sales for such Fiscal Quarter, including the specific jurisdictions in which such Net Sales were invoiced and the deductions taken to make the calculation of each Revenue Share Payment owed for that Fiscal Quarter (such written report, a "**Payment Report**"). For the avoidance of doubt, Company shall provide NovaQuest with a Payment Report pursuant to this Section 4.1(c) even if no Revenue Share Payment is owed for a given Fiscal Quarter.

4.2 **NovaQuest's Account.** All payments under this Agreement to NovaQuest shall be made in U.S. Dollars by wire transfer in immediately available funds to such accounts as NovaQuest designates in writing from time to time. With respect to Net Sales invoiced in a currency other than U.S. Dollars, such Net Sales will be converted into the U.S. Dollar equivalent using the conversion

rate existing in the United States (as reported in *The Wall Street Journal*, New York edition) for the applicable currency on the last Business Day of the applicable Fiscal Quarter. If *The Wall Street Journal* ceases to publish such exchange rate, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States on which the Parties reasonably agree.

4.3 **Taxes.** If any Governmental Authority requires Company to deduct or withhold any amount from, or NovaQuest to pay any present or future Tax, assessment, or other governmental charge on, any payment by Company to NovaQuest hereunder (a “**Withholding Payment**”), then Company shall, in addition to paying NovaQuest the amount reduced by such Withholding Payment, simultaneously pay NovaQuest an additional amount such that NovaQuest receives the full contractual amount of the applicable payment as if no such Withholding Payment had occurred. Notwithstanding the foregoing, Company shall not be required to pay any such additional amount to NovaQuest to the extent that a Withholding Payment is attributable to Excluded Taxes.

4.4 **Interest.** If any payment required to be paid by Company to NovaQuest under this Agreement is not made when due, then such outstanding payment will accrue interest, beginning on the date when the payment was due, at a rate equal to [\*\*\*] plus the Prime Rate, subject to any limitation under Applicable Law. Such rate will be compounded every ninety (90) calendar days, commencing on the date on which such payment was due. Payment of accrued interest will accompany payment of the outstanding payment. “**Prime Rate**” means the prime rate as reported in *The Wall Street Journal*, New York edition, on the date such payment is due.

## ARTICLE V

### INFORMATION RIGHTS; RECORD KEEPING; JOINT STEERING COMMITTEE

#### 5.1 Information Rights.

(a) In addition to Company’s other reporting and disclosure obligations contained in this Agreement, but subject to the remaining provisions of this Section 5.1(a) from and after the Closing Date, Company shall, and shall cause all other Responsible Parties to, promptly prepare and provide NovaQuest with reasonable notice and information regarding each of the following matters relating to the Product and to promptly respond to NovaQuest’s reasonable inquiries with respect thereto and promptly provide, upon NovaQuest’s reasonable request, information and documents related to each of the following matters:

- (i) general Development and commercial readiness overview and updates, including any issues regarding manufacturing of the Product;
- (ii) notification of scheduled meetings, including teleconferences, with a Governmental Authority;
- (iii) finalized briefing packages and minutes from meetings with a Governmental Authority, notifications, letters, and other communications with a Governmental Authority;
- (iv) material Regulatory Filings, including any NDA;

- Product;
- (v) safety update reports provided to a Governmental Authority and any actual or anticipated issues with the supply of the Product;
  - (vi) any matters arising from Patents Covering the Product and other intellectual property rights protecting the Product, including intellectual property rights owned or controlled by Third Parties, that might adversely impact the Program;
  - (vii) any decision or anticipated decision to cease Developing, marketing, selling, or otherwise Commercializing the Product;
  - (viii) anticipated expenses related to Development and Commercialization scale-up and budgets associated therewith;
  - (ix) clinical trial protocols, statistical analysis plans, final clinical study reports, and equivalent documents from pre-clinical trials;
  - (x) clinical trial enrollment, progress, and results of the Phase III Studies and general progress of the Development Plan;
  - (xi) receipt of Regulatory Approval;
  - (xii) the marketing, promotion, and other Commercialization activities on behalf of the Product, including forecasts of Net Sales and marketing plans; and
  - (xiii) each forecast to be provided pursuant to Section 5.1(c).

Company may reasonably select the means and format of communication for delivery of such information, including via summaries, reports, and presentations made during meetings of the Joint Steering Committee; provided, however, that upon NovaQuest's reasonable request, Company promptly shall provide complete and accurate copies of, or provide reasonable access to, any material information and documents related to the information provided by Company pursuant to this Section 5.1(a) and to the individuals responsible for generating, maintaining, or carrying out the activities relating to such information.

(b) Promptly following database lock with respect to any human clinical trial for the Product, Company shall deliver to NovaQuest complete and correct copies of all draft tables, graphs, and data listings arising from internal analyses (including any analysis performed by any contract research organization on a Responsible Party's behalf) of the data from such clinical trial.

(c) Company shall, and shall ensure that each other applicable Responsible Party shall, forecast and track orders for the Product in the Territory for each Fiscal Quarter. No later than thirty (30) calendar days prior to the anticipated date of the First Commercial Sale in the Territory, Company will provide NovaQuest with a copy of Company's good faith forecasted wholesaler and direct buyer unit demand for the Product in the Territory for the then-current Fiscal Year and will then provide such a forecast for each subsequent Fiscal Year to NovaQuest no later than thirty (30) calendar days prior to the start of each such Fiscal Year. Each such forecast shall take into account the forecasts provided by Responsible Parties. NovaQuest agrees and acknowledges, with respect to all forecasts provided under this Section 5.1(c), that (i) such forecasts shall be Company's Confidential Information and, without limitation, NovaQuest shall not disclose, or permit the

disclosure, of such forecasts in any manner that specifically identifies, or permits the specific identification of, the source of the forecasted amounts deriving therefrom; (ii) no such forecasts are intended to be predictive of actual Net Sales or other amounts and are subjective in many respects; (iii) such forecasts should not be construed as financial guidance, and should not be relied on by any Person as such; and (iv) Company will not be subject to any liability to NovaQuest, its Affiliates, or any Third Party in respect of such forecasts, including in relation to use thereof by NovaQuest or its Affiliates or any of their agents, consultants, accountants, counsel or other representatives in connection with preparing projections, forecasts, financial statements or other information or the dissemination thereof to NovaQuest's shareholders, investors or other Persons.

## 5.2 Company's Record Keeping; NovaQuest's Audit Rights.

(a) Records. Company shall, and shall ensure that the applicable Responsible Parties shall keep and maintain for a period of at least three (3) years from the end of any Fiscal Quarter (except as otherwise provided herein) accounts and records of all data reasonably required to verify:

(i) any and all information required to be provided to NovaQuest under this Agreement, including pursuant to Section 5.1; and

(ii) (A) the gross amount invoiced by any Responsible Party to Third Parties for sales of the Product in the Territory and (B) the calculations of (y) Net Sales and (z) the Revenue Share Payments.

Company's and the Responsible Parties' recordkeeping obligations under this Section 5.2 shall survive the termination of this Agreement until the date that is three (3) years following the last day on which a payment is due under this Agreement (the "**Recordkeeping Period**").

( b ) Audit. From the Effective Date until the expiration of the Recordkeeping Period, upon prior written notice to Company, NovaQuest shall have the right to review and audit, through an independent certified public accountant selected by NovaQuest, those accounts and records of Company and the other Responsible Parties as NovaQuest determines is reasonably necessary to verify Company's and Responsible Parties' compliance with this Agreement. Such review and audits shall occur during normal business hours and not more than once per year. NovaQuest shall be solely responsible for all of the expenses of any such audit, unless the independent certified public accountant's report shows, in respect of any Fiscal Year then being reviewed, an underpayment of amounts due to NovaQuest hereunder for such Fiscal Year by more than [\*\*\*], in which case Company shall be responsible for the reasonable expenses incurred by NovaQuest for the independent certified public accountant's services. If the report shows an underpayment of amounts due to NovaQuest hereunder, then Company will pay NovaQuest an amount equal to such underpayment, plus interest on such amounts in accordance with Section 4.4, within thirty (30) calendar days after receipt of notice of such underpayment and copy of the relevant portion of the audit report.

## 5.3 Joint Steering Committee.

(a) Establishment. To provide periodic communication of progress against the Development Plan and Company's Commercialization efforts, Company and NovaQuest shall form a joint steering committee (the "**Joint Steering Committee**"). The Joint Steering Committee shall be the primary forum for the Parties to: (i) exchange information regarding the Program and the

Product; (ii) review and comment on the Development and Commercialization of the Product; (iii) discuss potential material amendments to the Development Plan (including any potential amendment to the Development Budget) and clinical trial protocols; (iv) review clinical study reports and Commercialization plans; and (v) discuss any matters, issues, or problems relating to the foregoing. Company will reasonably consider comments from NovaQuest's JSC Members regarding the matters described in this Section 5.3(a).

(b) Membership. The Joint Steering Committee shall consist of two (2) senior executives of Company appointed by Company and two (2) senior executives of, or consultants to, NovaQuest appointed by NovaQuest (each member of the Joint Steering Committee, a "**JSC Member**"); provided, however, that any consultant appointed by NovaQuest shall execute and deliver to Company a confidentiality agreement containing confidentiality and non-disclosure obligations no less stringent than those set forth in ARTICLE VI hereof. Upon reasonable request of a Party, other representatives of such Party may attend meetings of the Joint Steering Committee. A Party may change either or both of its JSC Members at any time but shall give notice to the other Party of any such change as soon as reasonably practical.

(c) Meetings. The Joint Steering Committee shall meet within thirty (30) calendar days after the Closing Date and then at least one time every four (4) months thereafter until the earlier of a termination of the Program or U.S. Approval. Following U.S. Approval, the Joint Steering Committee shall meet at least two (2) times each Fiscal Year, but no less than one time every six (6) months. Such meetings shall be conducted either in person at a mutually agreed upon location, or by telephone or videoconference, as the Parties agree (and if the Parties do not agree, then it shall be held by telephone on the tenth (10th) Business Day of the next Fiscal Quarter at 9:00 AM Eastern Time). Notwithstanding the foregoing, the Joint Steering Committee shall meet in person at least once per Fiscal Year. Reasonably in advance of each such meeting, Company shall deliver to NovaQuest's JSC Members an agenda of the meeting and any background materials to be discussed. Finally, if at any time during the Term, a material development occurs regarding the Product, including any matter described in Section 5.4 below, then either Company or NovaQuest may request a special meeting of the Joint Steering Committee, and the JSC Members will use commercially reasonable efforts to convene such special meeting as quickly as practicable, but no later than ten (10) Business Days after such request.

**5.4 Notice of Certain Events.** Company will notify NovaQuest in writing with respect to the following matters promptly upon Company's or a Responsible Party's knowledge thereof (and Company shall be responsible for ensuring that each Responsible Party notifies Company of such matters upon such Responsible Party becoming aware thereof):

(a) the occurrence of any Material Adverse Event;

(b) any decision, material contemplation, or discussion by Company or any other Responsible Party to cease the Development or Commercialization of the Product in the Territory;

(c) the actual or threatened revocation, withdrawal, suspension, cancellation, termination, or material modification of any approvals or authorizations, including any Regulatory Approval, from any Governmental Authority with respect to the Product;

(d) Company's or any other Responsible Party's being debarred, excluded, suspended, or otherwise ineligible to participate in government health care programs;

(e) Company's or any other Responsible Party's becoming a party to a settlement, consent, or similar agreement with any Governmental Authority regarding the Product;

(f) Company's or any other Responsible Party's being charged with, or convicted of, violating any Applicable Law regarding the Product;

(g) any recall, suspension, market withdrawal, seizure, warning letter, other written communication asserting lack of compliance with any Applicable Law in any material respect, or any serious adverse event with respect to the Product;

(h) any clinical trial of the Product being suspended, put on hold, or terminated prior to completion as a result of any action by the FDA or other Governmental Authority or as a result of a Responsible Party's voluntary decision; and

(i) the receipt by Company or any other Responsible Party of any adverse written notice from any Governmental Authority regarding the approvability or approval of the Product.

Any notice provided pursuant to this Section 5.4 shall include a reasonably detailed description of the event giving rise to the requirement to provide such notice, along with complete and correct copies of all material documentation related thereto.

5.5 **Data Room.** Within two (2) Business Days after the Effective Date, Company shall deliver to NovaQuest on one or more USBs, an electronic copy of all the documents and information contained in the virtual online data room hosted on behalf of Company by VENUE in the online workspace captioned Project Sweat on the Effective Date, together with a written certification from any authorized officer of Company to verify the completeness and accuracy of all such documents so delivered.

## ARTICLE VI

### CONFIDENTIAL INFORMATION

6.1 **Definition of Confidential Information.** For purposes of this Agreement, the term "**Confidential Information**" of a Party means the terms of this Agreement and any information or materials furnished by or on behalf of such Party or its Affiliates (the "**Disclosing Party**") to another Party or its Affiliates (the "**Receiving Party**") pursuant to this Agreement or learned through observation during visit(s) to any facility of the Disclosing Party or its Affiliates, in each case which information (a) is of a nature that is commonly known to be of a confidential, (b) if disclosed in tangible form, is marked "Confidential" or with other similar designation to indicate its confidential or proprietary nature or (c) if disclosed orally, is indicated orally to be confidential or proprietary at the time of such disclosure. Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by written documentation or other competent evidence:

(a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time it was disclosed to or learned by the Receiving Party hereunder;

(b) was generally available to the public or otherwise part of the public domain at the time it was disclosed to or learned by the Receiving Party hereunder;

(c) became generally available to the public or otherwise part of the public domain after it was disclosed to or learned by the Receiving Party hereunder, other than through any act or omission of the Receiving Party in breach of this Agreement;

(d) was lawfully disclosed to the Receiving Party after it was disclosed to or learned by the Receiving Party hereunder, by a Third Party that, to the Receiving Party's knowledge, is not bound by any obligation of confidentiality with respect to such information; or

(e) is independently developed by the Receiving Party without the benefit or use of the Confidential Information of the Disclosing Party.

6.2 **Obligations.** Except as authorized in this Agreement or except upon the Disclosing Party's prior written consent, Receiving Party agrees that for the Term and for five (5) years thereafter, it will:

(a) maintain in confidence, and not disclose to any Person or entity, the Disclosing Party's Confidential Information;

(b) not use the Disclosing Party's Confidential Information for any purpose, except for performing Receiving Party's obligations and exercising its rights and remedies under this Agreement; and

(c) protect the Disclosing Party's Confidential Information in its possession by using substantially the same or higher degree of care as it uses to protect its own Confidential Information (but no less than a reasonable degree of care); provided, however, that the foregoing obligations of confidentiality, non-disclosure and non-use with respect to any Confidential Information constituting a trade secret will extend for so long as any such Confidential Information remains a trade secret under Applicable Law.

Notwithstanding anything to the contrary in this Agreement, the Disclosing Party is entitled to seek injunctive relief to restrain the breach or threatened breach by the Receiving Party of this ARTICLE VI without having to prove actual damages or threatened irreparable harm or post any bond. Such injunctive relief will be in addition to any rights and remedies available to the Disclosing Party at law, in equity, and under this Agreement for such breach or threatened breach.

### 6.3 Permitted Disclosures.

(a) **Permitted Persons.** The Receiving Party may disclose the Disclosing Party's Confidential Information, without the Disclosing Party's prior written permission, to:

(i) its Affiliates and Receiving Party's and its Affiliates' limited partners, members, managers, directors and individuals or bodies responsible for governance of Receiving Party (including, with respect to NovaQuest, NovaQuest's investment committee and limited partner advisory committee), employees, agents, consultants, attorneys, accountants, banks and other actual or potential financing sources, and actual or potential permitted assignees, purchasers, transferees, or successors-in-interest under Section 11.6 and, in the case of the Company, Licensees or potential

Licensees, in each case, who need to know such Confidential Information (including to provide financing to Receiving Party, to assist Receiving Party in evaluating the transactions contemplated hereby, or in fulfilling its obligations or exploiting its rights hereunder (or to determine their interest in providing such financing or assistance)) and who are, prior to receiving such disclosure, bound by customary written contractual or professional confidentiality and non-use obligations no less stringent than those contained herein;

(ii) other Persons who are (A) investors or potential investors (or advisors or fiduciaries (including trustees) or underwriters or placement agents to such Persons) in connection with a private placement or other equity, debt, or other investment or potential investment transaction in or with Receiving Party (including, with respect to NovaQuest, an investment or potential investment in or with a NovaQuest Affiliate to which NovaQuest has, consistent with Section 11.6, assigned or otherwise sold, transferred, pledged, or contributed its rights to receive payment under this Agreement), who need to know such Confidential Information in connection with such equity, debt, or other investment or potential investment transaction or (B) in the case of NovaQuest, potential investment targets (provided, however, that, (y) for the purpose of this Section 6.3(a)(ii), Receiving Party may disclose only Confidential Information of Disclosing Party pertinent to the investment or potential investment transaction and may make such disclosures only in anticipation, and during the period, of such investment or potential investment transaction and (z) for the purpose of clause (B) of this Section 6.3(a)(ii), NovaQuest may disclose the identity of Company, the Product that is the subject of this Agreement, and the fact that this Agreement provides for Milestone Installment Payments and Revenue Share Payments to Persons who are, prior to receiving such disclosure, bound by customary contractual or professional confidentiality and non-use obligations; and

(iii) officers, employees, or advisors of any Governmental Authorities for the purpose of performing Product Development Activities, submitting Regulatory Filings for the Product, and obtaining Regulatory Approval.

The Receiving Party shall be responsible for any breach of this ARTICLE VI by any of the Third Parties described in this Section 6.3(a) to which it discloses Confidential Information (as if such Third Party was bound by the terms of this ARTICLE VI) and shall take all reasonably necessary measures to restrain such Third Parties from unauthorized disclosure or use of the Confidential Information.

(b) Legally Required. The Receiving Party may disclose the Disclosing Party's Confidential Information, without the Disclosing Party's prior written permission, to any Person to the extent such disclosure is necessary to comply with Applicable Law, applicable stock exchange or market requirements or an order or subpoena from a court of competent jurisdiction; provided, however, that the Receiving Party, to the extent it may legally do so, shall give reasonable advance notice to the Disclosing Party of such disclosure and, at the Disclosing Party's reasonable request and expense, the Receiving Party shall use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise). However, if the Receiving Party receives a request from an authorized representative of a U.S. or foreign Tax authority for a copy of this Agreement, then the Receiving Party may provide a copy of this Agreement to such Tax authority representative without advance notice to, or the permission or cooperation of, the Disclosing Party, but the Receiving Party shall notify the Disclosing Party of the disclosure as soon as reasonably practical.

(c) **NovaQuest Consent.** Notwithstanding anything to the contrary in this Section 6.3, Company shall not, and Company agrees to ensure that Responsible Parties shall not, without the prior written consent of NovaQuest, disclose to a Third Party any (i) information regarding NovaQuest's or its Affiliates' limited partners; (ii) financial information regarding NovaQuest or its Affiliates; or (iii) information regarding NovaQuest's or its Affiliates' transactions with Third Parties.

**6.4 Terms of Agreement.** The Parties agree that they will each treat the existence, contents and terms of this Agreement as confidential, and neither Party shall make any press release or other public disclosure that discloses or otherwise concerns this Agreement or any terms hereof, without the prior written consent of the other Party, except to the extent permitted under Section 6.3 or as otherwise permitted in accordance with this Section 6.4 or Section 6.5. Consistent with Section 6.3(b), the Parties agree to use reasonable efforts to provide the other with a copy of any filing required by a securities agency or the rules of a nationally recognized stock exchange on which the securities of the Disclosing Party are listed regarding this Agreement or its terms to review prior to filing and to consider any comments of the other Party in good faith, and to the extent either Party is required to file or disclose this Agreement with a securities agency or a nationally recognized stock exchange on which the securities of the Disclosing Party are listed, such Party shall consider in good faith the other Party's comments with respect to confidential treatment of this Agreement's terms and shall redact this Agreement in a manner allowed by such securities agency or nationally recognized stock exchange to protect sensitive terms, and shall be permitted to file this Agreement, as so redacted, with such securities agency or nationally recognized stock exchange. For purposes of clarity, each Party is free to discuss with Third Parties the information regarding this Agreement and the Parties' relationship disclosed in such securities filings and any other authorized public announcements.

**6.5 Use of Names.** Neither Party shall mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, publicly available promotional material, or other form of publicity without the prior written approval of such other Party in each instance. Notwithstanding the foregoing, the restrictions imposed by this Section 6.5 shall not prohibit a Receiving Party from making any disclosure identifying any such Person to the extent required by Applicable Law or the rules of a stock exchange on which the securities of the Disclosing Party are listed (or to which an application for listing has been submitted); provided that the Receiving Party shall provide the Disclosing Party with prior written notice of such disclosure and an opportunity to comment on, and propose edits to, such disclosure. Further, notwithstanding the foregoing, the Parties agree that NovaQuest shall have the right to publicly disclose the existence of this Agreement as a funding agreement with Milestone Installment Payments and payments based on Net Sales, the name of Company, the name and a description of the Product, and the amount of the Total Funding Commitment.

## ARTICLE VII

### REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

**7.1 Company's Representations and Warranties.** Company represents and warrants to NovaQuest as of the Effective Date, the Closing Date, and the date of each Development Payment by NovaQuest under Section 3.1(c), subject to disclosure schedules from the Company that provide

updates to the covered representations and warranties hereunder that have occurred only since the Closing Date, as follows. For the sake of clarity, no disclosure schedule provided by the Company shall (i) have the effect of curing any breach of a covenant under this Agreement or (ii) limit any rights NovaQuest may have under this Agreement in the event that such disclosure schedule discloses the occurrence of a Material Adverse Event.

(a) Organization. Company is a corporation duly incorporated, validly existing, and in good standing under the laws of the State of Delaware and is qualified to do business and legally permitted to perform its obligations under this Agreement in each jurisdiction where failure to be so qualified could reasonably be expected to have a Material Adverse Event.

(b) Authorization. Company has all necessary corporate or other power, right, and authority to carry on its business as it is presently carried on by Company and as contemplated by this Agreement, to enter into, to execute and to deliver this Agreement, and to perform all of the covenants, agreements, and obligations to be performed by Company hereunder. This Agreement has been duly executed and delivered by Company and, when executed and delivered by NovaQuest, constitutes Company's valid and binding obligation, enforceable against Company in accordance with its terms, subject to bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally and equitable principles.

(c) No Conflicts. The execution and delivery of this Agreement by Company and the performance by Company of its obligations hereunder does not and will not: (i) violate any provision of the organizational documents of Company; (ii) conflict with or violate any Applicable Law that applies to Company or its assets or properties; (iii) require any permit, authorization, consent, approval, exemption, or other action by, notice to, or filing with any entity or Governmental Authority (other than as expressly contemplated hereby); (iv) violate, conflict with, result in a material breach of, or constitute (with or without notice or lapse of time or both) a material default under, or an event that would give rise to any right of notice, modification, acceleration, payment, cancellation or termination under, or in any manner release any party thereto from any obligation under, any permit or contract to which Company is a party or by which any of its properties or assets are bound; or (v) result in the creation or imposition of any Encumbrance on any part of the properties or assets of Company (including the Product Assets).

(d) No Consent. No consent, approval, license, order, authorization, registration, declaration, or filing with or of any Person, other than Regulatory Approvals required with respect to the Product, is required by Company in connection with the execution and delivery by Company of this Agreement, the performance by Company of its obligations under this Agreement, or the consummation of any of the transactions contemplated hereby.

(e) Product Property. Company has good and valid title to, or a valid license or other right to use, (i) all Patents listed on Schedule 7.1(e) hereto, (ii) all data, trade secrets, Product Know-How, and other intellectual property rights used by it in the research, Development, and manufacture of Product; and (iii) all other Product Assets. Company has no payment obligation, whether secured or unsecured, that is senior to, *pari passu* with, or has priority over Company's payment obligations to NovaQuest under this Agreement. All of the Patents listed on Schedule 7.1(e) hereto are (A) in full force and effect and have not lapsed, expired, or otherwise terminated and (B) are, as of the Effective Date, the only Patents owned or controlled by Company that claim or Cover the Development, manufacture, use, or Commercialization of the Product. To the Company's

knowledge, no Person claims to be an inventor under any of the Patents listed on Schedule 7.1(e) hereto who is not a named inventor thereof.

(f) Litigation. To the Company's knowledge, there is no action, suit, claim, proceeding, interference, reexamination, opposition, post-grant review, or investigation pending or threatened against Company or its Affiliates, at law or in equity, arbitration proceeding to which Company or any Affiliate of Company is a party or subject, or Governmental Authority inquiry pending or threatened against Company or its Affiliates, that, if adversely determined, would: (i) question or defeat the validity or enforceability of any Product IP Rights; (ii) prevent, interfere with, or delay the consummation of the transactions contemplated by this Agreement; (iii) otherwise adversely affect the Product or NovaQuest's rights under this Agreement; or (iv) have, or reasonably be expected to result in, a Material Adverse Event.

(g) Infringement and Intellectual Property. To the Company's knowledge, the making, use, sale, offer for sale, or import of the Product by Company and its Affiliates, Licensees, or sublicensees does not, and will not, during the Term, infringe any Patent claim of any Third Party or misappropriate or make any unauthorized use of any other intellectual property or proprietary asset of any Third Party. To the knowledge of Company, the Patents Covering the Product are valid and enforceable and, to the Company's knowledge, no Third Party is infringing, misappropriating, or making any unauthorized use of a Patent Covering the Product or Product Know-How. None of the Patents Covering the Product or Product Know-How is subject to any outstanding decree, order, judgment, or stipulation restricting in any manner the use or licensing thereof by Company.

(h) Material Contracts; Other Agreements. All Material Contracts to which each Responsible Party is a party as of the Effective Date are listed in Schedule 7.1(h) and are enforceable and in full force and effect. Company has provided correct and complete copies of all such Material Contracts to NovaQuest. Each Responsible Party is in compliance with and has not materially breached, materially violated, or materially defaulted under, or received written notice that it has materially breached, violated, or defaulted under any of the terms or conditions of any such Material Contract. Company is not aware of any event that has occurred or circumstance or condition that exists that would, or would reasonably be expected to, constitute such a material breach, material violation, or material default with the lapse of time, giving of notice, or both. To the knowledge of Company, the counterparty of each such Material Contract is in compliance in all material respects with the terms and conditions of such Material Contract. Other than any such Material Contract, there are no contracts, agreements, commitments, or undertakings pursuant to which any Responsible Party in-licenses or otherwise has rights under any Patent or intellectual property rights of any Third Party that are material to the Development or Commercialization of the Product. Except pursuant to the Hercules Loan, Company has not granted an Encumbrance on any of the Product Assets or Company's payments to NovaQuest under this Agreement. Except as set forth on Schedule 7.1(h), as of the Effective Date Company has not granted any Licenses.

(i) Certain Regulatory Matters.

(i) Company holds all applicable approvals and authorizations from Governmental Authorities necessary for Company to conduct its business in the manner in which such business is being conducted and as contemplated hereunder with respect to the Product in the Territory, including the Development, manufacture, and testing of the Product, and all such approvals and authorizations are in good standing and in full force and effect. Company has not received any

notice or any other communication from any Governmental Authority regarding any actual or possible revocation, withdrawal, suspension, cancellation, termination, or material modification of any such approvals or authorizations.

(ii) Company has not, with respect to the Product, knowingly made any untrue statement of a material fact or fraudulent statement to the FDA or any other Governmental Authority, failed to disclose a material fact required to be disclosed to the FDA or other Governmental Authority, or committed an act, made a statement or failed to make a statement, that provides or could reasonably be expected to provide a basis for the FDA or other Governmental Authority to invoke the FDA's policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy of any other Governmental Authority.

(iii) Company is not and has never been: (A) debarred by a Governmental Authority; (B) a party to a settlement, consent, or similar agreement with a Governmental Authority regarding the Product; or (C) charged with, or convicted of, violating Applicable Law regarding the Product.

(iv) The Product is being and at all times has been (as applicable) developed, tested, manufactured, labeled, stored, distributed, promoted, marketed, and otherwise Commercialized in compliance in all material respects with all Applicable Laws, including, as applicable, with respect to investigational use, good clinical practices, good laboratory practices, good manufacturing practices, record keeping, security, and filing of reports.

(v) The Product has not been the subject of or subject to (as applicable) any recall, suspension, market withdrawal, seizure, warning letter, other written communication asserting lack of compliance with any Applicable Law in any material respect, or serious adverse event. No clinical trial of the Product has been suspended, put on hold, or terminated prior to completion as a result of any action by the FDA or other Governmental Authority or voluntarily. To the knowledge of Company, no event has occurred or circumstance exists that is reasonably likely to give rise to, or serve as a basis for, any of the foregoing events.

(vi) Company has, with respect to the Product and Program, provided to NovaQuest true and complete copies of all pre-clinical and clinical data, reports and analysis, all material correspondence with the FDA and other Governmental Authorities, interim analysis from ongoing trials, tables from recently completed clinical trials where no clinical study report is available, and any other information that is material to the development of the Product pursuant to the Program.

(vii) Neither Company nor its Affiliates have received any adverse written notice from any Governmental Authority regarding the approvability or approval of the Product.

(j) Financial Condition. Company's audited financial statements for the year ended December 31, 2018 delivered to NovaQuest fairly present, in conformity with GAAP, in all material respects Company's financial condition and Company's results of operations for the periods covered thereby. There has not been any material deterioration in Company's financial condition since the date of the most recent financial statements and projections delivered to NovaQuest.

(k) Full Disclosure. Company has delivered or provided to NovaQuest and included in the data room described in Section 5.5, true and complete copies of each agreement, contract, other document, or information that is included or referred to therein or in this Agreement or that has been requested by NovaQuest. All written statements and other writings furnished pursuant hereto, or in connection with this Agreement or the transactions contemplated hereby, are complete and accurate in all material respects. No representation or warranty by Company contained in this Agreement contains any untrue statement of a material fact or omits to state any material fact necessary in order to make any statement contained herein not misleading. To the knowledge of Company, there is no fact, event, or condition that materially adversely affects the Product that has not been set forth in this Agreement and the Schedules hereto.

**7.2 NovaQuest's Representations, Warranties, and Covenants.** NovaQuest represents, warrants, and covenants to Company as of the Effective Date:

(a) Organization. NovaQuest is a Delaware limited partnership duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization.

(b) Authorization. NovaQuest has all necessary power, right, and authority to carry on its business as it is presently carried on by NovaQuest, to enter into, execute, and deliver this Agreement and perform all of the covenants, agreements, and obligations to be performed by NovaQuest hereunder. This Agreement has been duly executed and delivered by NovaQuest and constitutes, when executed and delivered by Company, NovaQuest's valid and binding obligation, enforceable against NovaQuest in accordance with its terms, subject to bankruptcy, insolvency, reorganization, or similar laws affecting the rights of creditors generally and equitable principles.

(c) No Conflict. Neither the execution and delivery of this Agreement nor the performance or consummation of it or the transactions contemplated hereby will (i) conflict with any Applicable Law; (ii) in any material respect, violate, conflict with, result in a material breach or violation of, or constitute a material default under any material contract, agreement, commitment, or instrument to which NovaQuest is a party or by which NovaQuest or any of its assets are bound or committed; or (iii) violate the applicable formation documents for NovaQuest.

(d) No Consent. No consent, approval, license, order, authorization, registration, declaration, or filing with or of any Person is required by NovaQuest in connection with the execution and delivery by NovaQuest of this Agreement, the performance by it of its obligations under this Agreement, or the consummation by it of any of the transactions contemplated hereby or thereby.

(e) Availability of Funds. NovaQuest has, and shall have at all times during the Product Funding Period, the financial ability to timely satisfy its obligations to make Development Payments hereunder.

**7.3 Survival of Representations and Warranties.** All representations and warranties of the Parties hereunder shall survive the applicable dates referred to in the first sentence of Section 7.1 and the first sentence of Section 7.2 for the Term plus a period of five (5) years thereafter.

**7.4 Limitation of Liability; Special, Indirect and Other Losses.** NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, OR SPECIAL DAMAGES OF ANY KIND OR ANY LOST PROFITS ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT,

HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE AWARE OF THE LIKELIHOOD OF SUCH DAMAGES AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. THE FOREGOING LIMITATION OF LIABILITY WILL NOT APPLY TO BREACHES OF ARTICLE VI OR LIMIT OR MODIFY IN ANY WAY COMPANY'S INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT.

**7.5 Liquidated Damages.** COMPANY ACKNOWLEDGES THAT, WITH RESPECT TO A TERMINATION OF THE PROGRAM FOR ANY REASON OTHER THAN TECHNICAL FAILURE, NOVAQUEST'S ACTUAL DAMAGES RESULTING FROM EACH SUCH EVENT ARE DIFFICULT TO ESTIMATE AND MAY BE DIFFICULT FOR NOVAQUEST TO PROVE. ACCORDINGLY, THERE MAY BE NO ADEQUATE REMEDY AT LAW TO FULLY COMPENSATE NOVAQUEST. THEREFORE, ANY NON-TECHNICAL TERMINATION PAYMENT OR POST-PHASE III TERMINATION PAYMENT OWED BY COMPANY RESULTING FROM ITS TERMINATION OF THE PROGRAM FOR ANY REASON OTHER THAN TECHNICAL FAILURE SHALL BE DEEMED, SOLELY IN RESPECT THEREOF, LIQUIDATED DAMAGES AND NOT A PENALTY. EACH PARTY ACKNOWLEDGES THAT THE AMOUNT OF SUCH LIQUIDATED DAMAGES REPRESENTS A FAIR, REASONABLE, AND APPROPRIATE ESTIMATE OF NOVAQUEST'S ACTUAL DIRECT DAMAGES.

## ARTICLE VIII

### COVENANTS

#### 8.1 Notifications.

##### (a) Defaults, Termination and Litigation.

(i) Company shall promptly (but no later than within five (5) Business Days) notify NovaQuest in writing and with reasonable detail of any actual or threatened (or any receipt of notice of any actual or threatened): (A) default or breach or anticipated default or anticipated breach by Company under this Agreement (including the failure or likely failure to pay any Milestone Installment Payment or Revenue Share Payment when due) or under any agreement related to the Program or the Commercialization of the Product; (B) suspension of compliance or performance by Company under this Agreement; or (C) termination or expiration (in part or in whole) or any material waiver or amendment of or under any contract, license, or other agreement material to the Development, manufacture, or Commercialization of the Product in the Territory.

(ii) Company shall promptly (but no later than within ten (10) Business Days) notify NovaQuest in writing and with reasonable detail of the actual or, to the Company's knowledge, threatened commencement of (or receipt of notice of the actual or threatened commencement of) any dispute, claim, suit, litigation, injunction, or arbitration proceeding related to (A) the Product or Product Assets or (B) contracts, licenses, or agreements material to the Development, manufacture, or Commercialization of the Product, including those disputes, claims, suits, litigation, or arbitration proceedings alleging a Third Party's infringement or misappropriation of any of the Product IP Rights owned or licensed by a Responsible Party and those alleging a Responsible Party's (or any of their respective Affiliates', licensees', or sublicensees') infringement or misappropriation

of a Third Party's intellectual property in the making, use, sale, offer for sale, or importation of the Product, which in the case of each of clause (A) and (B) above could reasonably be expected to result in a Material Adverse Effect. Each such notification shall contain a reasonably detailed summary of the event described therein. At the request of NovaQuest, Company shall promptly discuss with NovaQuest, or provide in writing to NovaQuest, full particulars of the applicable matter.

(b) Intellectual Property Updates.

(i) Promptly after receipt by a Responsible Party of any notice with respect to any Governmental Authority taking final patent office action that cannot be appealed as part of the patent prosecution process under relevant patent office procedures relating to the status, validity, or change thereto, of any Patents Covering the Product, Company shall provide a complete and correct copy of each such notice to NovaQuest.

(ii) Company shall also keep NovaQuest reasonably informed, in accordance with its obligations under ARTICLE V and at other times upon reasonable request by NovaQuest, with regard to all material developments in the status, validity, prosecution efforts, or change thereto, of any of the Product IP Rights owned, licensed, or sublicensed by a Responsible Party.

**8.2 No Disposition of Rights.** Notwithstanding anything to the contrary herein, without NovaQuest's prior written consent, which shall not be unreasonably withheld or delayed, Company shall not and shall ensure that Responsible Parties do not, sell, transfer, assign, grant any License, otherwise dispose of or grant any Encumbrance in, to or under any Product Assets that are necessary or useful to the Development or Commercialization of the Product in the Territory, provided, however, that the foregoing shall not preclude or limit Company or its Affiliates from, without NovaQuest's consent, (i) effecting any such sale, transfer, assignment, or other disposition as part of any sale of all or substantially all of the Product Assets to a Permitted Company that assumes all of Company's obligations under this Agreement pursuant to a written assumption agreement in a form and substance acceptable to NovaQuest in its sole discretion, including by asset sale, merger, combination, sale of securities or otherwise, directly or indirectly, (ii) using, selling, or otherwise disposing of inventories of the Product in the ordinary course of business in connection with the Development or Commercialization of the Product, (iii) granting Licenses to Affiliates or Responsible Parties in the Territory or other licenses or sublicenses or other rights outside the Territory under Product Assets.

**8.3 Company IP Obligations.** Company shall (and shall cause each Responsible Party to):

(a) prosecute and maintain in full force and effect all Patents Covering the Product owned or controlled by it on or after the Effective Date and all Regulatory Approvals necessary for the Development, Commercialization or manufacture of the Product in the Territory;

(b) maintain, keep in full force and effect, and seek available patent term extensions for any such Patents referred to in Section 8.3(a);

(c) defend any challenge to the validity, patentability, enforceability, and/or non-infringement of any such Patents referred to in Section 8.3(a), or any opposition to any such Patents referred to in Section 8.3(a);

(d) if a Third Party is infringing such Patents referred to in Section 8.3(a), cause such infringement to cease, including by initiating legal proceedings against any Third Party infringer;

(e) promptly provide NovaQuest with written notice of any (i) action or settlement discussions relating to any alleged, actual, or potential infringement of the Product IP Rights and (ii) damages award or settlement with respect thereto; and

(f) maintain all material and confidential Product Know-How in confidence.

#### 8.4 Additional Covenants and Agreements of Company.

(a) Compliance with Law. With respect to the performance of this Agreement and the activities contemplated by this Agreement, Company shall comply, and shall cause each Responsible Party to comply, with all Applicable Laws.

(b) Noncontravention. During the Term, Company shall not grant any right to any Affiliate or Third Party that would conflict with the rights granted to NovaQuest hereunder or enter into any agreement that would impair Company's ability to perform its obligations under this Agreement.

(c) Material Contracts and Licenses. Company shall comply with all terms and conditions of, and fulfill all of its obligations under, all of the Material Contracts, except for such noncompliance that could not reasonably be expected to result in a Material Adverse Event. Company shall use commercially reasonable efforts to enforce against the other party(ies) to each Material Contract all material terms and conditions thereunder except where the failure to do so could not reasonably be expected to result in a Material Adverse Effect. Company shall not amend any Material Contract in any material respect or issue any waivers or consents or other approvals under any Material Contract without the prior written consent of NovaQuest (not to be unreasonably withheld or delayed), except where such amendment, waiver, or consent could not reasonably be expected to result in a Material Adverse Event. Company shall ensure that all Licenses granted after the Effective Date contain provisions that require the Licensees to notify Company of any Material Adverse Event and that allow Company to share information pertaining to the Development and Commercialization of the Product to NovaQuest as contemplated by this Agreement.

(d) Minimum Cash Balance. Until the earlier of (i) the date on which Company has paid NovaQuest all payments due and owing under Section 4.1(a) or (ii) the date on which the sum of all payments paid by Company to NovaQuest equal [\*\*\*] of the Total Funding Commitment, Company shall not permit its minimum cash balance to fall below the levels set forth below for more than thirty (30) Business Days:

(i) [\*\*\*] until the date that is six (6) months following the date on which Company submits an NDA to the FDA for the Product; and

(ii) [\*\*\*] at all times on and after the date that is six (6) months following the date on which Company submits an NDA to the FDA for the Product.

(e) Competing Products.

(i) During the Term, Company and its Affiliates shall not, and shall ensure that each Responsible Party shall not, directly or indirectly, at any time research, develop, market, promote, distribute, import, export, offer to sell, or sell any Competing Product.

(ii) During the Term, NovaQuest shall not, directly or indirectly, develop or commercialize a Competing Product or provide any debt, equity, or other financing to a Third Party for the specific purpose of developing or commercializing a Competing Product. For the avoidance of doubt, NovaQuest may, without violating this Section 8.4(e)(ii):

(A) make or hold investments in any Third Party that, at the time of such investment, is actively engaging in the development or commercialization of a Competing Product if either: (I) NovaQuest has no contractual rights to receive specific information regarding such Competing Product or participate in the decision making with respect to such Competing Product or (II) the proceeds of NovaQuest's investment are not contractually directed toward the development or commercialization of a Competing Product; and

(B) exercise any rights and perform any obligations under any contractual arrangement with a Third Party that was in existence on or before the Closing Date.

**8.5 Interim Covenants.** Except as otherwise contemplated by this Agreement, including the consummation of the transactions contemplated under the Vical Transaction, between the Effective Date and the Closing Date, unless NovaQuest otherwise provides its prior written consent, Company (a) shall conduct its operations in the ordinary course in all material respects and in a manner that will not impair its ability to perform its obligations under this Agreement; (b) shall not, without NovaQuest's written consent, not to be unreasonably withheld, conditioned or delayed, by its own action, amend in any material respect, or waive any material right of the Company under, the Vical Merger Agreement.

**8.6 Repayment of Hercules Loan.** Company shall have repaid in full all outstanding amounts under the Hercules Loan in accordance with the Payoff Letter, no later than three (3) Business Days after the Closing Date.

#### **8.7 Taxes.**

(a) Tax Treatment. The Parties agree to treat this Agreement (but for clarity, not the Warrant Agreement) for all U.S. federal and applicable state and local tax purposes as a single financial contract that is neither debt of the Company nor equity in the Company. The Parties shall file all tax and information returns consistent with the treatment set forth in this Section 8.7(a) and shall not take any position inconsistent with such treatment, except as otherwise required pursuant to a final determination within the meaning of section 1313 of the Internal Revenue Code of 1986, as amended.

(b) Allocation of Development Payments. The Parties agree to treat [\*\*\*] of the Development Payments as paid in exchange for the Warrant Agreement.

## **ARTICLE IX**

### **TERM AND TERMINATION**

9.1 **Term of Agreement.** The term of this Agreement shall commence as of the Effective Date and continue until terminated in accordance with this ARTICLE IX (the “*Term*”).

9.2 **Material Breaches.** The occurrence of any of the following events, actions, or omissions shall constitute a material breach of this Agreement by Company:

(a) Company breaches any material representation or warranty under this Agreement or the Security Agreement between the Parties and, to the extent curable, does not cure such breach within thirty (30) calendar days after the earlier of (i) NovaQuest’s provision of notice to Company of such breach or (ii) Company’s becoming aware of such breach;

(b) Company materially breaches any agreement, covenant, or obligation in this Agreement or the Security Agreement between the Parties, or a Responsible Party other than Company materially breaches any agreement, covenant, or obligation in this Agreement applicable to Responsible Parties, and, to the extent curable, does not cure such breach within thirty (30) calendar days after the earlier of (i) NovaQuest’s provision of notice to Company of such breach or (ii) Company’s becoming aware of such breach;

(c) a Responsible Party terminates the Program in any material respect for any reason other than Technical Failure;

(d) Company or any Affiliate of Company that is materially involved in the Development or Commercialization of the Product in the Territory (i) files a petition seeking to take advantage of any laws relating to bankruptcy, insolvency, reorganization, winding up, or composition for adjustment of debts; (ii) consents to, or fails to contest within sixty (60) calendar days and in appropriate manner, any petition filed against it in an involuntary case under such bankruptcy laws or other laws; (iii) applies for, consents to, or fails to contest within sixty (60) calendar days and in appropriate manner the appointment of, or the taking of possession by, a receiver, custodian, trustee, or liquidator of itself or of a substantial part of its property; (iv) admits in writing its inability to pay its debts as they become due; (v) makes a general assignment for the benefit of creditors; or (vi) takes any corporate action for the purpose of authorizing any of the foregoing; or

(e) a case or other proceeding is commenced against the Company or any Affiliate of Company that is materially involved in the Development or Commercialization of the Product in the Territory in any court of competent jurisdiction seeking (i) relief under any laws relating to bankruptcy, insolvency, reorganization, winding up, or adjustment of debts or (ii) the appointment of a trustee, receiver, custodian, liquidator, or the like for a Responsible Party for all or any substantial part of its assets; and under either clause (i) or (ii) of this 9.2(d), such case or proceeding has continued without dismissal or stay for a period of sixty (60) consecutive calendar days, or an order granting the relief requested in such case or proceeding (including an order for relief under such federal bankruptcy laws) is entered.

### 9.3 **Consequences of Material Breach and Uncured NovaQuest Funding Breach.**

(a) Upon the occurrence of any material breach of this Agreement by Company, including a material breach that is not cured as set forth in Section 9.2(b), NovaQuest may, without limiting any of its rights or remedies, terminate all of its remaining payment obligations under this Agreement immediately upon written notice to Company. Notwithstanding such termination by NovaQuest of its remaining payment obligations hereunder, Company’s payment obligations under

ARTICLE IV shall survive until they are fully and completely satisfied, except if and when termination should occur prior to the Closing Date. If NovaQuest provides Company such written notice of termination of its remaining payment obligations, all terms of this Agreement shall terminate except as provided in this Section 9.3 and Section 9.5.

(b) Upon the occurrence of an Uncured NovaQuest Funding Breach, Company may, without limiting any of its rights or remedies, terminate this Agreement immediately upon written notice to NovaQuest.

9.4 **Termination for Delay of Closing.** Either Party may terminate this Agreement in its entirety upon written notice to the other Party if the Closing has not occurred on or before the End Date, as defined in Section 9.1 of the Vical Merger Agreement.

9.5 **Survival.** Notwithstanding anything to the contrary contained in this Agreement, ARTICLE IV (except in the case of a termination by the Company pursuant to Section 9.3(b) or 9.4), Section 5.2, ARTICLE VI, ARTICLE VII, Section 9.3, this Section 9.5, ARTICLE X, and ARTICLE XI shall survive the termination of this Agreement in accordance with their respective terms for any reason other than an automatic termination pursuant to Section 9.4.

## ARTICLE X

### INDEMNIFICATION

10.1 **General Obligations.** Company hereby agrees to indemnify, defend, hold harmless, and reimburse NovaQuest and its Affiliates and their respective managers, directors, officers, employees, agents, and its and their respective successors, heirs, and assigns (collectively, the “*NovaQuest Indemnitees*”) from and against any losses, costs, claims, damages, Liabilities, or expenses (including reasonable attorneys’ and professional fees and other expenses of litigation) (each, a “*Loss*” and collectively, “*Losses*”) actually incurred by NovaQuest Indemnitees arising out of claims, suits, actions, or demands, in each case brought by a Third Party, or settlements or judgments arising therefrom (including personal injury, products liability, and intellectual property infringement or misappropriation claims) (each a “*Third Party Claim*”) as a result or arising out of:

(a) a Responsible Party’s, or its or their respective agent’s or contractor’s Development, promotion, marketing, handling, manufacture, Commercialization, packaging, labeling, storage, distribution, pricing, reimbursement, transport, use, sale, or other disposition of the Product;

(b) any material breach by a Responsible Party of a representation or warranty of a Responsible Party contained in this Agreement or in any other agreement between the Parties or the breach or default in any material respect by a Responsible Party of any covenant, agreement, or obligation of Company contained in this Agreement or in any other agreement between the Parties;

(c) a Responsible Party’s failure to comply with Applicable Law; or

(d) the negligence or willful misconduct related to this Agreement of a Responsible Party, or contractors or any of their respective directors, employees, or agents.

## 10.2 Procedures.

(a) Notice. A NovaQuest Indemnitee seeking indemnification (the “**Indemnified Party**”) under Section 10.1 shall give prompt written notice to Company (the “**Indemnifying Party**”) of the assertion of any claim in respect of which indemnity may be sought hereunder. Such notice shall include a description of the claim and the nature and amount of the applicable Loss, to the extent known at such time. The failure of an Indemnified Party to notify the Indemnifying Party on a timely basis or provide such information as set forth above will not relieve the Indemnifying Party of any liability that it may have to the Indemnified Party unless the Indemnifying Party demonstrates that the defense of such action is materially prejudiced by the Indemnified Party’s failure to give such notice and then solely to the extent thereof. The Indemnified Party shall provide the Indemnifying Party with complete and correct copies of all papers and official documents received in connection with any Third Party Claims for which indemnity is sought hereunder and such other information with respect thereto as the Indemnifying Party may reasonably request. The Parties shall keep each other reasonably informed of any facts or circumstances that may be of material relevance in connection with the Loss for which indemnification is sought.

(b) In General. The Indemnifying Party may assume the defense of any Third Party Claim for which indemnity is sought hereunder by giving written notice thereof to the Indemnified Party within thirty (30) calendar days after the Indemnifying Party’s receipt of a notice provided pursuant to Section 10.2(a). Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. If the Indemnifying Party assumes the defense of a Third Party Claim, then the Indemnified Party shall promptly deliver to the Indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim.

(c) Right to Participate in Defense. Without limiting Section 10.2(b), any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim assumed by the Indemnifying Party and to employ counsel of its choice for such purpose. However, such employment shall be at the Indemnified Party’s own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing; (ii) the Indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 10.2(b) (in which case the Indemnified Party may control the defense); or (iii) the interests of the Indemnified Party and the Indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Laws, ethical rules, or equitable principles.

(d) Settlement. With respect to any Third Party Claim, the Indemnifying Party shall have the right to consent to the entry of any judgment or enter into any settlement with respect to such Third Party Claim, only with the prior written consent of the Indemnified Party.

(e) Cooperation. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim in respect of which indemnity is sought hereunder, the Indemnified Party shall, and shall cause each of its indemnitees to, reasonably cooperate in the defense or prosecution thereof, and the Indemnifying Party shall reimburse the Indemnified Party for all its reasonable out-of-pocket expenses in connection therewith. If the Indemnifying Party chooses not to defend any Third Party Claim in respect of which indemnity is sought hereunder, then the

Indemnifying Party shall cooperate with the Indemnified Party in the defense or prosecution thereof, including by furnishing such records, information, and testimony, providing such witnesses and attending such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the Indemnified Party to, and reasonable retention by the Indemnifying Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnifying Parties and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder.

(f) Breach by the Indemnifying Party of its Obligations. If the Indemnifying Party fails to timely (and in any event within thirty (30) calendar days) assume and diligently conduct the defense of any such Third Party Claim, then its right to defend that Third Party Claim shall terminate and the Indemnified Party may assume the defense of, and settle, such claim with counsel of its own choice and on such terms as it deems appropriate, without any obligation to obtain the consent of the Indemnifying Party.

## ARTICLE XI

### MISCELLANEOUS

11.1 **Governing Law.** This Agreement shall be governed by and construed, interpreted, and enforced in accordance with the laws of the State of New York, as applied to agreements executed and performed entirely in the State of New York, without giving effect to the principles of conflicts of law thereof.

#### 11.2 **Dispute Resolution.**

(a) Subject to Section 11.3, prior to the initiation of any Arbitration between the Parties, any dispute, controversy, or claim arising under, out of, or in connection with this Agreement, including any subsequent amendments, regarding the validity, enforceability, construction, performance, or breach hereof (a “*Dispute*”) shall be first addressed between the Parties’ Senior Officers. Either Party shall have the right to refer a Dispute to the Parties’ Senior Officers for attempted resolution by sending a written notice to the other Party requesting the same (the “*Dispute Notice*”). If either Party provides a Dispute Notice, then the Senior Officer (or his or her designee) from each Party shall, by phone or in-person, discuss the Dispute in good faith, commencing within fourteen (14) calendar days after the delivery of the Dispute Notice and continuing until at least twenty-eight (28) calendar days after the delivery of the Dispute Notice.

(b) If the two Senior Officers (or their designees) have not reached a mutually acceptable resolution to the Dispute within twenty-eight (28) calendar days after the delivery of the Dispute Notice, then the Dispute shall be resolved by final, binding arbitration conducted under the rules (the “*AAA Rules*”) of the American Arbitration Association (the “*AAA*”), as amended from time to time, except as provided in this Section 11.2 (“*Arbitration*”).

(c) Selection of Arbitrators. The Arbitration tribunal shall consist of three (3) arbitrators, which shall be selected as follows: (i) one (1) arbitrator shall be selected by Company; (ii) one (1) arbitrator shall be selected by NovaQuest; and (iii) one (1) arbitrator shall be selected by the two (2) foregoing arbitrators (each such arbitrator, an “*Arbitrator*”). Each of the Arbitrators shall have

prior experience in the biopharmaceutical industry. No Arbitrator shall be a current or former employee, shareholder, officer, or director of, or consultant, or advisor to, or other representative of, either Party. If (A) either Party fails to select an Arbitrator within thirty (30) calendar days of the Arbitration Notice or (B) the two (2) Arbitrators selected by the Parties fail to select the third (3rd) Arbitrator within fifteen (15) calendar days after the selection of the first two (2) Arbitrators by the Parties, then, at the request of either Party, the AAA shall make such selection(s) on behalf of the Parties in accordance with the AAA Rules.

(d) Venue and Language. The venue of the Arbitration shall be New York, New York. The Arbitration shall be conducted in English, and all foreign language documents shall be submitted in the original language and shall be accompanied by a translation into English.

(e) Time Periods. Upon the written mutual agreement of both Parties, any time period specified in this Section 11.2 or the AAA Rules shall be extended or accelerated according to the Parties' written mutual agreement. The Arbitrators shall take into account both the desirability of making discovery efficient and cost-effective and the needs of the Parties for an understanding of any legitimate issue raised in the Arbitration.

(f) Consolidation of Disputes. In order to facilitate the comprehensive resolution of related disputes, and upon request of any Party to the Arbitration proceeding, the Arbitrators may consolidate the Arbitration proceeding with any other Arbitration proceeding relating to this Agreement. The Arbitrators shall not consolidate such Arbitrations unless they determine that (i) there are issues of fact or law common to the proceedings so that a consolidated proceeding would be more efficient than separate proceedings, and (ii) no Party would be prejudiced as a result of such consolidation through undue delay or otherwise.

(g) Costs. The costs of the Arbitration, including reasonable fees plus expenses to be paid to the Arbitrator(s) and the reasonable out-of-pocket costs (including the costs incurred for translation of the documents into English, reasonable attorneys' and expert witness fees, and reasonable travel expenses) of the prevailing Party shall be borne by (i) the losing Party, if the Arbitrator(s) rule in favor of one Party on all disputed issues in the Arbitration and (ii) by the Parties, as allocated in writing by the Arbitrator(s) in a manner with a reasonable relationship to the outcome of the Arbitration, if the Arbitrator(s) rule in favor of one Party with respect to some issues and in favor of the other Party with respect to other issues and, in either case ((i) or (ii)), paid within thirty (30) calendar days from the final decision by the Arbitrator.

(h) Decision to be Binding. The decision by the Arbitrators shall be final and binding on the Parties, non-reviewable and non-appealable, and judgment upon any arbitral award may be entered and enforced by any court or other judicial authority of competent jurisdiction.

(i) Confidentiality. All Disputes under this Agreement shall be kept confidential. In any Arbitration proceeding, the Arbitrator(s) shall take all measures necessary for the protection of Confidential Information and the Product. All settlement negotiations, proceedings, and any award and any information obtained from the other Party in connection with the Arbitration shall be deemed Confidential Information subject to ARTICLE VI; provided, however, that the Parties further agree that such Confidential Information may be disclosed to the extent necessary to enforce any award or enforce this Agreement to arbitrate.

11.3 **Equitable Relief.** Each of the Parties hereto acknowledges that the other Party may have no adequate remedy at law if it fails to perform any of its obligations under ARTICLE VI of this Agreement. In such event, each of the Parties agrees that the other Party shall have the right, in addition to any other rights it may have (whether at law or in equity), to pursue equitable remedies such as injunction and specific performance for the breach or threatened breach of any provision of such ARTICLE VI from any court of competent jurisdiction.

11.4 **Expenses.** Except as expressly set forth herein, each Party shall be responsible for and bear all of its own costs and expenses (including any legal fees, any accountants' fees, and any brokers', finders', or investment banking fees or any prior commitment in respect thereof) with regard to the negotiation and consummation of the transactions contemplated by this Agreement. Notwithstanding the foregoing, each Party represents and warrants to the other that the other Party will not be liable for any brokerage commission, finder's fee, or other like payment in connection with the transactions contemplated hereby because of any action taken by, or agreement or understanding reached by, that Party.

11.5 **Relationship of the Parties.** Nothing in this Agreement is intended to be construed so as to suggest that either Party (except as expressly set forth herein) is obligated to provide, directly or indirectly, any advice, consultations, or other services to the other Party. Neither Party shall have any responsibility for the hiring, termination, or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever or to create or impose any contractual or other liability on the other Party without such Party's approval. For all purposes and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party shall be that of independent contractor. This Agreement is not a partnership agreement, and nothing in this Agreement shall be construed to establish a relationship of co-partners or joint venturers between the Parties.

11.6 **Successors and Assigns.** Neither this Agreement nor any rights or obligations hereunder may be assigned in whole or in part by either Party, by operation of law or otherwise, without the prior written consent of the other Party; provided, however, that (i) NovaQuest may, without such consent, (a) assign or otherwise transfer this Agreement to an Affiliate of NovaQuest and (b) assign, sell, pledge, contribute, or otherwise transfer, in whole or in part, its rights to receive any payments under this Agreement, its rights to enforce such payment rights, and its rights to conduct audits or receive information and audit findings under ARTICLE V to any Person, and such Person(ii) Company may, without such consent, assign, sell, pledge, contribute or otherwise transfer this Agreement, including all of its rights and obligations to a Permitted Company in connection with a transaction, or series of related transactions, of the nature described in clause (i) of Section 8.2. This Agreement shall be binding upon, and subject to the terms of the foregoing sentence, inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns. Any assignment or attempted assignment not in accordance with this Section 11.6 shall be null and void.

11.7 **Notices.** All notices, consents, waivers, requests, and other communications hereunder shall be in writing and shall be delivered in person, sent by confirmed electronic mail, sent by overnight courier (e.g., Federal Express), confirmed facsimile transmission or posted by

registered or certified mail, return receipt requested, with postage prepaid, to following addresses of the Parties:

**If to Company:**

Brickell Biotech, Inc.  
5777 Central Avenue, Suite 102  
Boulder, CO 80301  
Attention: Andy Sklawer  
Telephone: 305-582-4657  
E-mail: [asklawer@brickellbio.com](mailto:asklawer@brickellbio.com)

with a copy to:

Mayer Brown LLP  
1221 Avenue of the Americas  
New York, NY 10020  
Attention: Anna T. Pinedo  
Telephone: 212-506-2275  
E-mail: [apinedo@mayerbrown.com](mailto:apinedo@mayerbrown.com)

**If to NovaQuest:**

NovaQuest Co-Investment Fund X  
4208 Six Forks Road, Suite 920  
Raleigh, NC 27609  
Attention: Jonathan Tunnicliffe  
Telephone:  
E-mail: [jonathan.tunnicliffe@nqcapital.com](mailto:jonathan.tunnicliffe@nqcapital.com)

with a copy to:

Wyrick Robbins Yates & Ponton LLP  
4101 Lake Boone Trail, Suite 300  
Raleigh, North Carolina 27607  
Attn: Daniel S. Porper  
Telephone: 919-781-4000  
E-mail: [dporper@wyrick.com](mailto:dporper@wyrick.com)

or to such other address or addresses as NovaQuest or Company may from time to time designate by notice as provided herein. Any such notice shall be deemed given (a) when actually received when so delivered personally or by overnight courier; (b) if mailed, other than during a period of general discontinuance or disruption of postal service due to strike, lockout or otherwise, on the fifth (5th) calendar day after its postmarked date thereof; or (c) if sent by e-mail with acknowledgement of receipt, transmission on the date sent if such day is a Business Day or the next following Business Day if such day is not a Business Day.

11.8 **Severability.** If any provision hereof should be held invalid, illegal, or unenforceable in any jurisdiction, then the Parties shall negotiate in good faith a valid, legal, and enforceable substitute provision that most nearly reflects the original intent of the Parties. All other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties as nearly as may be possible. Such invalidity, illegality, or unenforceability shall not affect the validity, legality, or enforceability of such provision in any other jurisdiction. Nothing in this Agreement shall be interpreted so as to require a Party to violate any Applicable Law.

11.9 **Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be, or construed as, a waiver of the same or any other term or condition of this Agreement on any future occasion.

11.10 **Entire Agreement.** This Agreement (including the Exhibits and Schedules hereto) and the Security Agreement set forth all of the covenants, promises, agreements, warranties, representations, conditions, and understandings between the Parties relating to the subject matter hereof and thereof and supersedes and terminates all prior agreements and understandings between the Parties. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties relating to the subject matter hereof other than as set forth in this Agreement (including the Exhibits and Schedules hereto) and the Security Agreement. The Parties acknowledge and agree that the Parties' respective rights and obligations with regard to the subject matter herein are enshrined in this Agreement and the Security Agreement. Any conflict or inconsistency between the main body of this Agreement, the Exhibits or Schedules and/or any other documents to be delivered pursuant hereto shall be resolved in accordance with the following order of priority: (a) main body of this Agreement; (b) Exhibits and Schedules; and (c) other documents.

11.11 **Third Party Beneficiaries.** Except with regard to the NovaQuest Indemnitees under ARTICLE X, all rights, benefits, and remedies under this Agreement are solely intended for the benefit of the Parties (including their permitted successors and assigns), and no Third Party (except the NovaQuest Indemnitees with regard to their rights, benefits, and remedies under ARTICLE X of this Agreement and except for the Parties' permitted successors and assigns) shall have any rights whatsoever to (a) enforce any obligation contained in this Agreement; (b) seek a benefit or remedy for any breach of this Agreement; or (c) take any other action relating to this Agreement under any legal theory, including actions in contract, tort (including negligence, gross negligence and strict liability), or as a defense, setoff, or counterclaim to any action or claim brought or made by the Parties (or any of their permitted successors and assigns).

11.12 **Interpretation.** When a reference is made in this Agreement to Articles, Sections, Schedules, or Exhibits, such reference shall be to an Article, Section, Schedule, or Exhibit to this Agreement unless otherwise indicated. The words "include," "includes," and "including" when used herein shall be deemed in each case to be followed by the words "without limitation" and shall not be construed to limit any general statement that it follows to the specific or similar items or matters immediately following it. The headings and captions in this Agreement are for convenience and reference purposes only and shall not be considered a part of or affect the construction or

interpretation of any provision of this Agreement. Unless specified otherwise, all statements of, or references to, monetary amounts in this Agreement are to U.S. Dollars. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP, but only to the extent consistent with its usage and the other definitions in this Agreement. Provisions that require that a Party or the Parties “agree,” “consent,” “approve” or the like shall require that such agreement, consent, or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise. Words of any gender include the other gender, and words using the singular or plural number also include the plural or singular number, respectively. Neither Party hereto shall be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one Party or the other. If any notice or other action or omission is required to be taken by a Party under this Agreement on a day that is not a Business Day, then such notice or other action or omission shall be deemed to require to be taken on the next occurring Business Day.

11.13 **Amendments.** This Agreement, including any attachments or Exhibits hereto, may be amended, modified, or supplemented only by a written amendment or agreement signed by an authorized officer of both NovaQuest and Company.

11.14 **No Implied Licenses.** Each Party acknowledges that the rights granted in this Agreement are limited to the scope expressly granted, and all other rights to each Party’s respective technologies and intellectual property rights are expressly reserved to the Party owning or controlling such technologies and intellectual property rights.

11.15 **Time.** Time is of the essence with respect to this Agreement and each of its provisions.

11.16 **Counterparts.** This Agreement may be executed in any number of counterparts with the same effect as if each of the Parties hereto had signed the same document. All counterparts shall be construed together and shall constitute one agreement. This Agreement, to the extent signed and delivered by means of a facsimile machine or via e-mail in .pdf file format, shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

11.17 **Further Assurances.** Each of the Parties hereto shall execute and deliver such additional documents, certificates, and instruments and shall perform such additional acts as may be reasonably requested and necessary or appropriate to carry out the purposes and intent of all of the provisions of this Agreement and to consummate all of the transactions contemplated by this Agreement.

11.18 **Remedies.** Neither the failure nor any delay by any Party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege. Unless specifically and expressly stated in this Agreement as exclusive, each remedy of the Parties specified in this Agreement is not exclusive, and, subject to the terms of this Agreement, is cumulative. The Parties shall be entitled to pursue any available legal or equitable remedy for breach of this Agreement or any provision hereof.

*[Signature Page Follows]*

**IN WITNESS WHEREOF**, the Parties have executed this Funding Agreement in duplicate originals by their duly authorized representatives as of the Effective Date.

**Brickell Biotech, Inc.**

By:           /s/ Robert B. Brown            
Name:           Robert B. Brown            
Title:           Chief Executive Officer          

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**IN WITNESS WHEREOF**, the Parties have executed this Funding Agreement in duplicate originals by their duly authorized representatives as of the Effective Date.

**NovaQuest Co-Investment Fund X, L.P.**

By: **NQ POF V GP, LTD., its general partner**

By: /s/ John L. Bradley, Jr.  
Name: John L. Bradley, Jr.  
Title: Director

**Exhibit A**

**U.S. Security Agreement**

[See Exhibit 10.17]

**Exhibit B**

**Form of Warrant Agreement**

[See Exhibit 4.1]

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**Exhibit C**  
**Development Plan**

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**Exhibit D**  
**Investment Schedule**

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**Exhibit E**

**Phase III Study Protocol**

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<b>Estimated Eligible Expenses (Per Quarter for Remainder of Development Plan)</b>				
<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>
<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>
<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>
<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>
<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>	<b>Quarter:</b>
<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>	<b>Amount:</b>

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**Exhibit G**

**Sofpironium Bromide**

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**Exhibit H**

**Company Bank Account Information**

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## FIRST AMENDMENT TO FUNDING AGREEMENT

This First Amendment to Funding Agreement (this "**Amendment**") is made as of August 30, 2019 (the "**Effective Date**"), between Brickell Biotech, Inc., a Delaware corporation with a principal place of business at 5777 Central Avenue, Suite 102, Boulder, Colorado 80301 ("**Company**") and NovaQuest Co-Investment Fund X, L.P., a Delaware limited partnership, with a place of business at 4208 Six Forks Road, Suite 920 Raleigh, NC 27609 ("**NovaQuest**"). Company and NovaQuest are each referred to herein by name or, individually, as a "**Party**" or, collectively, as "**Parties**."

### INTRODUCTION

- A. The Parties entered into that certain Funding Agreement, dated as of June 2, 2019 (the "**Agreement**").
- B. The Parties wish to amend the Agreement as more particularly set forth below.

NOW, THEREFORE, in consideration of the premises and mutual covenants herein and in the Agreement below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Allocation of Development Payments.** Section 8.7(b) of the Agreement shall be deleted in its entirety and replaced with the following:

“(b) Allocation of Development Payments. The Parties agree to treat [\*\*\*] of the Development Payments as paid in exchange for the Warrant Agreement.”

2. **Defined Terms; Section References.** Capitalized terms used herein and not otherwise defined herein have the meanings (as such meaning may be modified herein, if applicable) ascribed to such terms in the Agreement. Any reference made in this Amendment to an Article, Section, clause, Exhibit or Schedule shall be to an Article, Section, clause, Exhibit or Schedule to the Agreement unless otherwise specifically indicated.

3. **Survival.** To the extent not expressly amended or waived herein, the Parties hereto acknowledge and agree that the Agreement remains unchanged and in full force and effect in its entirety, which such terms are hereby ratified and confirmed.

4. **Governing Law.** This Amendment shall be governed by and construed, interpreted, and enforced in accordance with the laws of the State of New York, as applied to agreements executed and performed entirely in the State of New York, without giving effect to the principles of conflicts of law thereof.

5. **Effect of Amendment.** Whenever the Agreement is referred to in the Agreement or in any other agreements, documents and instruments, such reference shall be deemed to be to the Agreement as amended by this Amendment.

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6. **Counterparts.** This Amendment may be executed in counterparts (including by electronic transmission, including “.PDF”), each of which shall be an original and all of which taken together shall constitute one instrument.

*[Signature Pages Follow]*



**NovaQuest Co-Investment Fund X, L.P.**

By: **NQ POF V GP, LTD., its general partner**

By: /s/ Ronald J. Wooten  
Name: Ronald J. Wooten  
Title: Director

*[Signature Page to First Amendment to Funding Agreement]*

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED  
BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

**DATED AS OF MARCH 31, 2015**

**BY AND BETWEEN**

**BRICKELL BIOTECH, INC. AND**

**KAKEN PHARMACEUTICAL CO., LTD.**

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## TABLE OF CONTENTS

Page

ARTICLE 1	DEFINITIONS	1
ARTICLE 2	LICENSES	13
2.1	License Grants	13
2.2	Additional Licensing Provisions	14
2.3	Performance by Affiliates, Subcontractors and Sublicensees	14
2.4	[***]	16
2.5	Field Expansion	16
2.6	Restrictive Covenants	16
2.7	[***] License Agreement	17
2.8	Disclaimer of Patent Application from License	18
ARTICLE 3	GOVERNANCE	18
3.1	Development and Regulatory Committee	18
3.2	Limits on JDRC and Committee Authority	20
3.3	Decision Making	20
3.4	Actions	20
3.5	Exchange of Information	20
3.6	Minutes of JDRC Meetings	20
ARTICLE 4	DEVELOPMENT	21
4.1	Overview	21
4.2	Development Activities, [***] Clinical Trials, Missed Development Dates and Compliance	22
4.3	Development Plan	23
4.4	Development Costs	24
4.5	Records, Reports and Information	25
4.6	Development Data	25
4.7	Right of Reference and Use	26
4.8	Access to Records	26
4.9	Rights to Audit	26
4.10	Dispute Resolution Procedures	27

ARTICLE 5 REGULATORY 27

5.1 Regulatory Filings and Regulatory Approvals 27

5.2 Communications 29

## TABLE OF CONTENTS

Page

5.3	Adverse Event Reporting; Safety Data Exchange and Medical Inquiries	29
5.4	Regulatory Authority Communications Received by a Party	30
5.5	Recall, Withdrawal, or Market Notification of Product	30
ARTICLE 6	COMMERCIALIZATION	31
6.1	Commercialization in the Field in the Territory	31
6.2	Commercialization Reports	31
6.3	Promotional Materials	32
6.4	Commercialization Data	32
6.5	Global Branding Strategy	32
ARTICLE 7	SUPPLY	33
7.1	Supply by [***]	33
7.2	Phase III Clinical Supply Agreement, Commercial Supply Agreement and Quality Agreements	33
7.3	Alternative Source of Phase III Clinical and Trial Commercial Supply	34
ARTICLE 8	PAYMENTS	34
8.1	Upfront Payment	34
8.2	Milestone Payments	34
8.3	Royalties	35
8.4	Taxes and Withholding	36
8.5	Currency Conversion	36
8.6	Late Payments	37
8.7	Records; Audits	37
ARTICLE 9	INTELLECTUAL PROPERTY MATTERS	38
9.1	Ownership of Intellectual Property	38
9.2	Disclosures; Disputes Regarding Inventions	38
9.3	Patent Filings, Prosecution and Maintenance	39
9.4	Defense and Enforcement of Patents	40
9.5	Patent Marking	44

9.6 Patent  
Challenge 44

ARTICLE 10 REPRESENTATIONS, WARRANTIES AND  
COVENANTS 44

10.1 Mutual Representations and  
Warranties 44

10.2 Additional Representations, Warranties and Covenants of  
Brickell 45

## TABLE OF CONTENTS

Page

10.3	Brickell Product Development	47
10.4	Disclaimer	47
10.5	No Other Representations or Warranties	47
ARTICLE 11	INDEMNIFICATION	47
11.1	Indemnification by Brickell	47
11.2	Indemnification by Kaken	47
11.3	Indemnification Procedures	48
11.4	Limitation of Liability	49
11.5	Insurance	50
ARTICLE 12	CONFIDENTIALITY	50
12.1	Confidential Information	50
12.2	Confidentiality Obligations	51
12.3	Permitted Disclosure and Use	51
12.4	Notification	52
12.5	Publicity; Filing of this Agreement	52
12.6	Publication	53
12.7	Use of Names	53
12.8	Survival	53
ARTICLE 13	TERM AND TERMINATION	53
13.1	Term	53
13.2	Termination for Breach	54
13.3	Termination as a Result of Bankruptcy	54
13.4	Termination by Kaken	54
ARTICLE 14	EFFECTS OF TERMINATION AND EXPIRATION	54
14.1	Termination By Brickell and Certain Terminations by Kaken	54
14.2	Termination by Kaken	56
14.3	Expiration of this Agreement	56
14.4	Accrued Rights	57
14.5	Survival	57

14.6 Remedies in Lieu of  
Termination 57

14.7 Rights in  
Bankruptcy 57

ARTICLE 15 DISPUTE  
RESOLUTION 58

TABLE OF CONTENTS

Page

15.1 General 58

15.2 Disputes Arising Between the Parties 58

15.3 Dispute Resolutions 58

15.4 Patent and Trademark Dispute Resolution 58

15.5 Arbitration 58

15.6 Injunctive Relief 59

ARTICLE 16 GENERAL TERMS 59

16.1 Entire Agreement; Amendment 59

16.2 Force Majeure 59

16.3 Notices 59

16.4 No Strict Construction; Interpretation 60

16.5 Assignment and Delegation 60

16.6 Compliance with Applicable Law; Further Actions 61

16.7 Third Party Beneficiary 61

16.8 Severability 61

16.9 No Waiver 61

16.10 Independent Contractors 61

16.11 English Language; Governing Law 61

16.12 Counterparts 62

<b>List of Schedules</b>
Schedule 1.5 [***] Patents Schedules
Schedule 2.7 [***] License Agreement
Schedule 4.3.2 Initial Development Plan Overview
Schedule 7 Terms for Phase II and Phase III Clinical Supply Agreement

## LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This License, Development and Commercialization Agreement (this “**Agreement**”), dated as of March 31, 2015 (the “**Effective Date**”), is made by and between Brickell Biotech, Inc., a Delaware corporation (“**Brickell**”) and Kaken Pharmaceutical Co. Ltd., a company legally organized and existing under the laws of Japan (“**Kaken**”). Brickell and Kaken are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### RECITALS

**WHEREAS**, Brickell has developed and is currently further developing a pharmaceutical product hereinafter defined as the Product for the treatment of [\*\*\*];

**WHEREAS**, Kaken has significant experience in the development and commercialization of pharmaceutical products in the Territory; and **WHEREAS**, Kaken and Brickell desire to establish a collaboration for the further development and commercialization of the Product in the Field in the Territory.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

As used in this Agreement, the following initially capitalized terms shall have the meanings set forth in this Article 1 or as otherwise defined elsewhere in this Agreement:

**1.1 “Affiliate”** means any Person directly or indirectly controlled by, controlling or under common control with, a Party, but only for so long as such control shall continue. For purposes of this definition, “control” (including, with correlative meanings, “controlled by”, “controlling” and “under common control with”) shall be presumed to exist with respect to a Person in the event of the possession, direct or indirect, of (i) the power to direct or cause the direction of the management and policies of such Person (whether through ownership of securities, by contract or otherwise), or (ii) at least fifty percent (50%) of the voting securities or other comparable equity interests. The Parties acknowledge that, in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case, such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct or cause the direction of the management and policies of such Person. For the avoidance of doubt, neither of the Parties shall be deemed to be an “Affiliate” of the other.

**1.2 “[\*\*\*] License Agreement”** means that certain License Agreement, dated as of [\*\*\*], by and among [\*\*\*], as amended by [\*\*\*].

**1.3 “Brickell Invention”** means an Invention that is made solely, or jointly with a Third Party, by an employee of Brickell or any of its Affiliates or a Person under an obligation of assignment to Brickell or any of its Affiliates in connection with the performance of Brickell’s obligations pursuant to this Agreement.

**1.4 “Brickell Know-How”** means all Know-How that (i) is Controlled by Brickell or any of its Affiliates as of the Effective Date which is necessary or reasonably useful for the Development or Commercialization of the Product in the Field in the Territory or Manufacture of the Product in the Field, including the Existing Development Data, or (ii) comes under the Control of Brickell during the Term (but excluding Brickell Inventions), which is necessary for the Development or Commercialization of the Product in the Field in the Territory or the Manufacture of the Product in the Field, including the New Brickell Development Data.

**1.5 “Brickell Patent”** means any Patent that (i) is Controlled by Brickell or any of its Affiliates as of the Effective Date, including the Patents listed in Schedule 1.5, which is necessary or reasonably useful for the Development or Commercialization of the Product in the Field in the Territory or the Manufacture of the Product in the Field, or (ii) comes under the Control of Brickell during the Term (but excluding Brickell Collaboration Patents), which is necessary for the Development or Commercialization of the Product in the Field in the Territory or the Manufacture of the Product in the Field.

**1.6 “Brickell Technology”** means the Brickell Patents, Brickell Collaboration Patents, Brickell Know-How and Brickell Inventions.

**1.7 “Business Day”** means a day (other than Saturday or Sunday) on which banks are open for business in Tokyo, Japan and in Miami, Florida, U.S.

**1.8 “Change of Control”** means, with respect to a Person, any of the following events: (i) any Person is or becomes the beneficial owner (except that a Person shall be deemed to have beneficial ownership of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all shares of such Person’s outstanding capital stock; (ii) such Person consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into such Person, other than (A) a merger or consolidation which would result in the voting securities of such Person outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of such Person or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of such Person (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of a majority of the total voting power of all shares of capital stock of such Person or (iii) such Person transfers all or substantially all of its assets to any Person other than a wholly owned Affiliate of such Person.

**1.9 “Clinical Trial”** means human clinical studies in which the Product is administered or otherwise evaluated in humans, including any Phase IV Clinical Trials sponsored by either Party or co-sponsored by both Parties or investigator initiated human clinical studies funded or otherwise supported by either Party or both Parties.

**1.10 “Commercialize”, “Commercializing” or “Commercialization”** means all activities directed to the marketing, promotion, selling or offering for sale of a Product for an indication, including planning, market research, Pre-Marketing, advertising, educating, marketing, promoting, importing, exporting, distributing and post-marketing safety surveillance and reporting. For clarity, “Commercialization” shall not include any activities related to clinical research, Manufacturing or Development of the Product.

**1.11 “Control”** means, when used in reference to intellectual property, other intangible property, or materials, that a Party owns or has a license or sublicense to such intellectual property, other intangible property or materials, and has the ability to grant a license or sublicense or other right to use such intellectual property, other intangible property or materials, as applicable, as provided for herein.

**1.12 “Cover(ed)”** means, with respect to any Patent and the subject matter at issue, that, but for a license granted under a Valid Claim of such Patent, the manufacture, development, use, sale, offer for sale or importation of the subject matter at issue would infringe such Valid Claim.

**1.13 “Develop”, “Developing” or “Development”** means all activities relating to research, non-clinical, preclinical and clinical trials (including manufacture of Placebo), toxicology testing, statistical analysis and reporting, preparation and submission of applications for Regulatory Approval of the Product, necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining all Regulatory Approvals for the Product and all other development-related activities that are deemed by the JDRC to be commercially useful, but shall not include any activities related to Commercialization or Manufacture.

**1.14 “Development Activities”** means those Development activities undertaken by or on behalf of a Party or any of its Affiliates with respect to the Product in the Field in the Territory set forth in the applicable Development Plan.

**1.15 “Development Costs”** means the costs and expenses incurred by a Party or any of its Affiliates attributable to, or reasonably allocable to, the Development Activities set forth in the applicable Development Plan.

**1.16 “Dollar”** means a U.S. dollar, and “\$” shall be interpreted accordingly.

**1.17 “Drug Substance”** means [\*\*\*].

**1.18 “Ex-Territory Exclusive Development Activities”** means those Development activities that are necessary for obtaining or maintaining Regulatory Approval for the Product in the Field outside the Territory other than U.S.-Japan Development Activities.

**1.19 “Facility”** means, as applicable, a Party’s Manufacturing facility and such other facilities used by such Party (or those of its Affiliates or Third Party contractors) in the manufacture, packaging, labeling or storage of (a) the Product or (b) materials utilized in the manufacture, packaging or labeling of the Product, in each case, with respect to the Product for Development or Commercialization in the Field in the Territory hereunder.

**1.20 “FDA”** means the U.S. Food and Drug Administration or its successor.

**1.21 “Field”** means the [\*\*\*].

**1.22 “First Commercial Sale”** means the first sale of the Product in a given country or other regulatory jurisdiction in the Territory by or on behalf of Kaken, any of its Affiliates or sublicensees to a Third Party, [\*\*\*], to the extent required for sale of a Product in a given country or regulatory jurisdiction, and any necessary labeling negotiations that may be required [\*\*\*] for such Product in such country or regulatory jurisdiction.

**1.23 “GAAP”** means generally accepted accounting principles in the United States.

**1.24 “Generic Version”** means, with respect to the Product in a given country in the Territory, a Third Party pharmaceutical product (other than the Product hereunder) that: (i) contains the Drug Substance as the sole active ingredient and (ii) is legally saleable as a substitute for the Product in such country.

**1.25 “Good Clinical Practices” or “GCP”** means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (i) as set forth in European Commission Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and brought into law by European Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice for investigational medicinal products, (ii) the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (“ICH”) Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the European Union, (iii) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (iv) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (v) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

**1.26 “Good Laboratory Practices” or “GLP”** means all applicable Good Laboratory Practice standards, including, as applicable, (i) as set forth in European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time as well as any Rules Governing Medicinal Products in the European Community Vol. III, ISBN 92.825 9619-2 (ex - OECD principles of GLP), (ii) the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58, and (iii) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time.

**1.27 “Good Manufacturing Practices” or “GMP”** means all applicable Good Manufacturing Practices including, (i) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (ii) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601 and 610, (iii) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, (iv) the principles detailed in the ICH Q7A guidelines, and (v) the equivalent Laws in any relevant country, each as may be amended and applicable from time to time.

**1.28 “Governmental Authority”** means any multinational, national, federal, prefectural, state, local, municipal or other governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal), in each case, having jurisdiction over the applicable subject matter.

**1.29 “IFRS”** means International Financial Reporting Standards, consistently applied.

**1.30 “IND”** means the equivalent application of an Investigational New Drug Application to the equivalent agency of the FDA in the Territory, such as a clinical trial application (“CTA”) or a clinical trial exemption (“CTX”), the filing of which is necessary to commence or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.

**1.31 “Invention”** means any invention or discovery, as determined in accordance with applicable Laws relating to inventorship in the country in which such invention or discovery is made.

**1.32 “Japanese GAAP”** means generally accepted accounting principles in Japan.

**1.33 “JPY”** means Japanese Yen and “Y” shall be interpreted accordingly.

**1.34 “JNDA”** means a Japanese New Drug Application as defined in the Pharmaceutical Affairs Law and the regulations promulgated thereunder.

**1.35 “Joint Invention”** means an Invention that is made jointly by an employee of, or Person under an obligation of assignment to, each of Brickell and Kaken or their respective Affiliates.

**1.36 “Kaken Applied Know-How”** means all Know-How that is (a) (i) Controlled by Kaken or any of its Affiliates as of the Effective Date or comes under the Control of Kaken or any of its Affiliates during the Term (other than as a result of the licenses granted by Brickell to Kaken under this Agreement), including the New Kaken Development Data, and (ii) incorporated by Kaken in the Product prior to any termination of this Agreement or (b) a Kaken Invention.

**1.37 “Kaken Applied Patent”** means any Patent that (a) (i) is Controlled by Kaken or any of its Affiliates as of the Effective Date or comes under the Control of Kaken or any of its Affiliates during the Term (other than as a result of the licenses granted by Brickell to Kaken under this Agreement) and (ii) claims any Kaken Applied Know-How or (b) is a Kaken Collaboration Patent.

**1.38 “Kaken Applied Technology”** means the Kaken Applied Know-How and the Kaken Applied Patents.

**1.39 “Kaken Invention”** means an Invention that is made, solely or jointly with a Third Party, by an employee of Kaken or any of its Affiliates or a Person under an obligation of assignment to Kaken or any of its Affiliates in connection with the performance of Kaken’s obligations pursuant to this Agreement.

**1.40 “Know-How”** means any proprietary data, results, material(s), technology, and nonpublic information of any type whatsoever, in any tangible or intangible form, including know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports and plans, market research, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

**1.41 “Laws”** means all laws, statutes, rules, regulations, directives, decisions, ordinances of any Governmental Authority.

**1.42 “Lien(s)”** means any lien, encumbrance, security interest of any kind whatsoever including, but not limited to, interests arising from options, pledges, mortgages, indentures, security agreements, rights of first refusal or rights of pre-emption, irrespective of whether such Lien arises under any agreement, covenant, other instrument, the mere operation of statutory or other Laws or by means of a judgment, order or decree of any court, judicial or administrative authority, and also means any approval or consent required from a Third Party to the exercise or full vesting of a right or title.

**1.43 “Manufacture” or “Manufacturing”** means all activities related to the manufacturing of the Product, or any ingredient thereof (including the Drug Substance), including manufacturing for clinical use or commercial sale, in-process and Product testing, release of Product, quality assurance activities related to manufacturing and release of Product, handling and storage of Product and ongoing stability tests and regulatory activities related to any of the foregoing; provided, however, that, for purposes of clarity, “Manufacture” [\*\*\*] unless mutually agreed to between the Parties.

**1.44 “Manufacturing Cost”** means, with respect to the Drug Substance, Product or Placebo, the costs calculated in accordance with GAAP, Japanese GAAP or IFRS that relate to the Drug Substance, Product or Placebo, respectively, that is either (1) supplied by a Third Party or (2) Manufactured directly by a Party or any of its Affiliates, determined in accordance with the Phase II Clinical Supply Agreement, Phase III Clinical Supply Agreement or Commercial Supply Agreement, as applicable.

**1.45 “Manufacturing Development Activities”** means development of test methods, stability testing, formulation development, process development, quality assurance activities, quality control activities, qualification and validation activities, analytic process development, manufacturing process validation, scale-up, and all other activities, including CMC-related activities, necessary for or related to the Manufacture of the Product for use in the Field.

**1.46 “Manufacturing Party”** means the Party performing Manufacturing activities for the Product.

**1.47 “Marketing Authorization Application” or “MAA”** means an application to the appropriate Regulatory Authority for approval to sell the Product (but excluding Pricing Approval) in any particular country or regulatory jurisdiction, including an NDA filed with the FDA in the United States and a JNDA filed with the MHLW in Japan.

**1.48 “Medical Science Liaison”** means an individual who is employed by or on behalf of Kaken or any of its Affiliates and who provides educational services and other educational efforts directed towards the medical and/or scientific community.

**1.49 “MHLW”** means Japan’s Ministry of Health, Labor and Welfare.

**1.50 “Net Sales”** means the gross amount invoiced by or on behalf of Kaken or any of its Affiliates (or any permitted distributors) or sublicensees on account of sales of the Product, less the [\*\*\*]:

- (a) [\*\*\*];
- (b) [\*\*\*];
- (c) [\*\*\*]; and
- (d) [\*\*\*].

A Product shall be considered [\*\*\*]. In the event Kaken [\*\*\*], and, in the [\*\*\*].

[\*\*\*], provided that [\*\*\*].

Net Sales amounts shall be determined from the books and records of Kaken, its Affiliates and sublicensees maintained in accordance with Japanese GAAP.

**1.51 “Patent Challenge”** means the commencement of any interference or opposition proceeding or other challenge to the validity or enforceability of, or opposition to any extension of or the grant of a supplementary protection certificate with respect to a Patent.

**1.52 “Patents”** means patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts thereof in any country.

**1.53 “Person”** shall mean any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

**1.54 “Phase I Clinical Trial”** means a human clinical trial that is intended to initially evaluate the safety and/or pharmacokinetics of a product or that would otherwise satisfy the requirements of 21 C.F.R. 312.21(a), or an equivalent clinical trial in a country other than the United States.

**1.55 “Phase II Clinical Trial”** means a human clinical trial for which the primary endpoints include a determination of dose ranges or an indication of efficacy of a product in patients being studied as described in 21 C.F.R. 312.21(b), or an equivalent clinical trial in a country other than the United States.

**1.56 “Phase IIA Clinical Trials”** means one (1) or more human clinical trials to preliminarily evaluate efficiency and safety of a candidate drug in the targeted patient population over a range of doses.

**1.57 “Phase DE Clinical Trials”** means one (1) or more controlled clinical trial(s) to evaluate further the efficacy and safety of a candidate drug in the targeted patient population and to define the optimal dosing regimen.

**1.58 “Phase III Clinical Trials”** means a clinical trial identified as a Phase III clinical trial in the Development Plan and conducted as a pivotal trial for purposes of filing a MAA for a Product that provides for the clinical study of such Product on a sufficient number of patients to confirm with statistical significance the efficacy, and confirm the safety of such Product, sufficient to support such MAA for such Product.

**1.59 “Phase IV Clinical Trials”** means certain post-marketing studies to delineate additional information about a pharmaceutical product’s risks, benefits, and optimal use, commenced after receipt of regulatory approval for a product in the indication for which such trial is being conducted.

**1.60 “Placebo”** means a substance or mixture of substances lacking presence of Drug Substance, manufactured for purposes of control treatment in Clinical Trials. For purposes herein, Placebo refers to finished but unlabeled form of such substance.

**1.61 “PMDA”** means the Japanese Pharmaceuticals and Medical Devices Agency.

**1.62 “Pre-Marketing”** means all sales and marketing activities undertaken prior to and in preparation for the launch of the Product in the Territory. Pre-Marketing shall include market research, key opinion leader development, advisory boards, medical education, disease-related public relations, health care economic studies, sales force training and other pre-launch activities prior to the First Commercial Sale of the Product in a given country or other regulatory jurisdiction in the Territory.

**1.63 “Pricing Approval”** means the approval, agreement, determination or decision from a Governmental Authority establishing the price and/or reimbursement for the Product for sale in a given country or regulatory jurisdiction, as required by applicable Law in such country or other regulatory jurisdiction prior to the sale of the Product in such country or regulatory jurisdiction.

**1.64 “Product”** means a [\*\*\*] containing the Drug Substance [\*\*\*].

**1.65 “Product Approval”** means the approval of a Governmental Authority necessary for the marketing and sale of the Product in a given country or regulatory jurisdiction, which may include the approval of an MAA (but shall not include any Pricing Approvals).

**1.66 “Product Complaint”** means any written, verbal or electronic expression of dissatisfaction regarding any Product sold by or on behalf of Kaken (or any of its Affiliates or sublicensees) in the Territory, including reports of actual or suspected product tampering, contamination, mislabeling or inclusion of improper ingredients.

**1.67 “Product Specifications”** means those Manufacturing, performance, quality control release, and packaging and labeling specifications for the Product in the Territory, which are initially as set forth in the applicable Product Approval for the Product or are otherwise required for a Clinical Trial.

**1.68 “Promotional Materials”** means all written, printed, video or graphic advertising, promotional, educational and communication materials (other than the Product labels and package inserts) for marketing, advertising and promoting of the Product in the Field in the Territory, for use (i) by a sales representative or a Medical Science Liaison or (ii) in advertisements, web sites or direct mail pieces.

**1.69 “Regulatory Approvals”** means all necessary approvals (including INDs, Product Approvals, Pricing Approvals and, in each case any supplements and amendments thereto), licenses, registrations or authorizations of any Governmental Authority, necessary for the manufacture, distribution, use, promotion and sale of the Product in a given country or regulatory jurisdiction.

**1.70 “Regulatory Authority”** means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or regulatory jurisdiction, including, (i) in the U.S., the FDA, and (ii) in Japan, the MHLW.

**1.71 “Regulatory Costs”** means the costs and expenses incurred by a Party or any of its Affiliates attributable to, or reasonably allocable to, the preparation, obtaining or maintaining of Regulatory Materials and Regulatory Approvals for the Product, including any filing fees.

**1.72 “Regulatory Data”** means any and all research data, pharmacology data, chemistry, manufacturing and control data, preclinical data, clinical data and all other documentation submitted, or required to be submitted, to Regulatory Authorities in association with Regulatory Filings for the Product (including any applicable Drug Master Files (“DMFs”), Chemistry, Manufacturing and Control (“CMC”) data, or similar documentation).

**1.73 “Regulatory Exclusivity”** means marketing or data exclusivity conferred by the applicable Regulatory Authority in a country or jurisdiction on the holder of a Product Approval for a pharmaceutical product in such country or jurisdiction, including, regulatory data exclusivity, orphan drug exclusivity, new chemical entity exclusivity and pediatric exclusivity.

**1.74 “Regulatory Materials”** means Regulatory Filings, notifications, communications, correspondence, registrations, Regulatory Approvals and/or other filings made to, received from or otherwise conducted with a Regulatory Authority that are necessary in order to Develop, Manufacture, obtain marketing authorization, market, sell or otherwise Commercialize the Product in a particular country or regulatory jurisdiction. Regulatory Materials include INDs, MAAs, presentations, responses, and applications for other Product Approvals.

**1.75 “Regulatory Filings”** means any filings that are required for any Regulatory Approval in the Territory.

**1.76 “Royalty Term”** means, [\*\*\*].

**1.77 “Territory”** means [\*\*\*].

**1.78 “Territory Exclusive Development Activities”** means those Development Activities [\*\*\*] that are necessary for obtaining or maintaining [\*\*\*] for the Product in the Field in the Territory.

**1.79** “**Third Party**” means any Person other than Brickell or Kaken or their respective Affiliates.

**1.80** “**U.S.**” means the United States of America and its possessions and territories.

**1.81** “**U.S.-Japan Development Activities**” means all Development activities that are necessary solely for [\*\*\*], which for clarity, include [\*\*\*].

**1.82** “**U.S.-Japan Phase III Clinical Trial**” mean the Phase III Clinical Trial conducted for purposes of [\*\*\*] for which Brickell shall be responsible for [\*\*\*] and for which Kaken shall be responsible for [\*\*\*] and the other details of which shall be set forth in the Development Plan.

**1.83** “**U.S.-Japan Phase III Development Activities**” means Development Activities related to the performance of the U.S.-Japan Phase III Clinical Trial.

**1.84** “**Valid Claim**” means (a) a claim of an issued and unexpired Brickell Patent that (i) has not been rejected, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken or (ii) has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue or disclaimer or (b) a claim included in a pending patent application of a Brickell Patent (whether filed before or after the Effective Date).

**Interpretation.** Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (a) “include”, “includes” and “including” are not limiting; (b) “hereof”, “hereto”, “herein” and “hereunder” and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (c) words of one gender include the other gender; (d) references to a contract or other agreement mean such contract or other agreement as from time to time amended, modified or supplemented; (e) references to a Person are also to its permitted successors and assigns; (f) references to an “Article”, “Section”, “Exhibit” or “Schedule” refer to an Article or Section of, or an Exhibit or Schedule to, this Agreement, unless expressly stated otherwise; and (g) references to a law include any amendment or modification to such law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before or after the date of this Agreement.

**Additional Definitions.** The following terms have the meanings set forth in the corresponding Sections of this Agreement:

<b>Term</b>	<b>Section</b>
“ <b>Abandoned Collaboration Patents</b> ”	9.3.2
“ <b>Abandoned Joint Inventions</b> ”	9.3.2
“ <b>Agreement</b> ”	Preamble
“ <b>Audit</b> ”	8.7
“ <b>Audited Party</b> ”	8.7

<b>“Auditing Party”</b>	8.7
<b>“Bankrupt Party”</b>	14.6
<b>“Breaching Party”</b>	13.2
<b>“Brickell”</b>	Preamble
<b>“Brickell Collaboration Patents”</b>	9.1.1
<b>“CMC”</b>	1.72
<b>“Commercial Supply Agreement”</b>	7.2
<b>“Confidential Information”</b>	12.1
<b>“Controlling Party”</b>	9.4.1(a)
<b>“CTA”</b>	1.29
<b>“CTX”</b>	1.29
<b>“Development Data”</b>	4.6
<b>“Development Plan”</b>	4.3.1
<b>“Development Supply Price”</b>	7.1
<b>“Disclosing Party”</b>	12.1
<b>“DMI’s”</b>	1.72
<b>“Effective Date”</b>	Preamble
<b>“Executive Officer”</b>	15.2
<b>“Existing Development Data”</b>	4.6.1
<b>“Global Branding Strategy”</b>	6.5
<b>“ICH”</b>	1.25
<b>“Indemnification Claim Notice”</b>	11.3.1
<b>“Indemnified Party” and “Indemnifying Party”</b>	11.3.1
<b>“Indemnitee” and “Indemnitees”</b>	11.3.1
<b>“Infringement Claim”</b>	9.4.1
<b>“Initial Development Plan Overview”</b>	4.3.2
<b>“Joint Collaboration Patents”</b>	9.1.1
<b>“Joint Collaboration Know-How”</b>	9.1.1
<b>“Joint Development and Regulatory Committee” or “JDRC”</b>	3.1
<b>“Kaken”</b>	Preamble
<b>“Kaken Collaboration Patents”</b>	9.1.1
<b>“Kaken Funded Patent Rights”</b>	9.3.1
<b>“Losses”</b>	11.1
<b>“Milestone Notification Notice”</b>	8.2
<b>“New Brickell Development Data”</b>	4.6.2
<b>“New Development Data”</b>	4.6.2
<b>“New Kaken Development Data”</b>	4.6.2
<b>“New Indication”</b>	2.5

“Party” or “Parties”	Preamble
“Patent Challenge”	9.6
“Phase II Clinical Supply Agreement”	7.2
“Phase III Clinical Supply Agreement”	7.2
“Quality Agreements”	7.2
“Receiving Party”	12.1
“Recovery”	9.4.2(c)(iv)
“Senior Officer”	4.10
“Term”	13.1
“Third Party Claim”	11.1
“Upfront Payment”	8.1
“VAT”	8.4(a)

**ARTICLE 2  
LICENSES**

**2.1 License Grants.**

**2.1.1 Grant to Kaken.** Subject to the terms and conditions of this Agreement, Brickell hereby grants to Kaken during the Term the following licenses or sublicenses, as applicable, [\*\*\*], and including [\*\*\*]: (i) an [\*\*\*], (ii) an [\*\*\*], (iii) an [\*\*\*], (iv) [\*\*\*] and (v) an [\*\*\*]. The licenses to Manufacture the Product and Drug Substance shall include the [\*\*\*] without the prior written consent of Brickell not to be unreasonably withheld or delayed and, if Brickell denies such consent, Brickell shall outline its concerns in writing to Kaken and allow Kaken adequate opportunity to address Brickell’s concerns. For purposes of this Section 2.1.1, [\*\*\*], except as otherwise noted.

**2.1.2 Grant to Brickell.** Subject to the terms and conditions of this Agreement, Kaken hereby grants to Brickell during the Term the following licenses or sublicenses, as applicable, each under [\*\*\*], an [\*\*\*]: (i) to [\*\*\*] and (ii) to [\*\*\*] and (iii) to [\*\*\*] or to [\*\*\*]. The licenses to Manufacture the Product and Drug Substance shall include the [\*\*\*] (iii) shall [\*\*\*] without the prior written consent of Kaken not to be unreasonably withheld or delayed and, if Kaken denies such consent, Kaken shall outline its concerns in writing to Brickell and allow Brickell an adequate opportunity to address Kaken’s concerns. For purposes of this Section 2.1.2, [\*\*\*], except as otherwise noted.

**2.2 Additional Licensing Provisions.**

**2.2.1 Negative Covenant.** Each Party covenants that it will not use or practice any of the other Party’s Patent rights or other intellectual property rights licensed (or sublicensed, as applicable) to it under this Article 2 except for the purposes expressly permitted in the applicable license grant.

**2.2.2 No Implied Licenses; Retained Rights.** Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party, whether by implication, estoppel or otherwise.

**2.2.3 Registration with Patent Offices.** [\*\*\*] as an [\*\*\*] and other similar Regulatory Authorities in other countries of the Territory and Brickell shall cooperate with Kaken to effect such registration. Kaken shall cooperate with Brickell and file any required documentation with Governmental Authorities to remove such registration upon the expiration or termination of this Agreement.

### **2.3 Performance by Affiliates, Subcontractors and Sublicensees**

**2.3.1 Performance by Affiliates.** The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates; provided, however, that each Party shall remain responsible for and be guarantor of the performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against an Affiliate, for any obligation or performance hereunder prior to proceeding directly against such Party. Wherever in this Agreement the Parties delegate responsibility to Affiliates, the Parties agree that such entities may not make decisions inconsistent with this Agreement, amend the terms of this Agreement or act contrary to its terms in any way.

**2.3.2 Subcontractors.** Each Party shall ensure that each of its subcontractors accepts and complies with all of the terms and conditions of this Agreement (including, without limitation, Section 2.6), and such Party shall guarantee its subcontractors' performance under this Agreement. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against a subcontractor, for any obligation or performance hereunder prior to proceeding directly against such Party.

**2.3.3 Sublicenses.** Subject to the penultimate sentence of Section 2.1.1, [\*\*\*] under the license granted pursuant to Section 2.1.1 at any given time during the Term [\*\*\*]; provided, however, that, with respect to each such sublicense (i) Brickell shall be notified in writing at least twenty (20) Business Days in advance of the grant (including a description of the rights to be granted, the identity of the sublicensee and the countries involved), and (ii) Kaken shall obtain the prior written consent of Brickell thereto, such consent not to be unreasonably withheld. Subject to the penultimate sentence of Section 2.1.2, [\*\*\*] under the license granted pursuant to Section 2.1.2 at any given time during the Term [\*\*\*]; provided, however, that, with respect to each such sublicense. Kaken shall be notified in writing within twenty (20) Business Days of the grant (including a description of the rights to be granted, the identity of the sublicensee and the countries involved).

**2.3.4 Conditions Applicable to Sublicensees and Subcontractors.** Each Party shall ensure that each of its sublicensees and subcontractors accepts and complies with all applicable terms and conditions of this Agreement, and each Party shall remain responsible for, and shall guarantee, the performance of its sublicensees and subcontractors hereunder, and any

such sublicense or subcontract shall (a) be subject and subordinate to the terms and conditions of this Agreement, (b) contain terms and conditions which are consistent with the terms and conditions of this Agreement, (c) not in any way diminish, reduce or eliminate any of its obligations under this Agreement, and (d) impose on the sublicensee or subcontractor all applicable obligations under the terms of this Agreement, including the reporting, audit, inspection and confidentiality provisions hereunder, as well as a provision prohibiting such sublicensee or subcontractor from further sublicensing or subcontracting. Each Party hereby expressly waives any requirement that the other Party exhaust any right, power or remedy, or proceed against a sublicensee or subcontractor, for any obligation or performance hereunder prior to proceeding directly against such Party. In addition, Kaken agrees to [\*\*\*].

**2.4** [\*\*\*]. From the [\*\*\*], each Party hereby covenants that it shall not (and shall cause its Affiliates not to) [\*\*\*] pursuant to this Agreement. From the Effective Date until the [\*\*\*], each Party hereby covenants that it shall not (and shall cause its Affiliates not to) [\*\*\*] pursuant to this Agreement. Notwithstanding the foregoing, [\*\*\*].

**2.5 Field Expansion.** If either Party wishes to [\*\*\*] the Product [\*\*\*], then such Party shall notify the other Party in writing of its proposal to expand the Field to include [\*\*\*]; provided, however, that any such expansion of the Field shall be in [\*\*\*], including the [\*\*\*]. Within ninety (90) days of the receipt of such notice, the other Party shall notify the proposing Party whether or not it wishes to participate [\*\*\*]. If the Parties so agree to such expansion of the Field to include [\*\*\*], the Parties shall amend this Agreement to give effect to such expanded Field; provided, however, that, if [\*\*\*], but shall be free to Develop and Commercialize the Product in the New Indication in the Territory at any time after First Commercial Sale of the Product in the Field in the Territory. For clarity, [\*\*\*].

## **2.6 Restrictive Covenants.**

**2.6.1 Ex-Territory Activities.** Kaken hereby covenants and agrees that it shall not (and shall cause its Affiliates, sublicensees and subcontractors not to), either directly or indirectly, market, distribute or sell the Product [\*\*\*]. Without limiting the generality of the foregoing, with respect to [\*\*\*], Kaken [\*\*\*] (i) engage in [\*\*\*].

**2.6.2 Ex-Field Activities.** Kaken hereby covenants and agrees that it shall not (and shall cause its Affiliates, sublicensees and subcontractors not to), either directly or indirectly, market, distribute or sell the Product [\*\*\*]. Without limiting the generality of the foregoing, Kaken [\*\*\*] (i) engage [\*\*\*].

**2.6.3 Kaken Contracts.** In the event that Kaken (or any of its Affiliates) enters into any agreement with a subcontractor (including any distributor or wholesaler) or a sublicensee for the Product, it shall include in any and all such agreements provisions substantially similar to those set forth in Sections 2.6.1 and 2.6.2, such that such subcontractor or sublicensee, as applicable, shall only be authorized to [\*\*\*].

**2.6.4 Within-Territory Activities.** Brickell hereby covenants and agrees that it [\*\*\*]. Without limiting the generality of the foregoing, with respect to such countries within the Territory, Brickell [\*\*\*].

**2.6.5 Brickell Contracts.** In the event that Brickell (or any of its Affiliates) enters into any agreements with a subcontractor (including, any distributors or wholesalers) or a sublicensee for the Product, it shall include in any and all said agreements provisions substantially similar to those set forth [\*\*\*], such that such subcontractor or sublicensee, as applicable, shall only be authorized to [\*\*\*].

**2.6.6 Jurisdictional Compliance.** It is the desire and intent of the Parties that the restrictive covenants contained in this Section 2.6 be enforced to the fullest extent permissible under the Laws and public policies applied in each jurisdiction in which enforcement is sought. Brickell and Kaken believe that the restrictive covenants in this Section 2.6 are valid and enforceable, However, if any restrictive covenant should for any reason become or be declared by a competent court or competition authority to be invalid or unenforceable in any jurisdiction, such restrictive covenant shall be deemed to have been amended to the extent necessary in order that such provision be valid and enforceable, and such amendment shall apply only with respect to the operation of such provision of this Section 2.6 in the particular jurisdiction in which such declaration is made.

**2.7 [\*\*\*] License Agreement.** Brickell represents and warrants to Kaken that the license agreement attached to this Agreement [\*\*\*] is a true copy of the [\*\*\*] and is complete other than for material financial terms which have been redacted, the [\*\*\*] is in full force and effect and to Brickell's knowledge no facts exist that would entitle any party thereto to terminate the [\*\*\*] or take legal action material adverse to the interests of either party [\*\*\*] or to the Parties to this Agreement. Brickell shall not [\*\*\*] or agree or consent to any further amendments [\*\*\*] that would adversely affect Kaken's rights under this Agreement without the prior written consent of Kaken. Brickell shall comply with all material terms of [\*\*\*] and each Party shall take any action reasonably requested by the other Party to prevent [\*\*\*]. Promptly after the Effective Date, Brickell shall [\*\*\*] reasonably satisfactory to Kaken that provides [\*\*\*] on the same or substantially similar terms as set forth in [\*\*\*]. Additionally, Brickell shall promptly notify Kaken in writing in the event [\*\*\*] and, if Brickell fails [\*\*\*], and, in such case, without limiting any legal, equitable or other remedies that Kaken may have under applicable Law or this Agreement, Kaken shall have the right to [\*\*\*].

**2.8 Disclaimer of Patent Application from License.** If at any time Kaken no longer wishes to have a license to any patent applications included in the Brickell Patents other than any patent applications listed on Schedule 1.5 and any claims thereof including any substitutions, divisions, continuations or continuations-in-part, then Kaken [\*\*\*], and the claims in such patent application, whether or not such claims subsequently issue as a patent, shall [\*\*\*] for purposes of this Agreement.

### ARTICLE 3 GOVERNANCE

**3.1 Development and Regulatory Committee.** Within thirty (30) days after the Effective Date, the Parties shall establish a joint development and regulatory committee (the “**Joint Development and Regulatory Committee**” or “**JDRC**”), which shall consist of [\*\*\*]. Each of Kaken and Brickell may replace any or all of its representatives on the JDRC at any time upon written notice to the other Party. Such representatives shall [\*\*\*]. A Party may designate a substitute to temporarily attend and perform the functions of such Party’s designee at any meeting of the JDRC. Meetings of the JDRC shall commence at a time to be mutually agreed upon by the Parties and the JDRC shall meet [\*\*\*], and in any case more or less frequently as Kaken and Brickell deem appropriate or as reasonably requested by either such Party, on such dates and at such places and times as the Parties shall agree. Meetings of the JDRC shall be in the form determined by the JDRC, which shall be either in person or by telephone or videoconference. Any meetings of the JDRC that are held in person shall alternate between the offices of Kaken and Brickell, or such other place as the Parties may agree. The members of the JDRC also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate. Kaken and Brickell each may, on advance notice to the other Party, invite non-member employees of such Party to attend meetings of the JDRC. The JDRC shall perform the following functions:

**3.1.1** Review and discuss the Development Plan and any material amendments thereto;

**3.1.2** Review and discuss any matters related to Regulatory Approvals for the Product in the Field in the Territory;

**3.1.3** Review, coordinate and discuss the overall strategy for Developing the Product in the Field in the Territory, including the overall strategy for seeking Regulatory Approvals for the Product in the Field in the Territory;

**3.1.4** Coordinate the preparation and implementation of the Development Plan;

**3.1.5** Facilitate the exchange of information between the Parties regarding the strategy for implementing the Development Activities, including sharing Development Data created pursuant to this Agreement and establishing procedures for the efficient sharing of information and materials necessary or useful for the Development of the Product in the Field in the Territory and in the U.S.;

**3.1.6** Ensure guidance, consultancy and access by both Parties to CMC information and data in support of filings, facility inspections and Product launch in the Territory and in the U.S.;

**3.1.7** Review the design of the clinical trial protocols and endpoints the conduct of all Clinical Trials included in the Development Activities as set forth in the Development Plan;

**3.1.8** Facilitate the exchange of information between the Parties regarding the development and contents of all submissions to Regulatory Authorities in the Territory for Regulatory Approvals and all necessary filing and registration activities related thereto;

**3.1.9** Review and discuss any Manufacturing Development Activities being performed by the Parties under the Development Plan and coordinate on the requirements for formulation of the Product in the U.S. and the Territory;

**3.1.10** Review and discuss any proposal to change the formulation of the Product for use in any Development Activities set forth in the applicable Development Plan;

**3.1.11** Review issues regarding pharmacovigilance and safety regarding the Product in the Territory and outside the Territory;  
and

**3.1.12** Have such other responsibilities as may be mutually agreed by the Parties in writing from time to time.

**3.2 Limits on JDRC and Committee Authority.** The JDRC shall not [\*\*\*]. In furtherance thereof, each Party shall retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers or discretion shall be delegated or vested in the JDRC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. For clarity, the JDRC and any other Committee shall have [\*\*\*].

**3.3 Decision Making.** The Parties shall make decisions with respect to the matters set forth in Section 3.1 that are discussed by the JDRC. All decisions of the Parties with respect to the matter set forth in Section 3.1 shall be made by [\*\*\*], with Kaken and Brickell each having [\*\*\*]. If the Parties cannot reach consensus within twenty (20) days after discussing the matter and attempting to reach such consensus, the disputed matter may be referred to the Senior Officers for resolution pursuant to Section 4.10.

**3.4 Actions.** In developing strategies, making decisions and exercising its rights under this Agreement (including acting through its representatives on any of the JDRC), each Party shall act in good faith and use its commercially reasonable efforts to achieve the goals of the then-current Development Plan.

**3.5 Exchange of Information.** Each Party shall keep the other Party fully and promptly informed as to its progress and activities relating to the Development of the Product in the Territory and outside the Territory, including with respect to regulatory matters and meetings with Regulatory Authorities, primarily by way of updates to the JDRC at their meetings, or as reasonably requested from time to time by the other Party.

**3.6 Minutes of JDRC Meetings.** Any minutes of all JDRC meetings shall be finalized in English no later than thirty (30) days after the meeting to which the minutes pertain. Any minutes of JDRC meetings that may be prepared shall have no legal effect whatsoever nor

shall act in any way to amend this Agreement or otherwise alter any of the Parties rights and obligations set forth herein.

## **ARTICLE 4 DEVELOPMENT**

### **4.1 Overview.**

**4.1.1 Overview of Development.** Subject to the terms and conditions of this Agreement, the Parties shall collaborate with respect to the Development of the Product as set forth in the Development Plan. Each Party shall utilize adequately skilled personnel to perform or oversee, as applicable, the Development Activities assigned to it under the Development Plan. Kaken shall be assigned and perform the [\*\*\*], which shall consist of [\*\*\*]. Brickell shall perform, or have performed, [\*\*\*] to be performed by Kaken and referenced in the Initial Development Plan Overview and Manufacturing Development Activities assigned to Kaken in accordance with [\*\*\*] and [\*\*\*]. For clarity, [\*\*\*].

**4.1.2 Manufacturing Development Activities.** Subject to the terms and conditions of this Agreement, the Parties shall collaborate with respect to the Manufacturing Development Activities for the Product as set forth in the Development Plan. Each Party shall utilize adequately skilled personnel to perform or oversee, as applicable, the Manufacturing Development Activities assigned to it under the Development Plan. The Parties shall [\*\*\*]. Brickell shall perform all Manufacturing Development Activities in connection with its clinical supply obligations under Article 7. Kaken shall perform all Manufacturing Development Activities in connection with its clinical and commercial supply obligations under Article 7 (including supply to Brickell). Notwithstanding anything to the contrary contained in this Agreement, [\*\*\*].

**4.1.3 Certain Additional Restrictions.** Kaken agrees and acknowledges that it and its Affiliates and sublicensees [\*\*\*] except in accordance with a Development Plan established pursuant to this Agreement. Brickell agrees and acknowledges that it and its Affiliates and sublicensees [\*\*\*] except in accordance with a Development Plan established pursuant to this Agreement and as otherwise permitted by the terms of this Agreement. Kaken shall [\*\*\*] under the Development Plan, upon the occurrence of (a) any of the events set forth in [\*\*\*], (b) [\*\*\*] after Kaken provides written notice thereof to Brickell or (c) Brickell [\*\*\*]. For clarity, in no event [\*\*\*].

### **4.2 Development Activities, [\*\*\*] Clinical Trials, Missed Development Dates and Compliance.**

**4.2.1 Development Activities.** Each Party shall [\*\*\*] to carry out the Development Activities to be assigned to it under the Development Plan and in accordance with the time frames to be set forth in the Development Plan. Without limiting the generality of the foregoing:

(a) Kaken shall [\*\*\*] to conduct the [\*\*\*] set forth in the Development Plan in accordance within the timelines set forth in the Development Plan;

(b) Kaken shall [\*\*\*] to conduct the Phase I Clinical Trial set forth in the Development Plan for the Product [\*\*\*] within the timelines set forth in the Development Plan;

(c) Kaken shall [\*\*\*] to conduct the [\*\*\*] set forth in the Development Plan for the Product [\*\*\*] within the timelines set forth in the Development Plan; and

(d) Brickell shall [\*\*\*] to conduct the [\*\*\*] set forth in the Development Plan for the Product [\*\*\*] and provide Kaken with the clinical study report for such [\*\*\*].

**4.2.2 [\*\*\*] Clinical Trials.** Either Party [\*\*\*] and Kaken may thereafter have the rights to Develop, Commercialize and Manufacture the Product [\*\*\*] if: (i) [\*\*\*] within the time period established by the JDRC for initiating such [\*\*\*] as set forth in the Development Plan, (ii) the Regulatory Authorities in Japan request that Kaken [\*\*\*] proposed to be used for the Product in the [\*\*\*] or (iii) Regulatory Authorities in Japan or the United [\*\*\*] would need to be different in order to obtain Regulatory Approvals in [\*\*\*] and such differences relate to Manufacturing Development Activities, including, for example, requiring [\*\*\*].

**4.2.3 Missed Development Dates.** Each Party shall promptly inform the other Party upon determining that it is likely to miss a Development date set forth in the Development Plan. To the extent that a Party (or any of its Affiliates) misses such a date by four (4) weeks or more, such Party shall provide to the JDRC a full explanation for such event.

**4.2.4 Compliance.** Each Party shall conduct its Development Activities, and Manufacturing Development Activities set forth in the applicable Development Plan, consistent with sound and ethical business and scientific practices, and in compliance with all applicable Laws, GCPs, GLPs and to the extent applicable, GMPs.

### **4.3 Development Plan.**

**4.3.1 General.** In connection with the Development of the Product for use in the Field in the Territory, the Parties shall conduct the Development Activities pursuant to a comprehensive development plan (the “**Development Plan**”). The Development Plan shall set forth, among other things, the following with respect to the Product in the Field in the Territory:

(a) any preclinical studies, toxicology studies, pharmaco-economic studies, process development studies and other clinical studies, in each case, together with all protocols, endpoints and investigators conducting such studies, provided however, that the Development Plan shall provide that [\*\*\*] referenced in the Initial Development Plan Overview with the formulation of the Product being used by Brickell in the U.S. as of the Effective Date;

- (b) any post-Product Approval clinical trials and studies, including Phase IV Clinical Trials;
- (c) all regulatory plans and other elements of obtaining and maintaining Regulatory Approvals in the Field;
- (d) subject to the provisions of Section 4.1.1, the allocation of the Development Activities, and the Manufacturing Development Activities set forth in the applicable Development Plan, in each case to be conducted by each Party and the timeline for completing such Development Activities and Manufacturing Development Activities, provided however, that [\*\*\*];
- (e) the plans and timeline for preparing and obtaining Regulatory Approvals; and
- (f) the Manufacturing Development Activities, as well as the plans, amounts and timelines for the Manufacture and supply of Product, necessary for the Development Activities, including the [\*\*\*] set forth in the applicable Development Plan, taking into account [\*\*\*].

**4.3.2 Initial Development Plan.** An overview of the initial Development Plan for the Development of the Product is attached to this Agreement as Schedule 4.3.2 (the “**Initial Development Plan Overview**”). On or before the date that is sixty (60) days after the Effective Date, the JDRC shall meet to prepare the initial Development Plan which shall be based on the Initial Development Plan Overview. Upon completion, the initial Development Plan shall be provided to the Parties for their written approval. If both Parties provide their written approval then the initial Development Plan shall be the Development Plan for purposes of this Agreement. If the Parties do not provide their written approval of the initial Development Plan within ninety (90) days after receiving it representatives of the Parties including each Party’s JDRC members shall meet and attempt to reach agreement on the Development Plan. If after thirty (30) days the Parties cannot reach agreement on the Development Plan the dispute shall be resolved pursuant to Section 4.10.

**4.3.3 Updating and Amending Development Plan and Additional Development Activities.**

(a) On or before [\*\*\*] during the Term beginning in the year after the year in which the initial Development Plan was approved pursuant to Section 4.3.2, the JDRC shall review and prepare a draft updated Development Plan which shall cover the Development Activities to be conducted during the upcoming calendar year, and the JDRC shall, on at least a quarterly basis, review and make suggestions to the Parties for amending the then-current Development Plan to reflect any changes, reprioritizations of, or additions to the Development Plan.

(b) Any and all changes to the Development Plan shall only be effective when in writing and signed by an authorized representative of both Parties. Once

approved by the Parties, each amended Development Plan shall become effective and supersede the previous Development Plan as of the date of such approval. Any disputes with respect to the Development Plan shall be resolved pursuant to Section 4.10.

#### **4.4 Development Costs.**

**4.4.1 Territory Exclusive Development Activities.** [\*\*\*].

**4.4.2 Ex-Territory Exclusive Development Activities.** [\*\*\*].

**4.4.3 [\*\*\*] Development Activities.** Kaken shall bear all Development Costs for U.S.-Japan Phase III Development Activities [\*\*\*].

**4.4.4 Other [\*\*\*] Development Activities.**

#### **4.5 Records, Reports and Information.**

**4.5.1 General.** Each Party shall maintain current and accurate records of all work conducted by it under the Development Plan and all data and other information resulting from such work. Such records shall include, as applicable, books, records, reports, research notes, charts, graphs, comments, computations, analyses, recordings, photographs, computer programs and documentation thereof (e.g., samples of materials and other graphic or written data generated in connection with the Development Activities). Such records shall properly reflect all work done and results achieved in the performance of the Development Activities in sufficient detail and in good scientific manner appropriate for regulatory and patent purposes. Each Party shall document all preclinical studies and clinical trials to be conducted pursuant to the Development Plan in formal written study reports according to applicable national and international (e.g., ICH, GCP and GLP) guidelines.

**4.5.2 Status Updates in the Territory.** Each Party shall provide the JDRC with reports detailing its respective Development Activities under the Development Plan and the results thereof at least five (5) Business Days prior to any JDRC meeting and provide updates regarding communications with Regulatory Authorities during the JDRC meetings. Without limiting the foregoing, each Party shall promptly, but in any event within five (5) Business Days after receipt thereof, provide to the other Party copies of any material documents or correspondence received from any Regulatory Authority related to Development Activities in the U.S. and Japan.

#### **4.6 Development Data.**

**4.6.1 Existing Development Data.** Subject to the rights and licenses granted to Kaken herein, [\*\*\*]. Within thirty (30) days after execution of this Agreement, Brickell shall provide Kaken with copies of all material reports of [\*\*\*] as of the Effective Date in its (or any of its Affiliates') possession or control.

**4.6.2 New Development Data.** All data, know-how and other results generated by or resulting from or in connection with the conduct of Development Activities shall be owned

[\*\*\*]. Such data shall include [\*\*\*]. Such data (i) [\*\*\*], (ii) if generated by or resulting from or in connection with [\*\*\*], and (iii) shall be referred [\*\*\*] whether generated by one or both Parties (or their respective Affiliates or sublicensees). The Party generating [\*\*\*] shall as soon as reasonably practical provide the other Party with copies of reports and summaries in English of such [\*\*\*].

**4.6.3 Preservation of Development Data.** Each Party shall preserve and provide the other Party with a right to access or a right to reference all Existing Development Data and all New Development Data in order to allow each Party to comply with applicable Law.

**4.7 Right of Reference and Use.** Subject to the terms of Sections 2.3, 2.4, 2.5 and 2.6, [\*\*\*] for the purposes of performing Development Activities and Commercialization activities pursuant to this Agreement. Subject to the terms of Sections 2.3, 2.4, and 2.6, [\*\*\*]. Brickell may further [\*\*\*].

**4.8 Access to Records.** Brickell shall have the right, not more than one (1) time per calendar year, to review all records under the Development Plan maintained by Kaken at reasonable times, upon written request; provided, however, that Kaken shall have the right to redact any portions thereof not solely related to the Development of the Product for use in the Field in the Territory. Kaken shall have the right, not more than one (1) time per calendar year, to review all records under the Development Plan maintained by Brickell at reasonable times, upon written request; provided, however, that Brickell shall have the right to redact any portions thereof not solely related to the Development of the Product.

**4.9 Rights to Audit.**

**4.9.1** Kaken shall ensure that Brickell's authorized representatives and any Regulatory Authorities, to the extent permitted by applicable Law, may, during regular business hours and upon reasonable advance written notice, not more than once annually (except for cause), (i) examine and inspect its facilities or, subject to any Third Party confidentiality restrictions and other obligations, the facilities of any subcontractor or any investigator site used by it in the performance of Development of the Product in the Field in the Territory hereunder, and (ii) subject to applicable Law and any Third Party confidentiality restrictions and other obligations, inspect all data, documentation and work product relating to the activities performed by it, the subcontractor or investigator site, including the medical records of any patient participating in any clinical study, in each case generated pursuant to the said Development. This right to inspect all data, documentation, and work product relating to the Product in the Field in the Territory may be exercised at any time during the Term upon reasonable notice (subject to each Party's record retention policies then in effect), or such longer period as shall be required by applicable Law.

**4.9.2** Brickell shall ensure that Kaken's authorized representatives and any Regulatory Authorities, to the extent permitted by applicable Law, may, during regular business hours and upon reasonable advance written notice, not more than once annually (except for cause), (i) examine and inspect its facilities or, subject to any Third Party confidentiality restrictions and other obligations, the facilities of any subcontractor or any investigator site used

by it in the performance of Development of the Product in accordance with this Agreement, and (H) subject to applicable Law and any Third Party confidentiality restrictions and other obligations, inspect all data, documentation and work product relating to the activities performed by it, the subcontractor or investigator site, including the medical records of any patient participating in any clinical study, in each case generated pursuant to the said Development under the Development Plan. This right to inspect all data, documentation, and work product relating to the Product may be exercised at any time during the Term upon reasonable notice (subject to each Party's record retention policies then in effect), or such longer period as shall be required by applicable Law.

**4.10 Dispute Resolution Procedures.** With respect to all disputes arising between the Parties related to matters discussed by JDRC or otherwise related to Development of the Product, if the Parties are unable to resolve such dispute pursuant to Section 3.3 within the time period set forth therein then, either Party may refer such dispute in writing to the President of each of the Parties, or a designee from senior management with decision-making authority (the President or such designee, the "**Senior Officer**"), for attempted resolution by good-faith negotiations within fifteen (15) calendar days after such notice is received. If the Senior Officers are unable to resolve such dispute within ten (10) calendar days after such dispute is first referred to them pursuant to this Section 4.10, then:

**4.10.1** If the dispute relates to any U.S.-Japan Development Activities, then Brickell shall have the final decision making authority;

**4.10.2** If the dispute relates to any Territory Exclusive Development Activities, then Kaken shall have the final decision making authority;

**4.10.3** If the dispute relates to any Ex-Territory Exclusive Development Activities, then Brickell shall have the final decision making authority; and

**4.10.4** If the dispute relates to any Manufacturing Development Activities, then Brickell shall have the final decision making authority. Notwithstanding the foregoing, if Kaken is entitled to exercise its rights set forth in the penultimate sentence of Section 4.1.2, then Kaken shall have final decision making for Manufacturing Development Activities for the Product for use in the Field in the Territory and Brickell shall have final decision making for all other Manufacturing Development Activities for the Product.

In resolving a dispute hereunder, each Party shall act in good faith. Nothing in this Section 4.10 shall affect the right of a Party to exercise its rights or remedies for a breach of this Agreement by the other Party.

## **ARTICLE 5 REGULATORY**

### **5.1 Regulatory Filings and Regulatory Approvals**

**5.1.1 General Responsibilities; Ownership of Regulatory Approvals. [\*\*\*].**

**5.1.2 Reporting.** Kaken shall provide Brickell with summaries (in English) of the IND and NDA submitted to Governmental Authorities in the Territory prior to filing thereof to give Brickell a reasonable opportunity to review prior to filing thereof.

**5.1.3 Brickell Cooperation.** Brickell shall cooperate in good faith with and provide reasonable assistance to Kaken in connection with all activities undertaken by Kaken relating to the obtaining and maintaining of the Regulatory Approvals.

**5.1.4 Copies.** Kaken shall provide to Brickell: (A) copies in electronic form containing each Regulatory Filing described in Section 5.1.2 as submitted and all Regulatory Data relevant thereto (in the original language in which it was filed) promptly following such submission, (B) summaries (in English) of each Regulatory Filing as submitted, if any, as soon as reasonably practicable following submission thereof.

**5.1.5 Ownership.** [\*\*\*].

**5.1.6 Right of Reference.** Brickell, its Affiliates, and their sublicensees, shall [\*\*\*] (subject to the last two sentences of Section 2.5) in connection with the Development, Commercialization and Manufacture of the Product in a manner consistent and fully in accordance with the terms of this Agreement. [\*\*\*].

**5.1.7 Provision of Regulatory Information to Kaken.** Brickell shall provide Kaken with summaries of the IND and NDA submitted to Governmental Authorities [\*\*\*] that are required for any Regulatory Approval for the Product filed by or on behalf of, and Controlled by, Brickell and all Regulatory Data relevant thereto, and [\*\*\*] solely to support its Development Activities and Commercialization of the Product in the Field in the Territory and in accordance with the terms of this Agreement.

**5.1.8 Certain Regulatory Approvals.**

(a) **Pricing Approvals.** To the extent that [\*\*\*] requires Pricing Approval for sale of the Product in the Field in such country or regulatory jurisdiction, Kaken shall (to the extent permitted by applicable Laws) [\*\*\*] toward obtaining and maintaining Pricing Approvals [\*\*\*], in its own name or the name of its sublicensees.

(b) **Manufacturing Approvals and Manufacturing Related Sections.** [\*\*\*], including any DMFs and CMC (or equivalent) sections of any Regulatory Materials, and will provide such Regulatory Materials [\*\*\*].

**5.1.9 Cost of Regulatory Activities.** All Regulatory Costs incurred in connection with the preparation of Regulatory Materials and obtaining of Product Approvals in the Territory [\*\*\*].

**5.2 Communications.** Notwithstanding the foregoing, except as may be required by applicable Law, Kaken shall not, with respect to the Product, communicate with (i) any Regulatory Authority having jurisdiction outside the Territory regarding the Product or (ii) any

Regulatory Authority with respect to the Product for use outside the Field, in each case, unless explicitly provided for in the Development Plan or requested or permitted in writing to do so by Brickell, or unless requested or ordered to do so by such Regulatory Authority, in which case Kaken shall as soon as practicable notify Brickell of such request or order and shall, to the extent consistent with precedent and normal regulatory approval processes or as permitted by applicable Law, not take any further actions or communicate with such Regulatory Authority further until Brickell has provided instruction as to how to proceed.

### **5.3 Adverse Event Reporting; Safety Data Exchange and Medical Inquiries**

**5.3.1 Pharmacovigilance.** Kaken shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product in the Field in the Territory (whether or not Product Approval has been achieved), in each case in accordance with applicable Law and this Agreement (and Kaken shall ensure that, in the Development and Commercialization of the Product, it will record, investigate, summarize, notify, report and review all adverse events in accordance with applicable Law). Brickell (or its designee) shall be responsible for the collection, review, assessment, tracking and filing of information related to adverse events associated with the Product in the countries outside the Territory. The safety units from each of the Parties shall meet and agree upon a written pharmacovigilance agreement for exchanging adverse event and other safety information relating to the Product prior to Kaken's first clinical activity; provided that Brickell shall be responsible for maintaining the global safety database for the Product. Such written pharmacovigilance agreement shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party (and its sublicensees or designees) to comply with applicable Laws and regulatory requirements in their respective markets.

**5.3.2 Medical Inquiries for the Product.** For questions and complaints arising with respect to Development Activities or Commercialization undertaken by Kaken, Kaken shall be responsible for handling all medical questions or inquiries [\*\*\*], including all Product Complaints, with regard to any Product sold by or on behalf of Kaken (or any of its Affiliates or sublicensees) in each case in accordance with applicable Law and this Agreement. Kaken shall submit a copy of any standardized responses to medical inquiries prior to use thereof for Brickell's review and comment. Brickell shall immediately forward any and all medical questions or inquiries which it receives with respect to any Product sold by or on behalf of Kaken (or any of its Affiliates or sublicensees) in the Territory to Kaken in accordance with all applicable Laws and Kaken shall immediately forward to Brickell any and all medical questions or inquiries that it receives with respect to Product (i) not sold by or on behalf of Kaken (or any of its Affiliates or sublicensees) in the Territory or (ii) outside the Territory, in each case in accordance with all applicable Laws.

### **5.4 Regulatory Authority Communications Received by a Party.**

**5.4.1 General.** Each Party shall immediately inform the other Party of notification of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority whether inside the Territory or outside the Territory which (i) raises any material concerns regarding the safety or efficacy of the Product; (ii)

indicates or suggests a potential material liability of either Party to Third Parties in connection with the Product; (iii) is reasonably likely to lead to a recall, market withdrawal or market notification with respect to the Product whether inside the Territory or outside the Territory; or (iv) relates to expedited and periodic reports of adverse events with respect to the Product whether inside the Territory or outside the Territory, or Product Complaints, and which may have an adverse impact on Regulatory Approval or the continued Commercialization of the Product whether inside the Territory or outside the Territory. Kaken shall be solely responsible for responding to any such communications relating to the Product in the Field in the Territory and Brickell shall be solely responsible for responding to any such communications relating to the Product in the Field outside the Territory. Each Party shall reasonably cooperate with and assist the other Party by providing the other Party, as promptly as practicable after a written request, such information and documentation which is in such Party's possession as may be necessary or reasonably helpful for the other Party to prepare a response to an inquiry from a Regulatory Authority with respect to the Product in the Field. Each Party shall also promptly provide the other Party with a copy of all correspondence received from a Regulatory Authority whether inside the Territory or outside the Territory specifically regarding the matters referred to above.

**5.5 Recall, Withdrawal, or Market Notification of Product.** In the event that any Governmental Authority sends a written notice threatening or initiating any action to remove the Product from the market in the Field whether inside the Territory or outside the Territory (in whole or in part), the Party receiving notice thereof shall notify the other Party of such communication immediately, but in no event later than two (2) Business Days, after receipt thereof. Notwithstanding the foregoing, in all cases Kaken shall determine whether to initiate any recall, withdrawal or market notification of the Product in the Field in the Territory, and Brickell shall determine whether to initiate any such recall, withdrawal or market notification of the Product in all other cases, including the scope of such recall or withdrawal (e.g., a full or partial recall, or a temporary or permanent recall) or market notification; provided, however, that, before Kaken or Brickell (as the case may be) initiates a recall, withdrawal or market notification, the Parties shall promptly meet and discuss in good faith the reasons therefor, provided that such discussions shall not delay any action that Kaken or Brickell (as the case may be) reasonably believes has to be taken in relation to any recall, withdrawal or market notification. In the event of any such recall, withdrawal or market notification, Kaken or Brickell (as the case may be), as the distributor of the Product, shall determine the necessary actions to be taken, and, shall implement such actions, with the other Party providing reasonable input (which the first Party shall in good faith consider and incorporate into any recall, withdrawal or market notification strategy) and reasonable assistance to conduct such recall, withdrawal or market notification. Without limiting the foregoing, Brickell shall have the right to propose that a Product recall, withdrawal or market notification should be initiated by Kaken, but Kaken shall make the final decision as to whether or not the recall, withdrawal or market notification will be initiated. Kaken shall at all times utilize its existing tracing system which will enable the Parties to identify customers within the Territory who have been supplied with Product, and to recall such Product from such customers as set forth in this Section 5.5. Kaken shall bear the costs and expenses of any recall or withdrawal with respect to the Product in the Field in the Territory (including costs associated with return, recall or destruction of the Products) if the cause of the recall is solely attributable to Kaken and Brickell shall bear the costs and expenses of any recall or withdrawal

with respect to the Product in the Field in the Territory (including costs associated with return, recall or destruction of the Products) if the cause of the recall is solely attributable to Brickell. In all other cases, Kaken and Brickell shall share such cost and expense in accordance [\*\*\*]. For clarity, Brickell (or its designee), as holder of the Regulatory Approval for the Products outside the Field and outside the Territory shall have sole discretion in determining whether to initiate any recall, withdrawal or market notification of the Products outside the Territory (or in the Territory but outside the Field), including the scope of such recall or withdrawal (e.g., a full or partial recall, or a temporary or permanent recall) or market notification, and nothing contained herein shall limit or otherwise restrict Brickell's ability with respect to any such recall or withdrawal or market notification.

## **ARTICLE 6 COMMERCIALIZATION**

**6.1 Commercialization in the Field in the Territory.** During the Term, Kaken shall [\*\*\*] for Commercializing the Product in the Territory for use in the Field in accordance with the terms and conditions of this Agreement and shall be responsible [\*\*\*]. Without limiting the foregoing, Kaken shall [\*\*\*].

**6.2 Commercialization Reports.** No later than [\*\*\*] Kaken will provide Brickell with a written report in such form as is acceptable to both Parties which summarizes Kaken's planned Commercialization Activities. By no later than March 1<sup>st</sup> for each calendar year during the Term, summarizing all significant Commercialization activities with respect to the Product in the Field in the Territory performed by or on behalf of Kaken (including by any Affiliates of sublicensees) during the prior calendar year and planned Commercialization Activities during the next calendar year (including a comparison of Commercialization activities actually performed in the prior calendar year against Commercialization activities previously projected to be performed in such calendar year), and Kaken shall provide interim reports with respect to such Commercialization activities within fifteen (15) days after the end of each calendar quarter (or such other time periods as Brickell may reasonably request).

### **6.3 Promotional Materials.**

**6.3.1 Creation of Promotional Materials.** [\*\*\*].

**6.3.2 Kaken Ownership of Promotional Materials.** During the Term, Kaken shall own all right, title and interest in and to any Promotional Materials created by Kaken.

**6.3.3 Use of Promotional Materials Exclusively for the Product.** The Promotional Materials, and any aspects of those uniquely tied to the Product, shall be used by Kaken [\*\*\*] in accordance with the terms of this Agreement.

**6.4 Commercialization Data.** [\*\*\*].

**6.5 Global Branding Strategy.** To the extent Brickell determines to utilize [\*\*\*], Kaken [\*\*\*], including with respect to any Promotional Materials; provided, that, in the event

Kaken believes the application of the [\*\*\*], Kaken shall present such concern to Brickell, and the Parties shall discuss whether appropriate revisions to the [\*\*\*] may make it appropriate for use [\*\*\*]. However, if the Parties are unable to resolve their differences regarding Kaken's implementing all or any portion of [\*\*\*] after such discussions, Kaken shall [\*\*\*]. Nothing in this Section 6.5 shall be construed to derogate from Kaken's ultimate right and responsibility to [\*\*\*] to Commercialize the Product in the Territory in accordance with the terms and conditions of this Agreement.

## **ARTICLE 7 SUPPLY**

**7.1 Supply by [\*\*\*].** As soon as practicable, but, in any event, within sixty (60) days after the Effective Date, the Parties shall enter into good faith negotiations regarding the terms of [\*\*\*], pursuant to which [\*\*\*] as set forth in the Development Plan within the timelines set forth in the Development Plan. The [\*\*\*].

**7.2 Phase III Clinical Supply Agreement, Commercial Supply Agreement and Quality Agreements.** As soon as practicable, but, in any event, within one-hundred twenty (120) days after the Effective Date, the Parties shall enter into good faith negotiations regarding the [\*\*\*]. The [\*\*\*], all references to Kaken shall be to Brickell and all references to Brickell shall be to Kaken. As soon as practicable, but, in any event, promptly [\*\*\*]. If, despite [\*\*\*], the Parties are unable to execute [\*\*\*] within twenty-four (24) months of the Effective Date, then the Parties shall meet to establish and implement a [\*\*\*]. The Parties shall also [\*\*\*] prior to any supply thereunder, each of which shall set forth the Parties' quality and compliance obligations with respect to Manufacture of the Drug Substance and Product.

**7.3 Alternative Source of Phase III Clinical and Trial Commercial Supply.** [\*\*\*].

## **ARTICLE 8 PAYMENTS**

**8.1 Upfront Payment.** [\*\*\*]

**8.2 Milestone Payments.** Kaken shall pay to Brickell the [\*\*\*] described in this Section 8.2 upon [\*\*\*]. A Party shall notify the other Party in writing of, but in no event later than twenty (20) Business Days after, [\*\*\*]. Kaken shall pay the [\*\*\*] by wire transfer of immediately available funds into an account designated by Brickell within twenty (20) Business Days [\*\*\*], but in all cases no later than (i) the time that such [\*\*\*] notice is delivered by Kaken to Brickell in the event Kaken [\*\*\*] or (ii) within twenty (20) Business Days [\*\*\*] in the event Brickell is [\*\*\*]; provided, however, that, in no event shall [\*\*\*] in this Section 8.2. Each such payment is nonrefundable and noncreditable against any other payments due hereunder.

***	***
***	
***	Ten Million Dollars (\$10,000,000)
***	***
***	
***	***
***	***

For clarity, \*\*\* shall be due and payable \*\*\*.

**8.3 Royalties.**

**8.3.1 Royalty Rates.** As further consideration for the rights granted to Kaken hereunder, and except as set forth in Section 8.3.3 with respect to \*\*\*, Kaken shall pay to Brickell \*\*\*:

***	***
***	***
***	***
***	***

\*\*\*.

**8.3.2 \*\*\* Compensation \*\*\*, \*\*\***

**8.3.3 Payments for \*\*\*, \*\*\***

**8.3.4 General. \*\*\***

**8.4 Taxes and Withholding.**

(a) **VAT.** The amounts provided for in this Agreement are exclusive of any value added tax.

(b) **Withholding Tax Matters.** Any income or other taxes which Kaken is required by Law to pay or withhold on behalf of Brickell with respect to any payments payable to Brickell pursuant to Section 8.3.1 or Section 8.3.3 shall be deducted from the amount of such payments due, and paid or withheld, as appropriate, by Kaken on behalf of Brickell. Any such tax required by applicable Law to be paid or withheld shall be an expense of, and borne by, Brickell. Kaken shall furnish Brickell with reasonable evidence of such payment or amount withheld, in electronic or written form, as soon as practicable after such payment is made or such amount is withheld. The Parties will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax laws or under any other applicable Law in

connection with the making of any required tax payment or withholding payment, or in connection with any claim to a refund of or credit for any such payment. For clarity, amounts shall not be withheld on any other amounts payable by Kaken hereunder pursuant to Section 8.3.1 or Section 8.3.3.

**8.5 Currency Conversion.** All payments hereunder shall be made [\*\*\*]. For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement [\*\*\*], any amount [\*\*\*] in a manner consistent with such Party's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates, such as the foreign exchange rates [\*\*\*].

**8.6 Late Payments.** Any amount required to be paid by a Party hereunder which is not paid on or within thirty (30) days after the date due shall bear interest at a rate equal to one percent (1%) per month. Such interest shall be computed on the basis of a year of 360 days for the actual number of days payment is delinquent.

**8.7 Records; Audits.** Kaken and its Affiliates, sublicensees and subcontractors shall keep true and accurate records and books of account containing all particulars that may be necessary for the purpose of confirming the accuracy of, and calculating, as applicable, all amounts payable to Brickell hereunder (including records of Net Sales), and any other records reasonably required to be maintained with respect to Kaken's obligations under this Agreement, and each Party shall maintain complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of all amounts payable or otherwise reimbursable hereunder, in each case for a minimum period of five (5) years or such longer period as required by applicable Law. Each Party shall have a right to request an audit of the other Party in order to confirm the accuracy of any of the foregoing (an "**Audit**"); provided, however, that each Party shall only have the right to request such Audit of the other Party one time during any given calendar year. Upon the written request by a Party (the "**Auditing Party**") to Audit the other Party (the "**Audited Party**"), the Auditing Party shall have the right to engage an independent, internationally recognized accounting firm to perform a review as is reasonably necessary to enable such accounting firm to calculate or otherwise confirm the accuracy of any of the foregoing for the calendar year(s) requested by the Auditing Party; provided that (i) such accountants shall be given access to, and shall be permitted to examine and copy such books and records of the Audited Party upon five (5) days' prior written notice to the Audited Party, and at all reasonable times on such Business Days, (ii) prior to any such examination taking place, such accountants shall enter into a confidentiality agreement with the Audited Party reasonably acceptable to the Audited Party in order to keep all information and data contained in such books and records strictly confidential and shall not disclose such information or copies of such books and records to any third person including the Auditing Party, but shall only use the same for the purpose of the reviews and/or calculations which they need to perform in order to determine any amounts being reviewed, and (iii) such accountants shall use reasonable efforts to minimize any disruption to the Audited Party's business. The Audited Party shall make personnel reasonably available during regular business hours to answer queries on all such books and records required for the purpose of the Audit. The accountants shall deliver a copy of their findings to each of the

Parties within twenty (20) days of the completion of the review, and, in the absence of fraud or manifest error, the findings of such accountant shall be final and binding on each of the Parties. Any underpayments by a Party shall be paid to the other Party within twenty (20) days of notification of the results of such inspection. Any overpayments made by a Party shall be refunded by the other Party within twenty (20) days of notification of the results of such inspection. The cost of the accountants shall be the responsibility of the Auditing Party unless the accountants' calculation shows that the actual amount Audited hereunder is different, by more than five percent (5%), from the amounts as previously calculated by the Audited Party. [\*\*\*].

## ARTICLE 9 INTELLECTUAL PROPERTY MATTERS

### 9.1 Ownership of Intellectual Property.

**9.1.1 General.** Subject to the provisions of this Section 9.1.1 and except as expressly set forth otherwise in this Agreement, (i) [\*\*\*]. The Parties hereby agree that (a) [\*\*\*] and (b) [\*\*\*]. Each Party shall promptly disclose to the other Party all Inventions made by it during the Term. The determination of inventorship for Inventions shall be made in accordance with the applicable Laws relating to inventorship in the country in which such Invention is made.

**9.1.2 Employees.** Each Party will require all of its and its Affiliates' employees to assign all Inventions that are developed, made or conceived by such employees according to the ownership principles described in Section 9.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions. Each Party will also use its commercially reasonable efforts to require any agents, independent contractors or sublicensees performing an activity pursuant to this Agreement to assign all Inventions that are developed, made or conceived by such agents, independent contractors or sublicensees to Brickell and/or Kaken according to the ownership principles described in Section 9.1.1 free and clear of all liens, encumbrances, charges, security interests, mortgages or other similar restrictions.

**9.2 Disclosures; Disputes Regarding Inventions.** Each Party shall; before filing a new Patent application (including provisionals and continuations-in-part) claiming an Invention, promptly disclose such Invention to the other Party and provide the other Party with a copy of the proposed patent application at least fifteen (15) days before filing such application or such shorter time as may be required to preserve Patent rights, including the avoidance of a statutory bar or prior publication. If the non-filing Party believes that the filing Party's proposed Patent application discloses Confidential Information of the non-filing Party, the non-filing Party shall so notify the filing Party within such fifteen (15) days after receipt thereof, and the filing Party shall amend its proposed application to comply with the confidentiality provisions of this Agreement. If the Parties are in agreement as to the designation of the Invention as a Brickell Invention, Joint Invention or Kaken Invention, as applicable, the Parties shall take such actions as are set forth in Section 9.3. If the Parties disagree as to whether an Invention is a Brickell Invention, Joint Invention or Kaken Invention, and are unable to reach agreement within thirty (30) days after commencing discussions, then the provisions of Article 15 shall apply to such dispute.

### **9.3 Patent Filings, Prosecution and Maintenance.**

#### **9.3.1 Brickell Patents.**

(a) Notwithstanding any other provision of this Agreement, promptly after the Effective Date, Brickell shall, at its own cost and expense, [\*\*\*].

(b) Subject to, and without limiting Kaken's rights under, Section 9.4 of this Agreement, Brickell shall [\*\*\*], at its cost and expense. If, during the Term, Brickell [\*\*\*], Brickell shall notify Kaken of such intention or decision at least sixty (60) days (or as soon as possible if less than sixty (60) days) prior to any filing or payment due date, or any other date that requires action, in connection with [\*\*\*].

**9.3.2 [\*\*\*] Patents.** Subject to, and without limiting Kaken's rights under, Section 9.4 of this Agreement, [\*\*\*]. Subject to, and without limiting Brickell's rights under, Section 9.4 of this Agreement, [\*\*\*]. The Parties shall discuss whether to file a Patent claiming [\*\*\*]. The Parties shall cooperate reasonably in the prosecution of all [\*\*\*] and shall share all material information relating thereto promptly after receipt of such information. If, during the Term, the prosecuting Party (1) intends to allow [\*\*\*] or decision at least thirty (30) days (or as soon as possible if less than thirty (30) days) prior to any filing or payment due date, or any other date that requires action, in connection with [\*\*\*], and the other Party shall thereupon have the right, but not the obligation, to [\*\*\*].

**9.3.3 Kaken [\*\*\*] Patents.** Kaken shall have the [\*\*\*]. If, during the Term, Kaken (i) intends to [\*\*\*] of such intention or decision at least thirty (30) days (or as soon as possible if less than thirty (30) days) prior to [\*\*\*], and Brickell shall thereupon [\*\*\*]. Kaken agrees to [\*\*\*] with respect to any decision to [\*\*\*], or with respect to [\*\*\*].

**9.3.4 Cooperation.** The Parties agree to cooperate in exercising their rights or obligations set forth in this Section 9.3, including obtaining and executing necessary powers of attorney and assignments by the named inventors, providing relevant technical reports to the filing Party concerning the Invention disclosed in any Patent that is the subject of this Section 9.3, obtaining execution of such other documents which are needed in the filing and prosecution of such Patents, and, as requested by a Party, updating each other regarding the status of such Patents, and otherwise cooperate with the other Party so far as reasonably necessary with respect to furnishing all information and data in its possession reasonably necessary to obtain or maintain such Patents.

**9.3.5 Patent Expenses.** Any expenses incurred by a Party in connection with the preparation, filing, prosecution and maintenance of any [\*\*\*], as applicable, shall be borne by the Party incurring such expenses.

#### **9.4 Defense and Enforcement of Patents.**

**9.4.1 Infringement of Third Party Patents.** Each of the Parties shall promptly, but in any event no later than thirty (30) days after receipt of notice thereof, notify the other

Party in writing in the event of any claims by a Third Party of alleged patent infringement by Kaken or Brickell or any of their respective Affiliates or sublicensees with respect to the , research, development, manufacture, use, sale, offer for sale or importation of a Product (each, an “**Infringement Claim**”). [\*\*\*]. With respect to any Infringement Claim in the Field in the Territory, the Parties shall attempt to negotiate in good faith a resolution with respect thereto. If the Parties cannot settle such Infringement Claim with the appropriate Third Parties within thirty (30) days after the receipt of the notice pursuant to this Section 9.4.1, then the following shall apply:

(a) In the case of any such claim against Kaken alone or against both Kaken and Brickell, in each case, with respect to the Product in the Field in the Territory, then Kaken shall be deemed to be the “**Controlling Party**” for purposes of such Infringement Claim. In the case of any claim against (i) Brickell alone, or (ii) with respect to the Product outside the Territory or outside the Field, then Brickell shall be deemed to be the “**Controlling Party**” for purposes of such Infringement Claim. In the event of worldwide litigation (such that related cases and/or claims are being pursued both inside and outside the Territory), each Party shall reasonably assist the other in its role as the Controlling Party in its respective territory.

(b) The Controlling Party shall assume control of the defense of such Infringement Claim. The non-Controlling Party, upon request of the Controlling Party, agrees to join in any such litigation, and in any event to reasonably cooperate with the Controlling Party, in each case, at the Controlling Party’s expense. The non-Controlling Party will have the right to consult with the Controlling Party concerning such Infringement Claim and to participate in and be represented by independent counsel in any litigation in which such non-Controlling Party is a party at its own expense. The Controlling Party shall have the exclusive right to settle any Infringement Claim without the consent of the other Party, unless such settlement shall have a material adverse impact on the other Party (in which case the consent of such other Party shall be required). For purposes of this Section 9.4.1(b), any settlement that would involve the waiver of rights (including the rights to receive payments) of such other Party shall be deemed a material adverse impact and shall require the consent of such other Party, such consent not to be unreasonably withheld.

(c) If a Party shall become engaged in or participate in any suit described in this Section 9.4.1, the other Party shall cooperate, and shall cause its and its Affiliates’ employees to cooperate, with such Party in all reasonable respects in connection therewith, including giving testimony and producing documents lawfully requested, and using its reasonable efforts to make available to the other, at no cost to the other (other than reimbursement of actually incurred, reasonable out-of-pocket travel and lodging expenses), such employees who may be helpful with respect to such suit, investigation, claim or other proceeding.

#### **9.4.2 Prosecution of Infringers.**

(a) **Notice.** If either Party (i) receives notice of any patent invalidity actions, any declaratory judgment actions or any alleged or threatened infringement of patents or patent applications or misappropriation of intellectual property [\*\*\*] comprising the (w) [\*\*\*],

or (ii) learns that a Third Party is infringing or allegedly infringing any Patent within the [\*\*\*] in each case, in the Territory, or if any Third Party claims that any such Patent is invalid or unenforceable it will promptly notify the other Party thereof, including providing evidence of infringement or the claim of invalidity or unenforceability reasonably available to such Party.

**(b) Enforcement of Patents.**

(i) (A) As between Brickell and Kaken, Kaken will have the first right (but not the obligation) to take the appropriate steps to enforce or defend any Patent within [\*\*\*] against infringement by a Third Party that is conducting the manufacture, sale, use, offer for sale or import of any pharmaceutical product in the Field in the Territory. Kaken may take steps including the initiation, prosecution and control of any suit, proceeding or other legal action by counsel of its own choice. Kaken shall bear the costs of such enforcement or defense, as applicable. Notwithstanding the foregoing, Brickell will have the right, at its own expense, to be represented in any such action by counsel of its own choice. (13) As between Brickell and Kaken, Kaken will have the first right (but not the obligation) to take the appropriate steps to enforce or defend [\*\*\*] against infringement by a Third Party that is conducting the manufacture, sale, use, offer for sale or import of any pharmaceutical product in the Field in the Territory. Kaken may take steps including the initiation, prosecution and control of any suit, proceeding or other legal action by counsel of its own choice. Kaken shall bear the costs of such enforcement or defense, as applicable. Notwithstanding the foregoing, Brickell will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(ii) If, pursuant to Section 9.4.2(b)(i), Kaken fails to institute such litigation or otherwise take steps to remedy the infringement of a [\*\*\*] within one hundred eighty (180) days of the date one Party has provided notice to the other Party pursuant to Section 9.4.2(a) of such infringement or claim, then Brickell will have the right (but not the obligation), at its own expense, to bring any such suit, action or proceeding by counsel of its own choice and Kaken will have the right, at its own expense, to be represented in any such action by counsel of its own choice. [\*\*\*].

(iii) As between Brickell and Kaken, Brickell will have the first right (but not the obligation) to take the appropriate steps to enforce or defend any Patent within [\*\*\*] against infringement by a Third Party that is conducting the manufacture, sale, use, offer for sale or import of any pharmaceutical product in the Field [\*\*\*]. Brickell may take steps including the initiation, prosecution and control of any suit, proceeding or other legal action by counsel of its own choice. Brickell shall bear the costs of such enforcement or defense, as applicable. Notwithstanding the foregoing, Kaken will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

(iv) If, pursuant to Section 9.4.2(b)(iii), Brickell fails to institute such litigation or otherwise take steps to remedy the infringement of [\*\*\*] within one hundred eighty (180) days of the date one Party has provided notice to the other Party pursuant to Section 9.4.2(a) of such infringement or claim, then Kaken will have the right (but not the obligation), at its own expense, to bring any such suit, action or proceeding by counsel of its own choice and

Brickell will have the right, at its own expense, to be represented in any such action by counsel of its own choice.

**(c) Cooperation; Damages.**

(i) If one Party brings any suit, action or proceeding under Section 9.4.2(b)(i) or (ii), the other Party agrees to be joined as party plaintiff if necessary to prosecute the suit, action or proceeding and to give the first Party reasonable authority to file and prosecute the suit, action or proceeding; provided, however, that neither Party will be required to transfer any right, title or interest in or to any property to the other Party or any other party to confer standing on a Party hereunder.

(ii) The Party not pursuing the suit, action or proceeding hereunder will provide reasonable assistance to the other Party, including by providing access to relevant documents and other evidence and making its employees available, subject to the other Party's reimbursement of any out-of-pocket costs incurred by the non-enforcing or defending Party in providing such assistance.

(iii) Kaken shall not, without the prior written consent of Brickell (in its sole discretion), enter into any compromise or settlement relating to any claim, suit or action that it brought under Section 9.4.2 involving [\*\*\*], that admits the invalidity or unenforceability of [\*\*\*], or requires Brickell to pay any sum of money, or otherwise adversely affects the rights of Brickell with respect to such Patents, the Product or Brickell's rights hereunder (including the rights to receive payments).

(iv) Any settlements, damages or other monetary awards (a "**Recovery**") recovered pursuant to a suit, action or proceeding brought pursuant to Section 9.4.2(b)(i)(A) will be allocated first to the costs and expenses of the Party taking such action, and second, to the costs and expenses (if any) of the other Party, with any remaining amounts (if any) to be allocated as follows: (i) to the extent that such Recovery is a payment for lost sales of the Product in the Field in the Territory, any such Recovery shall be retained by Kaken [\*\*\*] for purpose of this Agreement and subject to [\*\*\*] (ii) all remaining Recoveries shall be payable to Party taking such action to the extent such remaining Recoveries relate solely to the Product in the Field in the Territory (and, for purposes of clarity, all remaining Recoveries related to the Product [\*\*\*] or [\*\*\*] shall be payable to Brickell).

(v) **Infringement and Defense of Brickell Patents** [\*\*\*]. For clarity, with respect to any and all infringement or defense of any [\*\*\*], Brickell (or its designee) shall have [\*\*\*] to bring an appropriate suit or other action against any Person engaged in such infringement or defense of any such [\*\*\*], in its sole discretion and [\*\*\*].

**9.5 Patent Marking.** Kaken shall mark the Product marketed and sold by Kaken (or its Affiliate or distributor) hereunder with appropriate patent numbers or indicia at Brickell's reasonable request.

**9.6 Patent Challenge.**

**9.6.1** Kaken covenants that shall not and shall cause its Affiliates and sublicensees not to directly or indirectly (through assistance granted to a Third Party or otherwise), make any Patent Challenge to any Brickell Patent or Brickell Collaboration Patent. Kaken will include provisions in all agreements granting sublicensees of Kaken's rights hereunder providing that if the Affiliate or sublicensee of Kaken undertakes a Patent Challenge, then Kaken upon receipt of written notice from Brickell of such Patent Challenge will terminate the applicable sublicense agreement. If Kaken fails to so terminate such sublicense agreement, Brickell may terminate Kaken's right to sublicense and any sublicensees previously granted shall automatically terminate. In connection with such sublicense termination, Kaken shall cooperate with Brickell's reasonable requests to cause such a terminated sublicensee to discontinue activities with respect to the Development, Commercialization and Manufacture of the Drug Substances and Products.

**9.6.2** Brickell covenants that shall not and shall cause its Affiliates and sublicensees not to, directly or indirectly (through assistance granted to a Third Party or otherwise), make any Patent Challenge to any Kaken Applied Patents. Brickell will include provisions in all agreements granting sublicensees of Brickell's rights hereunder providing that if the Affiliate or sublicensee of Brickell undertakes a Patent Challenge, then Brickell upon receipt of written notice from Kaken of such Patent Challenge will terminate the applicable sublicense agreement. If Brickell fails to so terminate such sublicense agreement, Kaken may terminate Brickell's right to sublicense and any sublicensees previously granted shall automatically terminate. In connection with such sublicense termination, Brickell shall cooperate with Kaken's reasonable requests to cause such a terminated sublicensee to discontinue activities with respect to the Development, Commercialization and Manufacture of the Drug Substances and Products.

## **ARTICLE 10 REPRESENTATIONS, WARRANTIES AND COVENANTS**

**10.1 Mutual Representations and Warranties.** Each Party hereby represents and warrants (as applicable) to the other Party as follows, as of the Effective Date:

**10.1.1 Corporate Existence and Power.** It is a company or corporation duly organized, validly existing, and (but only as to Brickell) in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

**10.1.2 Authority and Binding Agreement.** (i) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and (iii) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, except as enforcement may be affected by bankruptcy, insolvency or other similar laws and by general principles of equity.

**10.1.3 No Conflicts.** The execution, delivery and performance of this Agreement in accordance with its terms by it does not (i) conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound or (ii) violate any Laws of any Governmental Authority having jurisdiction over it.

**10.1.4 All Consents and Approvals Obtained.** Except with respect to Regulatory Approvals for the Development, Manufacturing or Commercialization of the Product, (i) all necessary consents, approvals and authorizations of, and (ii) all notices to, and filings by such Party with, all Governmental Authorities and other Persons required to be obtained or provided by such Party as of the Effective Date in connection with the execution, delivery and performance of this Agreement have been obtained and provided, except for those approvals, if any, not required at the time of execution of this Agreement.

**10.2 Additional Representations, Warranties and Covenants of Brickell.** Brickell hereby represents, warrants and covenants to Kaken that, as of the Effective Date:

**10.2.1** To the knowledge of Brickell, the patent applications encompassed within the [\*\*\*] if such patent applications were issued as patents would be valid and enforceable patents and to Brickell's knowledge nothing has been done or omitted to be done by which they may cease to be valid and enforceable.

**10.2.2** To the knowledge of Brickell, which includes internal searches of relevant public records, there are no facts which would render the patent applications encompassed within the [\*\*\*], if and when issued, invalid or unenforceable.

**10.2.3** There are no claims, judgments or settlements against or owed by Brickell, nor any pending reissue, reexamination, interference, opposition or similar proceedings with respect to [\*\*\*], and Brickell has not received notice, and is not otherwise aware after conducting internal searches of relevant public records, in each case as of the Effective Date of any threatened claims or litigation or any reissue, reexamination, interference, opposition or similar proceedings seeking to invalidate or otherwise challenge the [\*\*\*].

**10.2.4** [\*\*\*], Brickell is the sole legal and beneficial owner of all the [\*\*\*], free and clear of any Liens, and no Person (including any Affiliate of Brickell) has any right, interest or claim in or to, and neither Brickell nor any of its Affiliates has entered into any agreement granting any right, interest or claim in or to, any [\*\*\*] to any Third Party (including any academic organization or agency).

**10.2.5** Schedule 1.5 is a complete and accurate list [\*\*\*].

**10.2.6** All application fees in connection with the [\*\*\*] have been paid and all material documents and certificates in connection therewith have been filed with the relevant patent, or other competent Governmental Authority, as the case may be, for the purposes of obtaining the patent issuance of the [\*\*\*].

**10.2.7** Brickell has taken all reasonable steps to maintain the confidentiality of and otherwise protect and enforce its rights in all Confidential Information of Brickell that is Brickell Know-How that it holds, or purports to hold, as a trade secret.

**10.2.8** No claim has been made to Brickell by a Third Party which alleges that Development, Commercialization or Manufacture of the Product infringes the intellectual property rights of a Third Party.

**10.2.9** As of the Effective Date, [\*\*\*], there have been no public uses or public disclosures of the inventions claimed in [\*\*\*] prior to the earliest filing date of each such respective patent or patent application.

**10.2.10** [\*\*\*] no written claim has been made by Brickell which (i) alleges that a Third Party is infringing [\*\*\*], or which otherwise disputes the right of a Third Party to use the intellectual property rights owned or used by the Third Party or (ii) alleges any unauthorized disclosure or misappropriation of [\*\*\*].

**10.2.11** Each director, consultant, contractor and employee of Brickell has irrevocably assigned in full to Brickell all of such individual's right, title and interest in and to [\*\*\*], where such rights do not vest in Brickell by operation of law. No current or former employee, director, consultant or independent contractor of Brickell owns (or, if applicable, will direct against Brickell) any right, license, claim or interest whatsoever in or with respect to [\*\*\*].

**10.2.12** [\*\*\*], no funding, facilities, or personnel of any Governmental Authority or any college, university, or other educational institution were used, directly or indirectly, to develop or create, in whole or in part, [\*\*\*].

**10.2.13** [\*\*\*] neither the execution, delivery, or performance of this Agreement nor the consummation of any of the transactions contemplated by this Agreement will, with or without notice or lapse of time, result in, or give any other Person the right or option to cause or declare: (a) a loss of, or Lien on, [\*\*\*], (b) a breach of or default under any contract relating to [\*\*\*], (c) the release, disclosure, or delivery of any [\*\*\*] by or to any escrow agent or other Person; or (d) the grant, assignment, or transfer to any other Person of any license or other right to interest under, to, or in any of [\*\*\*].

**10.2.14** Neither Brickell, its shareholders nor its Affiliates have entered into any agreement for, or are currently in any negotiations for, a Change of Control of Brickell.

### **10.3 Brickell Product Development.**

**10.3.1** All Confidential Information that Brickell has provided to Kaken related to the Product prior to the Effective Date, is [\*\*\*], true and complete in all materials respects.

**10.3.2** [\*\*\*], all work related to the Development, Regulatory Approvals, Manufacture and Commercialization of the Product [\*\*\*] heretofore has been and is being managed by Brickell in accordance with all applicable Laws. Brickell is [\*\*\*].

**10.4 Disclaimer.** Kaken understands that the Product is the subject of ongoing clinical research and development and that Brickell cannot ensure the safety or usefulness of the Product or that the Product will receive Regulatory Approvals. In addition, Brickell makes no warranties except as set forth in this Article 10 [\*\*\*].

**10.5 No Other Representations or Warranties.** EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NO REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, ARE MADE OR GIVEN BY OR ON BEHALF OF A PARTY. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, ALL REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE HEREBY EXPRESSLY EXCLUDED.

## **ARTICLE 11 INDEMNIFICATION**

**11.1 Indemnification by Brickell.** Brickell hereby agrees to save, indemnify, defend and hold Kaken, its Affiliates, and their respective directors, officers, agents and employees harmless from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") arising in connection with any and all charges, complaints, actions, suits, proceedings, hearings, investigations, claims, demands, judgments, orders, decrees, stipulations or injunctions by a Third Party (each a "Third Party Claim") resulting or otherwise arising from (i) any breach by Brickell of any of its representations, warranties, covenants or obligations pursuant to this Agreement or (ii) the negligence or willful misconduct by Brickell or its Affiliates or their respective officers, directors, employees, agents, consultants or sublicensee in performing any obligations under this Agreement; in each case except to the extent that such Losses are subject to indemnification by Kaken pursuant to Section 11.2.

**11.2 Indemnification by Kaken.** Kaken hereby agrees to save, indemnify, defend and hold Brickell, its Affiliates, and their respective directors, agents and employees harmless from and against any and all Losses arising in connection with any and all Third Party Claims resulting or otherwise arising from (i) any breach by Kaken of any of its representations, warranties, covenants or obligations pursuant to this Agreement or (ii) the negligence or willful misconduct by Kaken or its Affiliates or their respective officers, directors, employees, agents, consultants or sublicensees in performing any obligations under this Agreement.; in each case except to the extent that such Losses are subject to indemnification by Brickell pursuant to Section 11.1.

**11.3 Indemnification Procedures.**

**11.3.1 Notice of Claim.** All indemnification claims in respect of any indemnitee seeking indemnity under Section 11.1 or 11.2, as applicable (collectively, the “**Indemnitees**” and each an “**Indemnitee**”) will be made solely by the corresponding Party (the “**Indemnified Party**”). The Indemnified Party will give the indemnifying Party (the “**Indemnifying Party**”) prompt written notice (an “**Indemnification Claim Notice**”) of any Losses and any legal proceeding initiated by a Third Party against the Indemnified Party as to which the Indemnified Party intends to make a request for indemnification under Section 11.1 or 11.2, as applicable, but in no event will the Indemnifying Party be liable for any Losses that result from any delay in providing such notice which materially prejudices the defense of such proceeding. Each Indemnification Claim Notice shall contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss are known at such time). Together with the Indemnification Claim Notice, the Indemnified Party will furnish promptly to the Indemnifying Party copies of all notices and documents (including court papers) received by any Indemnitee in connection with the Third Party Claim.

**11.3.2 Control of Defense.** At its option, the Indemnifying Party may assume the defense of any Third Party Claim subject to indemnification as provided for in Section 11.1 or 11.2, as applicable, by giving written notice to the Indemnified Party within thirty (30) days after the Indemnifying Party’s receipt of an Indemnification Claim Notice. Upon assuming the defense of a Third Party Claim, the Indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel it selects, and such Indemnifying Party shall thereafter continue to defend such Third Party Claim in good faith. Should the Indemnifying Party assume the defense of a Third Party Claim (and continue to defend such Third Party Claim in good faith), the Indemnifying Party will not be liable to the Indemnified Party or any other Indemnitee for any legal expenses subsequently incurred by such Indemnified Party or other Indemnitee in connection with the analysis, defense or settlement of the Third Party Claim, unless the Indemnifying Party has failed to assume the defense and employ counsel in accordance with this Section 11.3.

**11.3.3 Right to Participate in Defense.** Without limiting Section 11.3.2, any Indemnitee will be entitled to participate in the defense of a Third Party Claim for which it has sought indemnification hereunder and to employ counsel of its choice for such purpose; provided, however, that such employment will be at the Indemnitee’s own expense unless (i) the employment thereof has been specifically authorized by the Indemnifying Party in writing, or (ii) the Indemnifying Party has failed to assume the defense (or continue to defend such Third Party Claim in good faith) and employ counsel in accordance with this Section 11.3, in which case the Indemnified Party will be allowed to control the defense.

**11.3.4 Settlement.** With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that will not result in the Indemnitee becoming subject to injunctive relief and as to which the Indemnifying Party will have acknowledged in writing the obligation to indemnify the Indemnitee hereunder, the Indemnifying Party will have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the Indemnifying Party, in its reasonable discretion, will deem appropriate (provided, however, that such terms shall include a complete

and unconditional release of the Indemnified Party from all liability with respect thereto), and will transfer to the Indemnified Party all amounts which said Indemnified Party will be liable to pay prior to the time of the entry of judgment. With respect to all other Losses in connection with Third Party Claims, where the Indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 11.3.2, the Indemnifying Party will have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, provided it obtains the prior written consent of the Indemnified Party (which consent will be at the Indemnified Party's reasonable discretion). The Indemnifying Party that has assumed the defense of (and continues to defend) the Third Party Claim in accordance with Section 11.3.2 will not be liable for any settlement or other disposition of a Loss by an Indemnitee that is reached without the written consent of such Indemnifying Party. Regardless of whether the Indemnifying Party chooses to defend or prosecute any Third Party Claim, no Indemnitee will admit any liability with respect to, or settle, compromise or discharge, any Third Party Claim without first offering to the Indemnifying Party the opportunity to assume the defense of the Third Party Claim in accordance with Section 11.3.2.

**11.3.5 Cooperation.** If the Indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party will, and will cause each other Indemnitee to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection with such Third Party Claim. Such cooperation will include access during normal business hours afforded to the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim, and making Indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder, and the Indemnifying Party will reimburse the Indemnified Party for all its reasonable out-of-pocket expenses incurred in connection with such cooperation.

**11.3.6 Expenses of the Indemnified Party.** Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim will be reimbursed on a calendar quarter basis by the Indemnifying Party, without prejudice to the Indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the Indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

**11.4 Limitation of Liability.** NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.4 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 11.1 or 11.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER

ARTICLE 12. EXCEPT AS EXPRESSLY SET FORTH IN ANY REPRESENTATION OR WARRANTY IN ARTICLE 10, KAKEN ACKNOWLEDGES AND AGREES THAT BRICKELL HAS MADE NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO, AND KAKEN SHALL HAVE NO CLAIM OR RIGHT (INCLUDING WITH RESPECT TO INDEMNIFICATION PURSUANT TO THIS ARTICLE 11 (OR OTHERWISE)) WITH RESPECT TO, ANY INFORMATION, DOCUMENTS OR MATERIALS FURNISHED TO OR FOR KAKEN BY BRICKELL, ANY OF ITS AFFILIATES, OR ANY OF ITS OR THEIR OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR ADVISORS, INCLUDING THE CONFIDENTIAL INFORMATION PACKAGE REGARDING THE PRODUCT PROVIDED TO KAKEN AND ANY INFORMATION, DOCUMENTS OR MATERIAL MADE AVAILABLE TO KAKEN IN ANY "DATA ROOM", MANAGEMENT PRESENTATION OR ANY OTHER FORM IN EXPECTATION OF THE TRANSACTION AND COLLABORATION CONTEMPLATED HEREBY.

**11.5 Insurance.** Each Party shall procure and maintain insurance, including clinical trials insurance and product liability insurance, adequate to cover its obligations hereunder. Certificates of insurance (in English) evidencing such coverage will be made available to the other Party upon written request.

## **ARTICLE 12 CONFIDENTIALITY**

**12.1 Confidential Information.** As used in this Agreement, the term "**Confidential Information**" means all information, whether it be written or oral, including all production schedules, lines of products, volumes of business, processes, new product developments, product designs, formulae, technical information, laboratory data, clinical data, patent information, know-how, trade secrets, financial and strategic information, marketing and promotional information and data, and other material relating to any products, projects or processes of one Party (the "**Disclosing Party**") that is provided to, or otherwise obtained by, the other Party (the "**Receiving Party**") in connection with this Agreement (including information exchanged prior to the date hereof in connection with the transactions set forth in this Agreement, including any information disclosed by either Party pursuant to the Confidential Disclosure Agreement between the Parties dated September 9, 2013. Notwithstanding the foregoing sentence, Confidential Information shall not include any information or materials that:

- (a) were already known to the Receiving Party (other than under an obligation of confidentiality), at the time of disclosure by the Disclosing Party, to the extent such Receiving Party has documentary evidence to that effect;
- (b) were generally available to the public or otherwise part of the public domain at the time of disclosure thereof to the Receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after disclosure or development thereof, as the case may be, and other than through any act or omission of a Party in breach of such Party's confidentiality obligations under this Agreement;

(d) were disclosed to a Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or

(e) were independently discovered or developed by or on behalf of the Receiving Party without the use of the Confidential Information belonging to the other Party, to the extent such Receiving Party has documentary evidence to that effect.

**12.2 Confidentiality Obligations.** Each of Kaken and Brickell shall keep all Confidential Information received from or on behalf of the other Party with the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of its obligations or the exercise of its rights pursuant to this Agreement or disclose the same to any other Person other than to such of its and its Affiliates' directors, managers, employees; independent contractors, agents, consultants or sublicensees who have a need to know such Confidential Information to implement the terms of this Agreement or enforce its rights under this Agreement; provided, however, that a Receiving Party shall advise any of its and its Affiliates' directors, managers, employees, independent contractors, agents, consultants or sublicensees who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure (including, in the case of a Third Party, by means of a written agreement with such Third Party having terms at least as protective as those contained in this Article 12) that all such directors, managers, employees, independent contractors, agents, consultants or sublicensees comply with such obligations. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents, tapes or other media containing Confidential Information of the Disclosing Party that remain in the possession of the Receiving Party or its directors, managers, employees, independent contractors, agents, consultants or sublicensees, except that the Receiving Party may keep one copy of the Confidential Information in the legal department files of the Receiving Party, solely for archival purposes. Such archival copy shall be deemed to be the property of the Disclosing Party, and shall continue to be subject to the provisions of this Article 12. It is understood that receipt of Confidential Information under this Agreement will not limit the Receiving Party from assigning its employees to any particular job or task in any way it may choose, subject to the terms and conditions of this Agreement.

**12.3 Permitted Disclosure and Use.** Notwithstanding Section 12.2, (i) either Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) comply with or enforce any of the provisions of this Agreement; (b) comply with applicable Law or (c) only to the extent such disclosure is reasonably necessary to obtain or maintain regulatory approval of a Product, as applicable, to the extent such disclosure is made to a Governmental Authority. If a Party deems it necessary to disclose Confidential Information of the other Party pursuant to this Section 12.3, such Party shall give reasonable advance written notice of such disclosure to the other Party to permit such other Party sufficient opportunity to object to such disclosure or to take measures to ensure confidential treatment of such information, including seeking a protective order or other

appropriate remedy. [\*\*\*]. In the event that a Party becomes aware that a Third Party recipient of Confidential Information has breached its confidentiality obligations, then such Party shall promptly inform the other Party of such event, and the Parties will cooperate in their investigation of such occurrence and enforcement of the provisions of the relevant confidentiality agreement.

**12.4 Notification.** The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, and will cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

**12.5 Publicity; Filing of this Agreement.**

**12.5.1 Publicity.** Each Party will be permitted to issue a press release announcing the execution of this Agreement, which the releasing Party will provide to the other Party in advance for the other Party's review and consent, which must be obtained prior to issuance of such press release. Except as otherwise provided in this Section 12.5, each Party shall maintain the confidentiality of all provisions of this Agreement, and without the prior written consent of the other Party, which consent shall not be unreasonably withheld, neither Party nor its respective Affiliates shall make any press release or other public announcement of or otherwise disclose the provisions of this Agreement to any Third Party, except for: (i) disclosure to those of its directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, potential strategic partners, advisors, agents and sublicensees whose duties reasonably require them to have access to this Agreement, provided that such directors, officers, employees, accountants, attorneys, underwriters, lenders and other financing sources, advisors, agents or sublicensees are required to maintain the confidentiality of this Agreement, (ii) disclosures required by the Tokyo Stock Exchange and any other disclosures made pursuant to any listing agreement with a national securities exchange, in which case the disclosing Party shall provide the nondisclosing Party with at least forty eight (48) hours' notice unless otherwise not practicable, but in any event no later than the time the disclosure required by the regulations of the Tokyo Stock Exchange or national securities exchange or listing agreement is made, (iii) disclosures as may be required by Law, in which case the disclosing Party shall provide the nondisclosing Party with prompt advance notice of such disclosure and cooperate with the nondisclosing Party to seek a protective order or other appropriate remedy, including a request for confidential treatment in the case of Brickell for a filing with the Securities and Exchange Commission; and (iv) other disclosures for which consent has previously been given. A Party may publicly disclose without regard to the preceding requirements of this Section 12.5 any information that was previously publicly disclosed pursuant to this Section 12.5.

**12.6 Publication.** Kaken shall submit copies of each proposed academic, scientific, medical and other publication or presentation that contains or refers to the Brickell Technology or otherwise relates to the Product or any research or Development related to the Product to Brickell at least thirty (30) days in advance of submitting such proposed publication or presentation to a publisher or other Third Party. Brickell shall have the right to review, comment

on and consent (but only with respect to Brickell's Confidential Information) to each such proposed publication or presentation at its sole discretion. Brickell shall have the right to remove any of its Confidential Information prior to submission for publication or presentation. Kaken shall redact or otherwise modify the proposed publication or presentation to remove any such Confidential Information of Brickell that Brickell has objected to. In addition, in the event that the document includes data, information or material generated by Brickell's scientists, and professional standards for authorship would be consistent with including Brickell's scientists as co-authors of the document, the names of such scientists will be included as co-authors. Brickell shall submit copies of each proposed academic, scientific, medical and other publication or presentation that contains or refers to the Kaken Applied Technology related to the Product to Kaken at least thirty (30) days in advance of submitting such proposed publication or presentation to a publisher or other Third Party. Kaken shall have the right to review, comment on and consent (but only with respect to Kaken's Confidential Information) to each such proposed publication or presentation at its sole discretion. Kaken shall have the right to remove any of its Confidential Information prior to submission for publication or presentation. Brickell shall redact or otherwise modify the proposed publication or presentation to remove any such Confidential Information of Kaken that Kaken has objected to. In addition, in the event that the document includes data, information or material generated by Kaken's scientists, and professional standards for authorship would be consistent with including Kaken's scientists as co-authors of the document, the names of such scientists will be included as co-authors.

**12.7 Use of Names.** Except as otherwise set forth in this Agreement, neither Party shall use the name of the other Party in relation to this transaction in any public announcement, press release or other public document without the written consent of such other Party, which consent shall not be unreasonably withheld; provided, however, that subject to Section 12.5, either Party may use the name of the other Party in any document filed with any Regulatory Authority or Governmental Authority, including the FDA and the Securities and Exchange Commission.

**12.8 Survival.** The obligations and prohibitions contained in this Article 12 as they apply to Confidential Information shall survive the expiration or termination of this Agreement for a period of ten (10) years.

### **ARTICLE 13 TERM AND TERMINATION**

**13.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect, [\*\*\*] (the "**Term**").

**13.2 Termination for Breach.** Either Party may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement upon written notice to the other Party in the event that the other Party (the "**Breaching Party**") shall have materially breached this Agreement. The Breaching Party shall have thirty (30) days after written notice thereof was provided to the Breaching Party by the non-breaching Party to remedy such default. Unless the Breaching Party has cured any such breach or default prior to the expiration of such thirty (30) day period, such termination shall become effective upon receipt of the written notice

of termination by the Breaching Party to be given within ten (10) days of the end of the thirty (30) day period.

**13.3 Termination as a Result of Bankruptcy.** Each Party shall have the right to terminate this Agreement upon written notice as a result of the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided that such termination shall be effective only if such proceeding is not dismissed within ninety (90) days after the filing thereof.

**13.4 Termination by Kaken.**

**13.4.1 Termination by Kaken Prior to Regulatory Approval.** At any time prior to the first Regulatory Approval of the Product in the Field in the Territory, Kaken shall have the right to terminate this Agreement in its entirety [\*\*\*].

**13.4.2 Termination by Kaken After Regulatory Approval.** At any time Kaken shall have the right to terminate this Agreement in its entirety [\*\*\*].

**13.4.3 Performance.** During such [\*\*\*] under Section 13.4.1 or [\*\*\*] under Section 13.4.2, Kaken shall continue to perform all of its obligations under this Agreement, including performing all Development Activities allocated to it pursuant to the Development Plan then in effect in accordance with the terms and conditions of this Agreement and bearing all cost associated therewith during such period.

**ARTICLE 14  
EFFECTS OF TERMINATION AND EXPIRATION**

**14.1 Termination By Brickell and Certain Terminations by Kaken.** Without limiting any other legal or equitable remedies that a Party may have, if this Agreement is terminated by Brickell in accordance with Sections 13.2 or 13.3 or if this Agreement is terminated by Kaken in accordance with Section 13.4, then the following provisions shall apply:

**14.1.1 Termination of Licenses.** All rights and licenses granted to Kaken hereunder shall immediately terminate and be of no further force and effect and Kaken shall cease Developing, Commercializing and Manufacturing the Product [\*\*\*].

**14.1.2 Survival of License.** [\*\*\*].

**14.1.3 Assignments.** Kaken will as soon as reasonably practical after receipt of Brickell's request, and at no cost to Brickell:

- (a) [\*\*\*];
- (b) [\*\*\*];
- (c) [\*\*\*];

- (d) [\*\*\*];
- (e) [\*\*\*]; and
- (f) [\*\*\*];

provided, however, that, to the extent any agreement or other asset described in this Section 14.1.3 is not assignable by Kaken, then such agreement or other asset will not be assigned, and, upon the request of Brickell, for a period of [\*\*\*] after the termination of this Agreement Kaken will take such steps as may be reasonably necessary to allow Brickell to obtain and enjoy the benefits of such agreement or other asset. For purposes of clarity, (1) Brickell shall have the right to request that Kaken take any or all of the foregoing actions in whole or in part, or with respect to all or any portion of the assets set forth in the foregoing provisions and (2) to the extent Brickell requests Kaken to transfer its right, title and interest in the items set forth in this Section 14.1.3 to Brickell, Kaken shall also cause its Affiliates and sublicensees to transfer and assign to Brickell all of such Affiliates' and sublicensees' right, title and interest in and to the foregoing items set forth in this Section 14.1.3.

**14.1.4 Disclosure and Delivery.** Kaken will as soon as reasonably practical transfer to Brickell copies of any physical embodiment of any Kaken Applied Know-How, to the extent then used in connection with the Development, Commercialization or Manufacture of the Product. Such transfer shall be effected by the delivery of material documents, to the extent such Kaken Applied Know-How is embodied in such documents.

**14.1.5 Disposition of Inventory.** Kaken and its Affiliates will be entitled, [\*\*\*], as applicable, in accordance with the terms and conditions set forth in this Agreement and otherwise complies with the terms set forth in this Agreement.

**14.2 Termination by Kaken.** Without limiting any other legal or equitable remedies that Kaken may have, if this Agreement is terminated by Kaken in accordance with Section 13.2 the provisions of [\*\*\*] shall apply[\*\*\*].

**14.3 Expiration of this Agreement.** Upon expiration of this Agreement pursuant to Section 13.1 with respect to a given country, all rights and licenses granted to Kaken shall terminate with respect to such country; provided, however, that, [\*\*\*].

**14.4 Accrued Rights.** Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to the effective date of such termination. Such termination will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

**14.5 Survival.** Notwithstanding anything to the contrary contained herein, the following Sections and Articles shall survive any expiration or termination of this Agreement: Section 2.2.3 (last sentence), 4.6.3, 4.7, 5.1.6, 8.3 (to the extent accruing prior to termination), 8.4 through 8.7 and 10.5 and Article 1, Article 11, Article 12, Article 14, Article 15 and Article

16. Except as set forth in this Article 14 or otherwise expressly set forth herein, upon termination or expiration of this Agreement all other rights and obligations of the Parties shall cease.

**14.6 Remedies in Lieu of Termination.** Without limiting any other legal or equitable rights or remedies available to Kaken whether pursuant to this Agreement or under applicable Law, in the event Kaken would be entitled to terminate this Agreement pursuant to Section 13.2 on account of Brickell's breach of Sections 2.1, 2.4, 2.5, 2.6, 4.4, 4.6.1, 7.1 or 12.2, and such breach occurs [\*\*\*]

**14.7 Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Brickell and Kaken are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of certain rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party (such Party, the "**Bankrupt Party**") under the U.S. Bankruptcy Code, (a) the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to such other Party and all embodiments of such intellectual property, which, if not already in such other Party's possession, shall be promptly delivered to it (x) upon any such commencement of a bankruptcy proceeding upon such other Party's written request therefore, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement or (y) if not delivered under clause (x), following the rejection of this Agreement by the Bankrupt Party upon written request therefore by the other Party and (b) the Bankrupt Party shall not unreasonably interfere with the other Party's rights to intellectual property and all embodiments of intellectual property, and shall assist and not unreasonably interfere with the other Party in obtaining intellectual property and all embodiments of intellectual property from another entity. The "embodiments" of intellectual property includes all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Products, filings with Regulatory Authorities and related rights and Brickell Know-How in the case that Brickell is the Bankrupt Party and Kaken Applied Know-How in the case Kaken is the Bankrupt Party.

## **ARTICLE 15 DISPUTE RESOLUTION**

**15.1 General.** The Parties recognize that, from time to time during the Term, disputes may arise as to certain matters which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 15 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement (other than a dispute addressed in Section 4.10).

**15.2 Disputes Arising Between the Parties.** With respect to all disputes arising between the Parties and not from the JDRC, including any alleged failure to perform, or breach,

of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within thirty (30) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Chief Executive Officers of each of the Parties, or a designee from senior management with decision-making authority (the Chief Executive Officer or such designee, the “**Executive Officer**”) for attempted resolution by good-faith negotiations within thirty (30) days after such notice is received.

**15.3 Dispute Resolutions.** If the Executive Officers are not able to resolve such dispute referred to them under Section 15.2 within such thirty (30) day period, then either Party shall have the right, but not the obligation, to submit such controversy or claim to non-binding mediation with the consent of the other Party. If the Parties are unable to resolve such dispute within thirty (30) calendar days after such dispute is mutually referred to non-binding mediation in accordance with this Section 15.3 or within thirty (30) calendar days after the dispute is referred to the Chief Executive Officers under Section 15.2, as the case may be, then either Party may refer the matter to arbitration in accordance with Section 15.5 unless such any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Product or of any trademark rights relating to any Product in which case it shall be resolved in accordance with Section 15.4.

**15.4 Patent and Trademark Dispute Resolution.** Any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any patent rights covering the manufacture, use or sale of any Product or of any trademark rights relating to any Product shall be submitted to a court of competent jurisdiction in the Territory.

**15.5 Arbitration.** All disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce (the “Rules”) by three arbitrators. Each party shall nominate one arbitrator and the two arbitrators so selected shall nominate the third arbitrator. If the parties’ two arbitrators cannot agree on a third arbitrator, the third arbitrator shall be appointed by the International Court of Arbitration of the International Chamber of Commerce in accordance with the Rules. The place of arbitration shall be San Francisco, California, U.S.A. The language of the arbitration shall be English. The arbitration and all disputes determined therein shall be governed by New York law. Unless the parties otherwise agree, the arbitrators shall apply the International Bar Association Rules on the Taking of Evidence in International Commercial Arbitration. Unless the parties otherwise agree, the arbitrators shall not have the power to appoint experts. The arbitrators shall not issue any award, grant any relief or take any action that is prohibited by or inconsistent with the provisions of this Agreement and may not, under any circumstances, award punitive or exemplary damages. The award rendered by the panel of arbitrators shall be binding upon the parties hereto and judgment on the award may be entered in any court having jurisdiction thereof. Each party shall bear its own attorneys’ fees in connection with any arbitral proceedings and the arbitrators shall not include attorneys’ fees in any award.

**15.6 Injunctive Relief.** Nothing herein may prevent either Party from seeking a preliminary injunction or temporary restraining order, in any court of competent jurisdiction, so as to prevent any Confidential Information from being disclosed in violation of this Agreement.

## **ARTICLE 16 GENERAL TERMS**

**16.1 Entire Agreement; Amendment.** This Agreement, including the Schedules hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidential Disclosure Agreement between the Parties dated September 9, 2013 (which shall remain effective prior to the Effective Date). There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized representative of each Party.

**16.2 Force Majeure.** A Party shall be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party makes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure shall include conditions beyond the control of the Parties, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe. Notwithstanding the foregoing, a Party shall not be excused from making payments owed hereunder because of force majeure affecting such Party, unless such event of force majeure specifically prevents the prevented Party from making such payments, in which event such prevented Party shall use commercially reasonable efforts to make such payments through alternative means; provided, however, that in any case such payments shall continue to be due and payable hereunder.

**16.3 Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 16.3, and shall be deemed to have been given for all purposes (i) when delivered, if hand-delivered or sent by facsimile or e-mail on a Business Day, (ii) on the next Business Day if sent by a reputable international overnight courier service, or (iii) five (5) Business Days after mailing, if mailed by first-class certified or registered airmail, postage prepaid, return receipt requested. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:

If to Brickell:            [\*\*\*]

With a copy to: [\*\*\*]

If to Kaken: [\*\*\*]

With a copy to: [\*\*\*]

**16.4 No Strict Construction; Interpretation.** This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The headings of each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular Article or Section.

**16.5 Assignment and Delegation.** Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that Brickell may make such an assignment without Kaken's consent to (a) Affiliates (provided, however that Brickell will remain jointly and severally liable with, and will guarantee the performance of, the relevant Affiliate under this Agreement, and the relevant Affiliate assignee, will assume in writing all of Brickell's obligations under this Agreement) and (b) a successor to substantially all of the business of Brickell to which this Agreement relates, whether in a merger, sale of stock, sale of assets or other transaction, provided that such successor agrees to be bound by the terms of this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 16.5 shall be null, void and of no legal effect. Brickell may delegate one or more of its obligations under this Agreement to an exclusive licensee of the Product outside the Territory. For clarity, any Patent, Know-How or Invention, owned or Controlled by an Affiliate of Brickell that became an Affiliate of Brickell after the Effective Date as a result of a Change of Control of Brickell shall not be considered Brickell Technology for purposes of this Agreement.

**16.6 Compliance with Applicable Law; Further Actions.** Each Party shall comply with all applicable Law in performing its obligations pursuant to this Agreement. Each Party also agrees to execute, acknowledge and deliver such further instruments, and to perform all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

**16.7 Third Party Beneficiary.** [\*\*\*].

**16.8 Severability.** If any one or more of the provisions of this Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, such provision or provisions shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good-faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

**16.9 No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's

rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.

**16.10 Independent Contractors.** Each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind, or commit the other Party in any way. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners between the Parties.

**16.11 English Language; Governing Law.** This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement. This Agreement and all disputes arising out of or related to this Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.

**16.12 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

*[No Further Text on This Page]*

IN WITNESS WHEREOF, the Parties have executed this Agreement by their duly authorized representatives as of the Effective Date.

**BRICKELL BIOTECH, INC.**

By: /s/ Andrew Sklawer  
Name: Andrew Sklawer  
Title: Co-Founder and Vice President

**KAKEN PHARMACEUTICAL CO., LTD.**

By: /s/ Tetsuo Onuma  
Name: Tetsuo Onuma  
Title: President and Representative Director

[Signature Page to License, Development and Commercialization Agreement]

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SCHEDULE 1.5  
BRICKELL PATENTS

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SCHEDULE 2.7

[\*\*] License Agreement

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**EXHIBIT A**

List of Patents and Patent Applications

[\*\*\*]

**EXHIBIT B**

Annual Development Plan for Brickell Biotech, Inc.

[\*\*\*]

**AMENDMENT NO. I TO  
LICENSE AGREEMENT**

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**ATTACHMENT A**

List of Patents and Patent Applications

[\*\*\*]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT  
TO  
LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

This AMENDMENT (this “Amendment”) to the LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the “Agreement”) is made on this 7th day of April, 2015 (the “Amendment Effective Date”), by and between Brickell Biotech, Inc., a Delaware corporation (“Brickell”), and Kaken Pharmaceutical Co., Ltd., a company legally organized and existing under the law of Japan (“Kaken”).

WHEREAS, Brickell and Kaken entered into the Agreement on March 31, 2015; and

WHEREAS, Brickell and Kaken desire to amend the Agreement as set forth in this Amendment.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Amendment, the Parties agree as follows:

1. As used in this Amendment, capitalized terms shall have the same meanings set forth in the Agreement, unless otherwise defined in this Amendment.

2. Section 8.1 of the Agreement is hereby amended to add the following sentence at the end thereof:

“In addition, such [\*\*\*] shall be in consideration for [\*\*\*] under (a) the [\*\*\*] as set forth in Section 2.1.1(i) of the Agreement, with [\*\*\*], (b) the [\*\*\*] as set forth in Section 2.1.1(iii) of the Agreement to Manufacture the Product and Drug Substance in the Territory for purpose of (a) above, and (c) the [\*\*\*] as set forth in Section 2.1.1(iv) to Manufacture the Product and Drug Substance on Brickell’s behalf in accordance with the [\*\*\*].”

3. Section 8.2 of the Agreement is hereby amended to add the following sentence at the end of the first paragraph thereof:

“[\*\*\*]: (1) such first development milestone payment (in the amount of Ten Million Dollars (\$10,000,000)) [\*\*\*].”

4. Except as specifically set forth in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect.

5. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, Brickell and Kaken have executed this Amendment by their respective officers hereunto duly authorized, as of the Amendment Effective Date.

**BRICKELL BIOTECH, INC.**

By: /s/ Andrew Sklawer  
Name: Andrew Sklawer  
Title: Co-Founder and Vice President

**KAKEN PHARMACEUTICAL CO., LTD.**

By: /s/ Tetsuo Onuma  
Name: Tetsuo Onuma  
Title: President and Representative Director

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT NO. 3  
TO  
LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

**THIS AMENDMENT** (this “**Amendment**”), dated March 14, 2018 (the “**Amendment Effective Date**”), is entered into by and between Brickell Biotech, Inc., a Delaware corporation (“**Brickell**”), and Kaken Pharmaceutical Co., Ltd., a company legally organized and existing under the law of Japan (“**Kaken**”).

**WHEREAS**, Brickell and Kaken entered into a License, Development and Commercialization Agreement on March 31, 2015 and thereafter amended it on April 7, 2015, February 24, 2016, and October 6, 2017 (as amended, the “**Agreement**”);

**WHEREAS**, the Agreement provides, among other things, that Kaken has the right to [\*\*\*] by [\*\*\*];

**WHEREAS**, Brickell and Kaken entered into the ROFN Agreement on October 6, 2017 and Kaken [\*\*\*]; and

**WHEREAS**, Brickell desires to [\*\*\*] and Kaken is willing to assist Brickell in [\*\*\*] by [\*\*\*] as set forth in this Amendment.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Amendment, the Parties agree as follows:

1. As used in this Amendment, capitalized terms shall have the same meanings set forth in the Agreement, unless otherwise defined in this Amendment.

2. Section 8.2 of the Agreement shall be amended as follows:

a. [\*\*\*]

b. [\*\*\*]

c. The final paragraph of Section 8.2 shall be amended to read as follows:

[\*\*\*]

[\*\*\*]

3. [\*\*\*].

4. Except as specifically set forth in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect.

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5. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF**, Brickell and Kaken have executed this Amendment by their respective officers hereunto duly authorized, as of the Amendment Effective Date.

**BRICKELL BIOTECH, INC.**

**KAKEN PHARMACEUTICAL CO., LTD.**

By: /s/ Andrew Sklawer  
Name: Andrew Sklawer  
Title: COO

By: /s/ Tetsuo Onuma  
Name: Tetsuo Onuma  
Title: President and Representative Director

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT NO. 4  
TO  
LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

**THIS AMENDMENT** (this “*Amendment*”), dated May 22, 2018 (the “*Amendment Effective Date*”), is entered into by and between Brickell Biotech, Inc., a Delaware corporation (“*Brickell*”), and Kaken Pharmaceutical Co., Ltd., a company legally organized and existing under the law of Japan (“*Kaken*”).

**WHEREAS**, Brickell and Kaken entered into a License, Development and Commercialization Agreement on March 31, 2015 and thereafter amended it on April 7, 2015, February 24, 2016, October 6, 2017, and March 14, 2018 (as amended, the “*Agreement*”); and

**WHEREAS**, Brickell desires [\*\*\*] to [\*\*\*] and Kaken desires to provide Brickell with [\*\*\*] to [\*\*\*].

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Amendment, the Parties agree as follows:

1. As used in this Amendment, capitalized terms shall have the same meanings set forth in the Agreement, unless otherwise defined in this Amendment.

2. The following new Section shall be added to the Agreement as Section 8.8:

**8.8** [\*\*\*].

**8.8.1** [\*\*\*]. Before Brickell commences any of the [\*\*\*], Brickell shall obtain Kaken’s written consent on [\*\*\*], such consent not to be unreasonably withheld or delayed. Kaken shall have the right, during normal business hours, upon reasonable advance notice, and on dates previously discussed in good faith by the Parties, to reasonably monitor the activities of the [\*\*\*] with respect to such [\*\*\*]; provided, that Brickell representative(s) may, at Brickell’s election, be present with Kaken during any such monitoring activities. Subject to circumstances that are outside the reasonable control of Brickell, Brickell shall [\*\*\*] and provide Kaken with a [\*\*\*] reasonably acceptable to Kaken by no later than [\*\*\*]. For the avoidance of doubt, all [\*\*\*] shall constitute [\*\*\*] and without limiting the Parties’ rights or obligations set forth in Section 4.6.2, Brickell shall promptly provide Kaken with copies of [\*\*\*].

**8.8.2** For purposes of this Agreement, “*Phase III Criteria*” shall mean (i) the FDA’s positive review of [\*\*\*] to be conducted by Brickell, which [\*\*\*], (ii) receipt by Kaken of [\*\*\*] from Brickell reasonably acceptable to Kaken with respect to [\*\*\*] and (iii) Kaken and Brickell mutually agreeing that [\*\*\*] and that there will be [\*\*\*] as a result of [\*\*\*] in a manner necessary to satisfy FDA requirements.

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3. Section 8.2 of the Agreement shall be amended as follows:

[\*\*\*].

4. [\*\*\*]:

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

5. The Parties agree that if Kaken has [\*\*\*] as set forth in Section 3 of this Amendment [\*\*\*], then Brickell may terminate this Amendment at any time within thirty (30) days thereafter by written notice to Kaken, in which case this Amendment shall be of no effect from and after the date of such termination, and the terms set forth herein shall be void ab initio.

6. Except as specifically set forth in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect.

7. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF**, Brickell and Kaken have executed this Amendment by their respective officers hereunto duly authorized, as of the Amendment Effective Date.

**BRICKELL BIOTECH, INC.**

By: /s/ Andrew Sklawer  
Name: Andrew Sklawer  
Title: Chief Operating Officer

**KAKEN PHARMACEUTICAL CO., LTD.**

By: /s/ Tetsuo Onuma  
Name: Tetsuo Onuma  
Title: President and Representative Director

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT NO. 2 TO LICENSE, DEVELOPMENT  
AND COMMERCIALIZATION AGREEMENT**

**THIS AMENDMENT NO. 2** (this “*Amendment*”), dated October 6, 2017 (the “*Amendment Effective Date*”), is entered into by and between Brickell Biotech, Inc., a Delaware corporation (“*Brickell*”), and Kaken Pharmaceutical Co., Ltd., a company legally organized and existing under the law of Japan (“*Kaken*”).

**WHEREAS**, Brickell and Kaken entered into a License, Development and Commercialization Agreement on March 31, 2015 and thereafter amended it on April 7, 2015 and on February 24, 2016 (the agreement, as amended, shall be referred to herein as the “*Agreement*”); and

**WHEREAS**, Brickell and Kaken desire to amend the Agreement as set forth in this Amendment.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Amendment, the parties agree as follows:

1. As used in this Amendment, capitalized terms shall have the same meanings set forth in the Agreement, unless otherwise defined in this Amendment.
2. Section 8.2 of the Agreement is hereby amended to add the following paragraph at the end of the final paragraph thereof:

“[\*\*\*] \$10,000,000 [\*\*\*].”
3. Article 12 of the Agreement is amended as set forth below.
  - a. The first sentence of Section 12.1 is amended to read in its entirety as follows:

“As used in this Agreement, the term “**Confidential Information**” means all information, whether it be written or oral, including all production schedules, lines of products, volumes of business, processes, new product developments, product designs, formulae, technical information, laboratory data, clinical data, patent information, know-how, trade secrets, financial and strategic information, marketing and promotional information and data, and other material relating to any products, projects or processes of one Party (the “**Disclosing Party**”) that is provided to, or otherwise obtained by, the other Party (the “**Receiving Party**”) in connection with (i) this Agreement (including information exchanged prior to the date hereof in connection with the transactions set forth in this Agreement, including any information disclosed by either Party pursuant

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to the Confidential Disclosure Agreement between the Parties dated September 9, 2013) or (ii) the ROFN Agreement.”

b. The first two sentences of Section 12.2 are amended to read in their entirety as follows:

“Each of Kaken and Brickell shall keep all Confidential Information received from or on behalf of the other Party with the same degree of care with which it maintains the confidentiality of its own Confidential Information, but in all cases no less than a reasonable degree of care. Neither Party shall use such Confidential Information for any purpose other than in performance of its obligations or the exercise of its rights pursuant to this Agreement or the ROFN Agreement or disclose the same to any other Person other than to such of its and its Affiliates’ directors, managers, employees, independent contractors, agents, consultants or sublicensees who have a need to know such Confidential Information to implement the terms of this Agreement or the ROFN Agreement or enforce its rights under this Agreement or the ROFN Agreement; provided, however, that a Receiving Party shall advise any of its and its Affiliates’ directors, managers, employees, independent contractors, agents, consultants or sublicensees who receives such Confidential Information of the confidential nature thereof and of the obligations contained in this Agreement relating thereto, and the Receiving Party shall ensure (including, in the case of a Third Party, by means of a written agreement with such Third Party having terms at least as protective as those contained in this Article 12) that all such directors, managers, employees, independent contractors, agents, consultants or sublicensees comply with such obligations.”

c. The first sentence of Section 12.3 is amended to read in its entirety as follows:

“Notwithstanding Section 12.2, (i) either Party may disclose Confidential Information belonging to the other Party only to the extent such disclosure is reasonably necessary to: (a) comply with or enforce any of the provisions of this Agreement or the ROFN Agreement, (b) comply with applicable Law or (c) only to the extent such disclosure is reasonably necessary to obtain or maintain regulatory approval of a Product, as applicable, to the extent such disclosure is made to a Governmental Authority.”

4. The Agreement is hereby amended by adding the attached “**Exhibit A**” that is made a part of this Amendment.
5. The Agreement is hereby amended by adding the attached “**Exhibit B**” that is made a part of this Amendment.

6. The Agreement is hereby amended by adding the attached “**Exhibit C**” that is made a part of this Amendment. Concurrently with the signing of this Amendment, the Parties shall execute and deliver the ROFN Agreement set forth in **Exhibit C**.
7. Except as specifically set forth in this Amendment, all terms and conditions of the Agreement shall remain in full force and effect.
8. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF**, Brickell and Kaken have executed this Amendment by their respective officers hereunto duly authorized, as of the Amendment Effective Date.

**BRICKELL BIOTECH, INC.**

**KAKEN PHARMACEUTICAL CO., LTD.**

By: /s/ Andrew Sklawer  
Name: Andrew Sklawer  
Title: COO

By: /s/ Tetsuo Onuma  
Name: Tetsuo Onuma  
Title: President and Representative Director

**Exhibit A**

[\*\*\*] Topline Tables

[\*\*\*]

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**Exhibit B**

**EXERCISE NOTICE**

November 28, 2017

[\*\*\*]  
Brickell Biotech, Inc.  
5777 Central Avenue, Suite 102  
Boulder, Colorado USA 80301

Re: [\*\*\*]

Dear [\*\*\*]:

Pursuant to Section 8.2 of the License, Development and Commercialization Agreement entered into on March 31, 2015 and thereafter amended on April 7, 2015, February 24, 2016 and October 6, 2017 (the "***Agreement***"), by and between Brickell Biotech, Inc., a Delaware corporation ("***Brickell***"), and Kaken Pharmaceutical Co., Ltd., a company legally organized and existing under the law of Japan ("***Kaken***"), Kaken hereby [\*\*\*] (as defined in the Agreement) on the terms and conditions set forth in the Agreement.

Kaken shall [\*\*\*] designated by Brickell [\*\*\*].

Very truly yours,

Kaken Pharmaceutical Co., Ltd.

By: \_\_\_\_\_  
Name:  
Title:

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Exhibit C

**RIGHT OF FIRST NEGOTIATION AGREEMENT**

**THIS RIGHT OF FIRST NEGOTIATION AGREEMENT** (this “*ROFN Agreement*”), dated October 6, 2017 is entered into by and between Brickell Biotech, Inc., a Delaware corporation (“*Brickell*”), and Kaken Pharmaceutical Co., Ltd., a company legally organized and existing under the law of Japan (“*Kaken*”). Brickell and Kaken are sometimes referred to herein individually as a “*Party*” and collectively as the “*Parties*.”

**WHEREAS**, Brickell and Kaken entered into a License, Development and Commercialization Agreement on March 31, 2015 and thereafter amended it on April 7, 2015, February 24, 2016 and October 6, 2017 (the agreement, as amended, shall be referred to herein as the “*Agreement*”); and

**WHEREAS**, contingent upon and subject to Kaken [\*\*\*] (as defined in the Agreement), Brickell desires to grant Kaken as of the Effective Date (as defined below) certain rights with respect to Brickell development products.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this ROFN Agreement, the Parties agree as follows:

**1. Definitions.** The following terms shall have the following meanings:

- 1.1.** [\*\*\*] shall mean (a) [\*\*\*] (b) [\*\*\*] (c) [\*\*\*] (d) [\*\*\*], including, [\*\*\*].
- 1.2.** “*Business Day*” means a day (other than Saturday or Sunday) on which banks are open for business in Tokyo, Japan and in New York, New York USA.
- 1.3.** “*Change of Control*” means, with respect to a Person, any of the following events: (i) any Person is or becomes the beneficial owner (except that a Person shall be deemed to have beneficial ownership of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all shares of such Person’s outstanding capital stock, (ii) such Person consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into such Person, other than (A) a merger or consolidation which would result in the voting securities of such Person outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of such Person or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of such Person (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of a majority of the total voting power of all shares of

capital stock of such Person, or (iii) such Person transfers all or substantially all of its assets to any Person other than a wholly owned affiliate of such Person.

- 1.4. “**Effective Date**” shall mean the date [\*\*\*] (as defined in the Agreement).
- 1.5. “**Person**” shall mean any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.
- 1.6. “**Initial Proof of Concept Clinical Trial**” means a study of a pharmaceutical product the goal of which is to demonstrate the proof of the concept in human patients to evaluate safety and initial pharmacologic activity and/or efficacy in healthy volunteers and/or individuals who have a certain disease or condition before embarking on a Phase IIB Clinical Trial.
- 1.7. “**Phase IIB Clinical Trial**” means a study of a pharmaceutical product in human patients to determine efficacy and statistical trends prior to initiation of Phase III pivotal studies. These studies will also evaluate potential doses and dosing regimens to optimize the therapy under investigation.
- 1.8. “**Territory**” means [\*\*\*].

## 2. Rights of First Negotiation.

- 2.1. **Brickell Products.** [\*\*\*].
- 2.2. **Condition Precedent.** [\*\*\*].
- 2.3. **ROFN Evaluation Period.** Kaken shall be entitled to exercise its right of first negotiation with respect to [\*\*\*] by providing written notice to Brickell (the “**ROFN Exercise Notice**”) within [\*\*\*] after Kaken’s receipt of the [\*\*\*] and the [\*\*\*] (the “**ROFN Evaluation Period**”).
- 2.4. **Negotiation Period.** Upon Brickell’s receipt of the ROFN Exercise Notice, Kaken shall have a period of one hundred and twenty (120) days (the “**Negotiation Period**”) to negotiate exclusively with Brickell reasonably and in good faith concerning the terms of an exclusive license to develop, manufacture, have manufactured and commercialize such Brickell Product in the Territory and manufacture and have manufactured the Brickell Products outside the Territory for sale in the Territory.
- 2.5. **Exclusivity.** Until Kaken receives an [\*\*\*] and thereafter during the ROFN Evaluation Period and, if Brickell timely receives a ROFN Exercise Notice, thereafter during the Negotiation Period, Brickell [\*\*\*], without the prior written consent of Kaken, directly or indirectly [\*\*\*]. Nothing in this Section 2 shall restrict Brickell or its affiliates from negotiating with, soliciting proposals from, entering into agreements with, or providing information to (x) its-own-actual and-

potential advisors, agents and representatives and/or (y) any third party contract research organization or contract manufacture or other service provider.

## **2.6. Termination of ROFN Rights.**

**2.6.1.** The ROFN Right with respect to the [\*\*\*] which was the subject of the [\*\*\*] shall terminate effective upon the earlier of (i) [\*\*\*] and (ii) [\*\*\*].

**2.6.2.** If (i) Kaken terminates the Agreement or (ii) Brickell terminates the Agreement as a result of an uncured breach by Kaken, Brickell shall have the right to terminate this ROFN Agreement upon written notice to Kaken.

**2.7. Activities Outside of the Territory.** Subject to the terms of this ROFN Agreement, Brickell and its successors shall be free to commercialize, license, sell or take any other actions with respect to the [\*\*\*] and the intellectual property rights related thereto, in Brickell's sole discretion. In addition, nothing in this ROFN Agreement shall restrict Brickell and its successors' rights to commercialize, license, sell or take any other actions with respect to [\*\*\*] and the intellectual property rights related thereto outside of the Territory and other products and their related intellectual property rights in any territory of the world.

**2.8. Activities Inside of the Territory.** Nothing in this ROFN Agreement shall restrict Brickell and its successors' rights to manufacture or have manufactured [\*\*\*] inside of the Territory for sale outside of the Territory.

**2.9. Effect of Brickell Ceasing Development.** Kaken acknowledges that Brickell shall have the sole discretion regarding the development of the [\*\*\*] inside and outside of the Territory and that Brickell may cease development of a [\*\*\*] at any time if Brickell so determines.

**2.10. Change of Control.** In the event of a Change of Control transaction, the following provisions of this Section 2 shall apply:

**2.10.1. Existing Successor Products.** All compounds that were controlled by Brickell's successor or such successor's affiliates that were not affiliates of Brickell prior to such Brickell Change of Control (collectively, the "Successor") shall not be included within the [\*\*\*].

**2.10.2. Independent Successor Product.** Compounds that, following such Brickell Change of Control, are developed, made or otherwise acquired or controlled by the Successor without use of Brickell's Confidential Information (as defined in the Agreement) shall not be deemed [\*\*\*].

## **3. Miscellaneous.**

**3.1. Entire Agreement; Amendment.** This ROFN Agreement and the Agreement sets forth the complete, final and exclusive agreement and all the covenants, promises,

agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof No subsequent alteration, amendment, change or addition to this ROFN Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized representative of each Party.

**3.2. Notices.** Any notice required or permitted to be given under this ROFN Agreement shall be in writing, shall specifically refer to this ROFN Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section 3.2, and shall be deemed to have been given for all purposes (i) when delivered, if hand-delivered or sent by facsimile or e-mail on a Business Day, (ii) on the next Business Day if sent by a reputable international overnight courier service, or (iii) five (5) Business Days after mailing, if mailed by first-class certified or registered airmail, postage prepaid, return receipt requested. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as described below:

If to Brickell: [\*\*\*]

With a copy to: [\*\*\*]

If to Kaken: [\*\*\*]

With a copy to: [\*\*\*]

**3.3. Assignment.** Neither this ROFN Agreement nor any of the rights, interests or obligations under this ROFN Agreement may be assigned or delegated, in whole or in part, by operation of law or otherwise, by any Party without the prior written consent of the other Party, and any such assignment without such prior written consent shall be null and void. Notwithstanding the foregoing, this ROFN Agreement may be assigned by Brickell without the consent of Kaken in connection with a Change of Control transaction, provided that, in connection with any such assignment, Brickell shall assign all of Brickell's obligations under this ROFN Agreement to its successor and Kaken shall continue to have all of its rights under this ROFN Agreement after such assignment.

**3.4. Severability.** If any one or more of the provisions of this ROFN Agreement are held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, such provision or provisions shall be considered severed from this ROFN Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good-faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this ROFN Agreement may be realized.

- 3.5. English Language; Governing Law.** This ROFN Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this ROFN Agreement, This ROFN Agreement and all disputes arising out of or related to this ROFN Agreement or any breach hereof shall be governed by and construed under the laws of the State of New York, without giving effect to any choice of law principles that would require the application of the laws of a different state.
- 3.6. Counterparts.** This ROFN Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF**, Brickell and Kaken have executed this ROFN Agreement by their respective officers hereunto duly authorized, as of the date set forth above.

**BRICKELL BIOTECH, INC.**

**KAKEN PHARMACEUTICAL CO., LTD.**

By:     /s/ Andrew Sklawer    

Name: Andrew Sklawer

Title: COO

By:     /s/ Tetsuo Onuma    

Name: Tetsuo Onuma

Title: President and Representative Director

*(Signature Page to ROFN Agreement)*

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**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT TO  
RIGHT OF FIRST NEGOTIATION AGREEMENT**

**THIS AMENDMENT** (this “*Amendment*”), effective as of the Amendment Effective Date (as defined below), is entered into by and between Brickell Biotech, Inc., a Delaware corporation (“*Brickell*”), and Kaken Pharmaceutical Co., Ltd., a company legally organized and existing under the law of Japan (“*Kaken*”).

**WHEREAS**, Brickell and Kaken entered into a License, Development and Commercialization Agreement on March 31, 2015 and thereafter amended it on April 7, 2015, February 24, 2016, and October 6, 2017 (as amended, the “*Agreement*”);

**WHEREAS**, the Agreement provides, among other things, that Kaken has the [\*\*\*] by [\*\*\*];

**WHEREAS**, Brickell and [\*\*\*]; and

**WHEREAS**, Brickell and Kaken desire to further amend the ROFN Agreement as set forth in this Amendment.

**NOW THEREFORE**, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Amendment, the Parties agree as follows:

1. As used in this Amendment, capitalized terms shall have the same meanings set forth in the Agreement, unless otherwise defined in this Amendment.
  2. This Amendment shall be effective as of the date of receipt by Brickell of the Development Milestone 1 Payment pursuant to Section 8.2 of the Agreement (the “*Amendment Effective Date*”).
  3. The second recital in the ROFN Agreement shall be deleted and amended in its entirety to read as follows:  
  
“**WHEREAS**, Kaken [\*\*\*] as of the Effective Date (as defined below) certain rights with respect to [\*\*\*].”
  4. Section 1.4 of the ROFN Agreement shall be amended to read as follows:  
  
“1.4. “**Effective Date**” shall mean [\*\*\*].”
  5. In the ROFN Agreement, the following term shall have the following meaning
-

“1.8 “Subsequent Clinical Trial” means, with respect to [\*\*\*], the first (and not any subsequent) study of that pharmaceutical product in human patients occurring after the Initial Proof of Concept Clinical Trial, regardless of the goal of the study.

The defined term “Territory” shall be renumbered as 1.9.”

6. Sections 2.1 through 2.5 of the ROFN Agreement are hereby deleted and amended in their entirety to read as follows:

2.1. **Brickell Products.** As of the Effective Date, Brickell hereby grants Kaken the rights set out in this Section 2 (each, a “*ROFN Right*”) to first negotiate with Brickell for an [\*\*\*].

2.2. [\*\*\*] **ROFN Rights.**

2.2.1 **Condition Precedent to [\*\*\*] ROFN Rights.** If Brickell conducts and completes an [\*\*\*], Brickell shall provide written notice to Kaken upon [\*\*\*] and Kaken will have a first right to negotiate with Brickell for [\*\*\*] if the ROFN Rights in respect of [\*\*\*] have (a) [\*\*\*], as set forth in this [\*\*\*] or (b) [\*\*\*] in accordance with Section [\*\*\*]. At the time Brickell issues the [\*\*\*], Brickell shall also physically or electronically deliver to Kaken, or provide Kaken access via secure electronic data room (any such delivery method, “**make available**,” and “**made available**” shall have a corresponding meaning) all material data related to [\*\*\*], including from such [\*\*\*], that Brickell then possesses (the “[\*\*\*]”).

2.2.2 [\*\*\*] **ROFN Evaluation Period.** Kaken shall be entitled to exercise its right of first negotiation with respect to such [\*\*\*] by providing written notice to Brickell (the “[\*\*\*] **ROFN Exercise Notice**”) within thirty (30) days after Kaken’s receipt of the [\*\*\*] and the [\*\*\*] (the “[\*\*\*] **ROFN Evaluation Period**”).

2.2.3 [\*\*\*] **Negotiation Period.** Upon Brickell’s receipt of the [\*\*\*], Kaken shall have a period of [\*\*\*] with Brickell [\*\*\*] concerning the terms of an [\*\*\*].

2.3. [\*\*\*] **ROFN Rights.**

2.3.1 **Conditions Precedent to [\*\*\*] ROFN Rights.** If Brickell conducts and completes a [\*\*\*], Brickell shall provide written notice to Kaken upon completion of the [\*\*\*] ([\*\*\*]) and Kaken will have a first right to negotiate with Brickell for [\*\*\*], regardless of whether Kaken exercised its ROFN Rights with respect to such Brickell Product pursuant to Section 2.2, provided, however, that Kaken shall [\*\*\*] or (ii) [\*\*\*]. At the time Brickell issues the [\*\*\*], Brickell shall make available to Kaken [\*\*\*].

2.3.2 **[\*\*\*] Evaluation Period.** Kaken shall be entitled to exercise its right of first negotiation with respect to [\*\*\*] by providing written notice to Brickell (the “[\*\*\*] **ROFN Exercise Notice**”) within [\*\*\*] after Kaken’s receipt of [\*\*\*] and [\*\*\*] (the “[\*\*\*] **ROFN Evaluation Period**”).

2.3.3 **[\*\*\*] Negotiation Period.** Upon Brickell’s receipt of the [\*\*\*], Kaken shall have a period of [\*\*\*] (the [\*\*\*]) to negotiate [\*\*\*].

2.4 [\*\*\*].

2.4.1 **[\*\*\*] ROFN Rights.** Until Kaken receives [\*\*\*] and thereafter during [\*\*\*] Evaluation Period and, if [\*\*\*] ROFN Exercise Notice, thereafter during the [\*\*\*] Negotiation Period, Brickell shall not (other than in connection with a Change in Control transaction), without the prior written consent of Kaken, directly or indirectly [\*\*\*].

2.4.2 **[\*\*\*] ROFN Rights.** If the conditions precedent for Kaken’s ROFN Rights set forth in Section 2.3.1 are satisfied then from the date [\*\*\*] until [\*\*\*] and, if [\*\*\*], thereafter [\*\*\*] Negotiation Period, Brickell [\*\*\*].

2.4.3 **Brickell Rights.** Nothing in this Section 2 shall restrict Brickell or its affiliates from negotiating with, soliciting proposals from, entering into agreements with, or providing information to, (x) its own actual and potential advisors, agents and representatives and/or (y) any third party contract research organization or contract manufacture or other service provider.

## 2.5. **Termination of ROFN Rights.**

2.5.1. The ROFN Right set forth in Section 2.2 with respect to a Brickell Product which was the subject of [\*\*\*] shall terminate effective upon the earlier of (i) Kaken’s failure to issue a [\*\*\*] ROFN Exercise Notice prior to the expiration of [\*\*\*] and (ii) the [\*\*\*].

2.5.2. The ROFN Right set forth in Section 2.3 with respect to [\*\*\*] which was the subject of the [\*\*\*] shall terminate effective upon the earlier of [\*\*\*].

2.5.3. If (i) Kaken terminates the Agreement or (ii) Brickell terminates the Agreement as a result of an uncured breach by Kaken, Brickell shall have the right to terminate this ROFN Agreement upon written notice to Kaken.

6. Except as specifically set forth in this Amendment, all terms and conditions of the ROFN Agreement shall remain in full force and effect.
7. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF**, Brickell and Kaken have executed this Amendment by their respective officers hereunto duly authorized, as of the Amendment Effective Date.

**BRICKELL BIOTECH, INC.**

**KAKEN PHARMACEUTICAL CO., LTD.**

By:     /s/ Andrew Sklawer      
Name: Andrew Sklawer  
Title: COO

By:     /s/ Tetsuo Onuma      
Name: Tetsuo Onuma  
Title: President and Representative Director

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**LICENSE AGREEMENT**

**THIS LICENSE AGREEMENT (“Agreement”)** is made effective as of December 15, 2012 (the “**Effective Date**”) by and among **BODOR LABORATORIES, INC.**, a Florida corporation, having an office located at 4400 Biscayne Boulevard, Suite 980, Miami, FL 33137 (“**BLI**”) and **NICHOLAS S. BODOR**, a Florida resident residing at 10225 Collins Ave., Apt 1002, Bal Harbour, FL, USA 33154 (“**Bodor**”) (collectively BLI and Bodor are referred to herein as “**Licensor**”), and **BRICKELL BIOTECH, INC.**, a Delaware corporation having an office located at 2600 Southwest Third Avenue, Suite 950, Miami, Florida 33129, and any Affiliates (collectively, “**Licensee**”). Licensor and Licensee are each individually referred to herein as a “**Party**” and collectively referred to as the “**Parties.**”

**BACKGROUND:**

**WHEREAS**, Licensor holds all right, title and interest in and to the intellectual property related to the Licensed Patents and Licensed Know-How; and

**WHEREAS**, Licensee wishes to obtain a license from Licensor to the Licensed Patents and Licensed Know-How, all on the terms and conditions set forth below.

**NOW, THEREFORE**, in consideration of the recitals, mutual covenants and promises contained herein, the Parties hereto agree as follows:

**ARTICLE I**

**DEFINITIONS**

As used in this Agreement, the following terms shall have the meanings indicated:

1.1 “*Affiliate*,” with respect to a Party, shall mean any corporation or non-corporate business entity, firm, partnership or other entity, which controls, is controlled by, or is under common control with such Party. For purposes of this definition, “control” shall mean the ownership of at least fifty percent (50%) of the voting stock of such entity or any other comparable equity or ownership interest, or (a) in the absence of the ownership of at least fifty percent (50%) of the voting stock of a corporation, or (b) in the case of a non-corporate business entity, possession, directly or indirectly, the power to direct, or cause the direction of, the management and policies of such entity whether through the ownership or control of voting securities, by contract or otherwise.

1.2 “*Commercially Reasonable Efforts*” shall mean those efforts normally extended by a pharmaceutical company similarly situated to Licensee to develop and commercialize pharmaceutical products and considering all aspects of the development cycle, including preclinical

and clinical results, or lack thereof, regulatory factors, financial factors, marketing factors and standard product planning with respect to comparable or potentially competing products.

1.3 “Field” shall mean the prescription use of the Licensed Product to [\*\*\*].

1.4 “Gross Sales” shall mean the prices actually charged by Licensee in the sale of a Licensed Product.

1.5 “Inventions” shall mean any patentable discovery, invention, improvement, idea, concept, technique, method, process, formula or technology within the Field.

1.6 “Licensed Know-How” shall mean any and all rights in any information, data, process, method that is necessary or desirable to practice in best mode any invention claimed in the Licensed Patents that has been developed by the Licensor on or prior to the Effective Date.

1.7 “Licensed Patent” shall mean the patent application(s) listed on Exhibit “A” (“**Exhibit A**”), any patents issuing thereon, and any continuations, continuations-in-part, reissues, re-examinations, extensions and foreign counterparts thereof.

1.8 “Licensed Product” shall mean any product or part thereof, process or service, the development, manufacture, use, import, export, offer for sale or sale of which is covered by, or which cannot be undertaken or completed without infringing, a Valid Claim set forth in any Licensed Patent, and/or which incorporates any Licensed Know-How.

1.9 “Net Sales” [\*\*\*]

1.10 “Sublicensee” shall mean any non-Affiliate third party to whom Licensee has granted the right to manufacture, distribute, or otherwise market a Licensed Product in accordance with the terms of this Agreement.

1.11 “Territory” shall mean [\*\*\*].

1.12 “Valid Claim” shall mean a claim of an issued and unexpired patent, including any regulatory or judicial extensions of the patent term, or a claim of a pending patent application, contained in the Licensed Patents, which has not been held un-patentable, invalid or unenforceable by a court or other government agency of competent jurisdiction and has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

## ARTICLE 2

### LICENSE

#### 2.1 Grant.

2.1.1 *Exclusive.* Licensor hereby grants to Licensee an [\*\*\*], license under the Licensed Patents and Licensed Know-How in the Field within the Territory to [\*\*\*] Licensed Product.

2.1.2 *Right of Sublicense.* Any sublicense granted by Licensee to any Sublicensee shall be subject to a written sublicense agreement that contains terms and conditions that (a) impose obligations that are comparable to the obligations applicable to Licensee under this Agreement including, but not limited to, the audit rights set forth in Section 3.8, (b) are at least as protective of the Licensed Patents, Licensed Know-How and Licensor Confidential Information (as defined in **Section 5.1**) as the terms contained in this Agreement and (c) include no provisions that would be a violation of any terms and conditions set forth in this Agreement. Without limiting the foregoing, each such sublicense agreement shall provide that Licensor is a third party beneficiary of such sublicense agreement, with the right to enforce the terms thereof in the event that Licensee does not enforce its rights. Licensee shall notify Licensor in writing of the grant of any such sublicense within ten (10) days thereof, which notice shall identify the Sublicensee and shall be accompanied by a copy of the applicable sublicense agreement. The terms of such sublicense agreements, and the identity of all Sublicensees shall be Confidential Information (as defined below) of Licensee. Licensee shall use Commercially Reasonable Efforts to monitor the performance of any Sublicensee under any sublicense granted pursuant to this **Section 2.1.2**.

2.1.3 *No Rights.* Licensor shall not be permitted, and shall cause its Affiliates to refrain from the practice of any rights granted to Licensee under this **Article 2** in the Field in the Territory during the Term of this Agreement.

2.1.4 *Additional Rights.* During the Term of this Agreement, Licensor shall not grant to any third party any right or license whatsoever under the Licensed Patents or Licensed Know-How in the Field. Licensor retains the right to grant other licenses outside the Field.

2.1.5 *New Inventions.* Any new Invention or discovery, whether patentable or not, made solely by Licensee or in combination with any third party, as a result of the exercise of this Agreement, shall be Licensee's property. The Parties shall reasonably cooperate in any patent application procedures for inventions or discoveries made under this section at Licensee's expense.

2.1.6 [\*\*\*].

2.1.7 *Limitations.* Except as expressly set forth herein, this Agreement does not grant to Licensee any right, title, interest, ownership or license by implication, estoppel or otherwise, to any intellectual property rights of Licensor.

## 2.2 *Obligations of Licensee.*

2.2.1 *Diligence Events.* Licensee shall use [\*\*\*] at its own cost and expense to develop a Licensed Product, to conduct all development necessary to obtain regulatory approval to market such Licensed Product, and to commercialize such Licensed Product, according to the applicable completion date listed in the table below for the Licensed Product.

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

2.2.2 *Development Plan.* Licensee will deliver to Licensor an annual updated development plan for the Licensed Product (the “**Development Plan**”) no later than January 31 of each year during the Term. The purpose of the Development Plan is [\*\*]. The Development Plan will include, at a minimum, the information listed in Exhibit “B” (“**Exhibit B**”).

2.2.3 *Licensee Diligence Default.* Where the Licensee fails to [\*\*] the Licensed Product in accordance with the Development Plan and Diligence Events, and fails to diligently undertake actions to remedy any such deficiency, and where mediation has failed to accomplish a satisfactory resolution, the Licensor may consider such failure to be a material breach under this Agreement and shall have the right to terminate this Agreement pursuant to **Section 4.2.2**.

2.3 *Obligations of Licensor.*

2.3.1 *Information.* On or before the Effective Date of this Agreement, Licensor shall provide Licensee with a copy of all tangible materials and information in its possession related to or involving the Licensed Patents. Such information and materials shall generally include but not be limited to all patent correspondence, patent searches, patent files, patent landscaping, inventor disclosures, and patent applications and schedules. Licensor shall provide and make available to Licensee all manufacturing information and data, all formulation information and data, and all clinical and pre-clinical data, including toxicity data, whether submitted or not, as part of any Investigative New Drug Application or New Drug Application filing of Licensor or its sublicensees or Affiliates with respect to a Licensed Product subject to provisions of confidentiality. Such rights shall include the right to reference any of Licensor’s regulatory filings with the FDA or any other governmental agency. Licensor agrees to use its reasonable efforts to identify and make available inventors and any key scientific personnel to discuss research, development and commercialization activities as reasonably required.

2.4 *Mutual Party Obligations.*

2.4.1 *Right of Access to Data.* Each Party will make available, at no cost, data and any reports, including but not limited to full study reports, of any non-clinical and/or clinical study in animals or humans, related to the Licensed Patents and Licensed Know-How, on a confidential basis within sixty (60) days of the generation of same, such that: (i) Licensor may share such data with any other party, on a confidential basis, as background information in respect of any other non-competing application outside of the Field and have the right to reference any or all such data, (ii) Licensee may share such data, on a confidential basis, as background information to its Affiliates, financing sources, and potential investors and have the right to reference any or all such data for

development of Licensed Product in the Field only, and (iii) Licensee shall utilize such data to ensure full compliance with the regulatory authorities and to inform future development of the Licensed Product, provided neither party shall be required to disclose internally developed information to any competitor without the permission of the developing party.

### ARTICLE 3

#### PAYMENTS AND REPORTS

3.1 *Milestone Payments and Clinical Obligations.* As consideration for the rights and licenses granted by Licensor to Licensee hereunder, Licensee agrees to pay Licensor the following amounts at the following times:

3.1.1 *Milestone Payments.* Licensee shall pay to Licensor milestone payments (each, a “**Milestone Payment**”) as set forth in the following table [\*\*\*] if and when each Milestone Event is achieved. Licensee shall notify Licensor promptly in writing (but in each case within thirty (30) days) of its achievement of each Milestone Event. Each Milestone Payment (other than Upfront payments) shall be due within sixty (60) days following the achievement of the applicable Milestone Event.

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

3.1.2 *Clinical Obligations.* Licensee shall [\*\*\*]. The activities undertaken and the results achieved from all clinical development efforts shall be made available to Licensor on a confidential basis and in a timely manner, subject to **Section 2.4.1**, including but not limited to the right to reference such information.

#### 3.2 *Royalties.*

3.2.1 *Patent Royalty.* Licensee will pay a royalty to Licensor [\*\*\*] (“**Patent Royalty**” or collectively, “**Patent Royalties**”). Except for sales pursuant to [\*\*\*]. The payment of a Patent Royalty shall commence [\*\*\*].

3.2.2 *Sublicense Royalty.* During the term of this Agreement, should Licensee enter into any sublicense with an unaffiliated third party (“**Sublicensee**”) for the sale of Licensed Products (“**Sublicensing Agreement**”), the rate for Patent Royalties payable to Licensor shall be in accordance with the following schedule based on the patent royalty rate set forth in the Sublicensing Agreement (the “**Sublicensee Patent Royalty Rate**”):

[***]	[***]
[***]	[***]
[***]	[***]

3.2.2.1 *Sublicense Royalty Examples.* For the avoidance of doubt: [\*\*\*].

3.2.3 *No Duplication of Royalties.* The Royalty on Net Sales of Licensed Products shall be [\*\*\*] upon a [\*\*\*] to any [\*\*\*].

3.3 *Sublicense Fee.* In addition and not in lieu of the fees set forth in Section 3.1, Licensee shall pay Licensor the sum of [\*\*\*].

3.4 *Timing of Royalty Payments.* The Patent Royalty will be payable commencing [\*\*\*].

3.5 *Royalty Reports and Payments.* After [\*\*\*] by Licensee or Sublicensees of a Licensed Product for which a Patent Royalty is payable under this **Article 3**, Licensee shall make quarterly written reports to Licensor within forty-five (45) days after the end of each calendar quarter, stating in each such report the number, description, Gross Sales, and itemized Net Sales of such Licensed Product sold during the calendar quarter. Simultaneously with the delivery of each such report, Licensee shall pay to Licensor the Patent Royalty, if any, due to Licensor for the period of such report. If no Patent Royalty is due, Licensee shall so report. Such reports shall be Confidential Information of Licensee subject to **Article 5**, herein. [\*\*\*] payable with respect to the amount of [\*\*\*].

3.6 *Currency Conversion.* Where any currency conversion is to be made in connection with the calculation of any amounts hereunder, such conversion shall be made using the selling exchange rate for conversion of the foreign currency into U.S. dollars, quoted for current transactions reported in The Wall Street Journal for the last business day of the period to which such calculation pertains.

3.7 *Interest.* In addition to any other rights and remedies of Licensor under this Agreement, any amounts owed to Licensor under this Agreement shall, if not paid when due, accrue interest at a rate that is the lesser of [\*\*\*].

3.8 *Audits.* Licensee shall maintain, and shall cause its Sublicensees to maintain, complete and accurate books and records relating solely to Net Sales of the Licensed Product and any amounts payable to Licensor under this Agreement, which records shall contain sufficient information to permit Licensor to confirm the accuracy of any reports delivered to Licensor hereunder. The relevant party shall retain such records for at least eighteen (18) months following the end of the calendar year to which they pertain, during which time Licensor, or Licensor’s appointed agents, shall have the right, at Licensor’s expense, through an independent certified public accountant selected by Licensor (“**Licensor’s CPA**”), to inspect, copy, and audit such records during normal business hours to verify any reports and payments made. Licensor shall have the right to inspect Licensee’s books and records as needed in Licensor’s reasonable discretion. In the event that any audit performed under this **Section 3.8** reveals [\*\*\*], Licensee shall bear the full cost of

such audit and shall remit any amounts due to Licensor within sixty (60) days of receiving notice thereof from Licensor. In the event that any audit performed under this **Section 3.8** reveals an [\*\*\*], Licensor shall return the [\*\*\*] to Licensee within sixty (60) days of receiving the audit report or credit Licensee in an amount of [\*\*\*]. If Licensee disputes the findings of the Licensor's CPA, then within thirty (30) days after receipt by Licensee of Licensor's CPA's report, Licensee shall designate an independent certified public accountant (" **Licensee's CPA** ") to work with the Licensor's CPA in a commercially reasonable manner in an attempt to resolve the disputed findings. If the Licensor's CPA and the Licensee's CPA are unable to resolve the differences, the Licensor's CPA and the Licensee's CPA will agree upon an independent third-party CPA (The "**Independent Third-Party CPA**") and the Independent Third-Party CPA shall review and inspect the identical books, records, and other documents reviewed by the Licensor's CPA and the Licensee's CPA and issue an independent report pertaining thereto (the "Independent Third-Party Report"). The Independent Third-Party Report shall be binding upon both parties. If the Independent Third-Party Report reflects an [\*\*\*] then being reviewed, the reasonable and necessary fees and expenses of the Licensor's CPA and the Independent Third-Party's CPA shall be paid by the Licensee. Otherwise, the fees and expenses of the Licensee's CPA and the Independent Third-Party CPA shall be paid by the Licensor.

## ARTICLE 4

### TERM AND TERMINATION

4.1 *Term.* The term of this Agreement shall commence on the Effective Date, and shall continue in full force and effect until either (i) termination by either Party in accordance with Section 4.2 or (ii) upon the last to occur of [\*\*\*].

#### 4.2 *Termination for Cause.*

4.2.1 *By Licensee.* Licensee may terminate this Agreement for Cause. For purposes of this paragraph, "Cause" shall mean any material breach of any material provision of this Agreement by Licensor that is not cured within sixty (60) days after receipt by Licensor of written notice thereof from Licensee or, in the event that cure is not possible within such sixty (60) day period, Licensor shall have taken reasonable steps to ensure that the breach is cured as soon as reasonably possible.

4.2.2 *By Licensor.* Licensor may terminate this Agreement (i) for Cause or (ii) immediately upon written notice to Licensee if Licensee or any Sublicensee brings a patent challenge against Licensor, or assists others in bringing a patent challenge against Licensor (except as required under a court order or subpoena). For purposes of this paragraph, "Cause" shall mean any material breach of any material provision of this Agreement by Licensee that is not cured within sixty (60) days after receipt by Licensee of written notice thereof from Licensor or, in the event that cure is not possible within such sixty (60) day period, Licensee shall have taken reasonable steps to ensure that the breach is cured as soon as reasonably possible; provided, however, that if the material breach is non-payment to Licensor of amounts due, then Licensee shall have sixty (60) days to cure, except in circumstances where there is a good faith dispute between the Parties as to sums due and owing and the Parties are engaged in a dispute resolution process to determine the legitimacy of any demand for sums due and any undisputed amounts are paid in full.

4.2.3 *Termination for Insolvency of Bankruptcy.* Either Party may, by written notice, terminate this Agreement with immediate effect if the other Party: (i) makes a general assignment for the benefit of creditors; (ii) files an insolvency petition in bankruptcy; (iii) petitions for or acquiesces in the appointment of any receiver, trustee or similar officer to liquidate or conserve its business or any substantial part of its assets; (iv) commences proceeding involving its insolvency, bankruptcy, reorganization, adjustment of debt, dissolution, liquidation or any other similar proceeding for the release of financially distressed debtors under the laws of any jurisdiction; or (v) becomes a party to any proceeding or action of the type described above in (iii) or (iv), and such proceeding or actions remains =dismissed or =stayed for a period of more than ninety (90) days.

4.2.4 *Termination Without Cause.* Licensee may terminate this Agreement without cause, upon providing sixty (60) days written notice to Licensor by certified mail.

#### 4.3 *Effect of Termination.*

4.3.1 *Expiration.* Upon any expiration of this Agreement pursuant to **Section 4.1(i) or (ii)** hereof, the license granted to Licensee under **Article 2** shall survive such termination but shall convert to non-exclusive, fully paid up, irrevocable and perpetual license.

4.3.2 *Termination by Licensee pursuant to Section 4.2.1.* Upon termination of this Agreement by Licensee pursuant to **Section 4.2.1**, Licensee's license rights in **Article 2** shall survive such termination and remain in full force and effect; provided that Licensee fulfills its payment obligations and other obligations under **Article 3**. The foregoing shall be in addition to any other rights of Licensee against Licensor pursuant to this Agreement or applicable law.

4.3.3 *Termination by Licensor pursuant to Section 4.2.2.* Upon termination of this Agreement by Licensor pursuant to **Section 4.2.2**, (i) Licensee's license rights under the Licensed Patents and Licensed Know-How and all other rights of Licensee hereunder shall terminate. The foregoing shall be in addition to any other rights of Licensor against Licensee pursuant to this Agreement or applicable law and (ii) Licensee shall promptly return to Licensor all Licensor Confidential Information, and all other documentation in the possession of Licensee relating to the Licensed Products, including, without limitation, all studies, data, protocols, materials, results and regulatory filings.

4.3.4 *Termination by Licensee pursuant to Section 4.2.4.* Upon termination of this Agreement by Licensee pursuant to **Section 4.2.4**, Licensee's license rights under the Licensed Patents and Licensed Know-How and all other rights of Licensee hereunder shall terminate. Licensee shall promptly return to Licensor all Licensor Confidential Information, and all other documentation in the possession of Licensee relating to the Licensed Products, including, without limitation, all studies, results and regulatory filings.

4.3.5 *Remedies.* Termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring prior to such termination.

4.4 *Survival.* **Article 1, Section 3.5** and **Articles 4, 5 and 7 through 10**, shall survive expiration or termination of this Agreement for any reason.

## ARTICLE 5

### CONFIDENTIALITY

5.1 *Confidential Information.* Except as expressly provided in this Agreement, neither Party shall use, other than a Permitted Use, as defined below, or disclose to any third party, any confidential, proprietary or trade secret information (the “**Confidential Information**”) received from the other Party hereto, during the term of this Agreement and for five (5) years thereafter.

5.2 *Limitations.* Notwithstanding **Section 5.1** above, Confidential Information shall not include any of the following information which the receiving Party can demonstrate by competent evidence: (i) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure, as evidenced by the receiving Party’s written records; (ii) was generally available to the public or otherwise part of the public domain at the time of disclosure to the receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (iv) was independently developed by the receiving Party without reference to any information or materials disclosed by the disclosing Party, as evidenced by the receiving Party’s written records; or (v) was subsequently disclosed to the receiving Party by a person without breach of any legal obligation to the disclosing Party.

5.2.1 *Permitted Disclosures.* In addition, either Party may disclose Confidential Information of the other (i) to their legal representatives, employees and Affiliates, and legal representatives and employees of Affiliates, consultants and Sublicensees, to the extent such disclosure is reasonably necessary to achieve the purposes of this Agreement, and provided such representatives, employees, consultants and Sublicensees have agreed in writing to obligations of confidentiality with respect to such information no less stringent than those set forth herein; (ii) in connection with the filing and prosecution of the Licensed Patents; (iii) to a potential Sublicensee or as reasonably required in the course of a contemplated public offering or private financing provided that the receiving person shall have agreed in writing to obligations of confidentiality with respect to such information no less stringent than those set forth herein; or (iv) if disclosure is compelled to be disclosed by a court order or applicable law or regulation, provided that the Party compelled to make such disclosure requests confidential treatment of such information, provides the other Party with sufficient advance notice of the compelled disclosure to provide adequate time to seek a protective order and discloses only the minimum necessary to comply with the requirement to disclose.

5.2.2 *Permitted Use.* The Confidential Information may only be used to develop, market, and sell Licensed Products (each, a “**Permitted Use**” and, collectively, the “**Permitted Uses**”).

5.3 *Non-Disclosure.* The terms of this Agreement shall not be publicly disclosed by Licensee or Licensor to any third party unless both Parties expressly agree in writing. However,

this restriction shall not apply to communications required by law or regulation, except that in such event the Parties shall coordinate to the extent possible with respect to the details of any such announcement. This restriction shall not apply to disclosures of the terms of this Agreement made to officers, directors, shareholders, employees, investment bankers, attorneys and other professional advisors, consultants, prospective investors and/or strategic partners of either Party, all of whom shall take such information subject to provisions of confidentiality consistent herewith. Once a particular public disclosure has been approved with respect to a particular third party, further disclosures to such third party which do not differ materially therefrom may be made without obtaining any further consent of the other Party.

## ARTICLE 6

### PATENT RIGHTS AND RESPONSIBILITIES

6.1 *Patent Prosecution and Maintenance.* Licensor shall have the initial right and obligation [\*\*\*]. Licensor shall consider, to the extent possible, any comments made by Licensee and its counsel in connection therewith, and shall [\*\*\*] unless such comments would adversely affect the reasonable interests of Licensor. If Licensor intends to [\*\*\*].

6.2 *Patenting Costs.* Subsequent to the Effective Date of the License Agreement, Licensee shall be responsible for payment of [\*\*\*] which shall include but not be limited to issuance fees, grant fees, maintenance fees and [\*\*\*].

6.3 *Ongoing External Patenting Costs.* For any Patenting Costs [\*\*\*] (either orally or in writing, including via email) of all material actions necessary for the filing, prosecution, issuance and maintenance of such Licensed Patents, together with an estimate of Patenting Costs for same. [\*\*\*]. Payments directly to [\*\*\*] are made with the understanding that such payments [\*\*\*]. Time is of the essence with respect to such payments.

#### 6.4 *Infringement.*

6.4.1 *Disclosure.* In the event that either Licensor or Licensee becomes aware of the infringement of any Licensed Patents, each shall promptly inform the other in writing of all details available.

6.4.2 *Licensee Rights.* In the event of infringement by a third party of any Licensed Patents, Licensee may enforce the Licensed Patents against the infringers by appropriate legal proceedings or otherwise. Licensor agrees to join in any enforcement proceedings at the request of Licensee, and at Licensee's expense. Licensee shall be responsible for all costs and expenses of any enforcement activities, including legal proceedings, against infringers in which Licensee participates. Licensor may at their own expense be represented by their counsel in any such legal proceedings acting in an advisory but not controlling capacity.

6.4.3 *Allocation.* After deduction of the costs and expenses of enforcement for which Licensee is responsible under **Section 6.4.2**, all recoveries by way of royalties and damages with respect to infringement actions instituted during the terms of this Agreement, excluding any

prosecuted by Licensor under **Section 6.4.4**, shall belong to Licensee and shall be considered Net Sales under this Agreement, giving rise to royalty obligations under **Article 3**.

6.4.4 *Licensor Rights*. In the event of infringement by a third party of any Licensed Patents which Licensor wishes to prosecute, Licensor shall first make a written request or demand that Licensee proceed with such prosecution. In the event that Licensee fails or declines to proceed within thirty days after receipt of a written request or demand by Licensor to do so, then Licensor in their own discretion, may prosecute the infringer in the name of Licensor and Licensee. Any actions by Licensor pursuant to this clause shall be at their own expense. Licensor may collect and retain for their use any and all recoveries in any proceeding pursuant to their rights under this clause. Recoveries collected and retained by Licensor under this **Section 6.4.4** shall not be considered Net Sales or give rise to royalty obligations under **Article 3**. Licensee will execute any documents necessary for Licensor to exercise their rights under this clause.

6.5 *Default Rights*. Licensee shall have the right but not the obligation to intercede in the event Licensor defaults in its obligations or materially fails to take timely steps to manage and protect the Licensed Patents in a commercially reasonable manner to ensure the preservation and uninterrupted use of the entirety of the license rights granted hereunder.

## ARTICLE 7

### INDEMNIFICATION

7.1 *By Licensee*. Licensee agrees to indemnify, hold harmless, and defend Licensor and its Affiliates, officers, directors, partners, employees, and agents (each, "**Licensor Indemnitee**"), from and against any and all losses, damages, costs, fees, expenses (including attorneys' fees), fines, penalties and other liabilities resulting from, arising out of, or related to, (i) any product, process, or service that is made, used, sold, imported or performed by Licensee (or its Sublicensees, agents, contractors, distributors, consultants or employees) in the exercise of the license rights granted herein or otherwise in connection with the Licensed Patents or Licensed Know-How and (ii) any material breach of any of its representations, warranties, covenants or agreements under this Agreement; provided, however, that Licensee shall not be liable for any negligence or intentional wrongdoing on the part of any Licensor Indemnitee.

7.2 *By Licensor*. The Licensor agrees to indemnify, hold harmless, and defend Licensee and its Affiliates, officers, directors, partners, employees, and agents (each, "Licensee Indemnitee"), from and against any and all losses, and other liabilities resulting from, arising out of, or related to, any product, process, or service that was made, used, sold, imported or performed by Licensor (or its Sublicensees, agents, contractors, distributors, consultants, or employees) in connection with the Licensed Patents or Licensed Know-How occurring prior to the Effective Date of this Agreement.

7.3 *Procedure*. All indemnification obligations in this Agreement are conditioned upon the party seeking indemnification: (i) promptly notifying the indemnifying party of any claim or liability of which the party seeking indemnification becomes aware (including a copy of any related complaint, summons, notice or other instrument); provided, however, that failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its

obligations hereunder except to the extent that the indemnifying party is prejudiced by such failure; (ii) cooperating with the indemnifying party in the defense of any such claim or liability (at the indemnifying party's expense); and (iii) not compromising or settling any claim or liability without prior written consent of the indemnifying party. Except with the written consent of each indemnitee, no indemnitor shall enter into any settlement that does not include the unconditional release of each indemnitee from all liability with respect to indemnified claims.

7.4 *Insurance.* Prior to the first commercial sale of any Licensed Product, Licensee will procure and maintain at its expense comprehensive general liability insurance with a reputable insurer in the amount of not less than [\*\*\*]. Such comprehensive general liability insurance shall [\*\*\*]. Licensee will maintain such insurance during the period that any Licensed Product is being distributed, sold or provided by Licensee. Licensee will provide Licensor with written evidence of such insurance upon request of Licensor, and will provide Licensor with written notice at least thirty (30) days prior to any cancellation, non-renewal, reduction or other material change in such insurance.

## ARTICLE 8

### REPRESENTATIONS AND WARRANTIES

8.1 *Licensor.* Licensor represents and warrants that: (i) it is a corporation duly organized validly existing and in good standing under the laws of the State of Florida; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate actions on the part of Licensor; (iii) Licensor is the sole and exclusive owner of all right, title and interest in and to the Licensed Patents; (iv) none of the Licensed Patents has been legally declared invalid or is the subject of a pending or threatened action or proceeding for opposition or cancellation, or any reexamination, opposition or interference proceeding, or any form of proceeding for a declaration of invalidity, or other proceeding or action to invalidate, render unenforceable, limit in scope, or otherwise limit any Licensor's rights in the Licensed Patents; (v) Licensor has the right to grant the rights and licenses granted herein; (vi) it has not previously granted, and will not grant during the Term of this Agreement, any right, license or interest in or to the Licensed Know-How or Licensed Patents or any portion thereof in the Field, inconsistent with the license granted to Licensee herein; and (vii) the list of patents and patent applications in **Exhibit A** is a complete and accurate list of all patents and patent applications owned or controlled by Licensor as of the Effective Date that relate to the Field.

8.2 *Licensee.* Licensee represents and warrants that: (i) it is a corporation duly organized validly existing and in good standing under the laws of the State of Delaware and (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of Licensee.

8.3 *Warranty Exclusions.* EXCEPT AS EXPRESSLY SET FORTH IN THIS **ARTICLE 8**, NO PARTY MAKES ANY OTHER EXPRESS OR IMPLIED WARRANTY AS TO THE LICENSED KNOW-HOW, LICENSED PATENTS OR THE LICENSED PRODUCTS, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF TITLE, NON-

INFRINGEMENT, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND HEREBY DISCLAIMS THE SAME.

## ARTICLE 9

### DISPUTE RESOLUTION

9.1 *Mediation.* Excluding emergency actions for injunctive relief contemplated by **Section 9.4**, in the event of any dispute, a complaining party shall promptly communicate the circumstances of any disagreement in writing with sufficient facts to enable the responding party to understand and react to the complaint. The respondent shall then promptly act in good faith to engage in direct written and oral communications with the complainant including, as required, one or more executive officers of each Party to negotiate a formal resolution to any dispute. Should such dispute not be remedied to the satisfaction of the complainant within thirty (30) days of such communication, the Parties hereby agree to undertake mediation at a shared cost for a period of no less than thirty (30) days in an effort to resolve such issue without formal legal action as set forth in **Section 9.2**.

9.2 *Disputes.* Subject to **Sections 9.1 and 9.4**, should mediation be unsuccessful, the Parties agree that all disputes, controversies or differences which may arise between them or for the breach of any of the terms hereof shall be referred to and settled by arbitration in accordance with the Rules of the American Arbitration Association (“**Rules**”) as currently in force by one or more arbitrators appointed under such Rules. Such arbitration hereunder shall be conducted in the English language and shall be held in Miami-Dade County, Florida. The determination of the arbitration shall be final, binding and conclusive upon the Parties hereto. Notwithstanding anything herein to the contrary, the relevant cure periods for breach under this Agreement shall be suspended while either Party pursues resolution to a dispute through arbitration.

9.3 *Prevailing Party.* The substantially prevailing Party shall be entitled to reimbursement of reasonable fees and costs, including attorneys’ fees.

9.4 *Injunctive Relief.* Notwithstanding anything to the contrary contained in this **Article 9**, either Party may seek a preliminary injunction or other provisional equitable relief in a court of competent jurisdiction if, in its reasonable judgment, such action is necessary to avoid irreparable harm to itself or to preserve its rights under this Agreement.

## ARTICLE 10

### GENERAL

10.1 *Governing Law.* This Agreement shall be governed by and construed in accordance with the laws of the State of Florida, without reference to principles of conflicts of laws.

10.2 *Independent Contractors.* The relationship of the Parties hereto is that of independent contractors. The Parties hereto are not deemed to be agents, partners or joint ventures of the other for any purpose as a result of this Agreement or the transactions contemplated thereby.

10.3 *Assignment*. This Agreement shall not be assignable or transferable, by operation of law or otherwise, by either Party without the other Party's written consent, which shall not be unreasonably withheld, except that either Party or its permitted assignees may assign this Agreement (i) in whole or in part to an Affiliate of the assigning Party provided that the assigning Party agrees in writing to remain liable for the Affiliate's performance of its obligations under this Agreement; or (ii) in whole to an independent third party who acquires all or substantially all of the assets of the assigning Party or the assets of the business of the assigning Party to which this Agreement relates; provided that in each case the assignee agrees in writing to assume the assigning Party's obligations under this Agreement. Any attempt to assign or transfer this Agreement or any portion thereof in violation of this **Section 10.3** shall be void. For the avoidance of doubt, in addition to the above, Licensor shall be permitted to transfer ownership of one or more of the Licensed Patents provided that the new owner becomes a party to this Agreement and added to the definition of Licensor. Upon such transfer, the transferring party shall no longer be a party to this Agreement and shall be automatically released from any and all obligations under this Agreement with no further action required.

10.4 *Right to Independently Develop*. Nothing in this Agreement will impair Licensee's right to independently acquire, license, develop for itself, or have others develop for it, intellectual property and technology performing similar functions as the Licensed Know-How or Licensed Patents or to market and distribute products based on such other intellectual property and technology, provided that the Licensee is in compliance with the obligations set forth in Article 5.

10.5 *Notices*. Any required notices hereunder shall be given in writing by certified mail or overnight express delivery service at the address of each Party set forth in the recitals, or to such other address as either Party may indicate on its behalf by written notice. Notice shall be deemed served when delivered or, if delivery is not accomplished by reason or some fault of the addressee, when tendered.

10.6 *Force Majeure*. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses (except for payment obligations) on account of failure of performance by the defaulting Party if the failure is occasioned by war, strike, fire, Act of God, earthquake, flood, lockout, embargo, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control and not caused by the negligence, intentional conduct or misconduct of the non-performing Party and the non-performing Party has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance.

10.7 *Compliance with Laws*. Each Party shall furnish to the other Party any information reasonably related to the subject matter of this Agreement requested or required by that Party during the term of this Agreement or any extensions hereof to enable that Party to comply with the requirements of any U.S. or foreign federal, state and/or government agency.

10.8 *Limitation Of Liability*. EXCEPT AS PROVIDED UNDER **ARTICLE 7**, OR IN THE EVENT OF A BREACH UNDER **ARTICLE 5**, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT

DAMAGES ARISING OUT OF THE PERFORMANCE OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

10.9 *Further Assurances.* At any time or from time to time on and after the date of this Agreement, Licensor shall at the reasonable written request of Licensee (i) deliver to Licensee such records, data or other documents consistent with the provisions of this Agreement, (ii) execute and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as Licensee may reasonably deem necessary or desirable in order for Licensee to obtain the full benefits of this Agreement and the transactions contemplated hereby.

10.10 *Severability.* In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall remain in full force and effect without said provision. The Parties shall in good faith negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties in entering this Agreement.

10.11 *Waiver.* The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce that provision or any other provision.

10.12 *Entire Agreement and Amendments.* This Agreement sets forth the entire agreement and understanding of the Parties with respect to the subject matter hereof, and supersedes all prior discussions, agreements and writings in relating thereto. This Agreement may not be altered, amended or modified in any way except by a writing signed by both Parties. Future amendments shall be made in substantially the same form as indicated in Exhibit 2 of this Agreement.

10.13 *Counterparts.* This Agreement may be executed in two counterparts which may be delivered by fax or email, each of which shall be deemed an original and which together shall constitute one instrument. Upon request, each party shall provide an original signature to the other party.

*Signature page follows*

IN WITNESS WHEREOF, Licensor and Licensee have executed this License Agreement by their respective duly authorized representatives.

**BODOR LABORATORIES, INC.**

By: /s/ Erik T. Bodor

Date: December 17<sup>th</sup>, 2012

By: /s/ Nicholas Bodor  
Nicholas Bodor, Individually

**BRICKELL BIOTECH, INC.**

By: /s/ Andrew Sklawer  
Andrew Sklawer, Vice President

**Date:** December 15, 2012

**EXHIBIT A**

**List of Patents and Patent Applications**

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**EXHIBIT B**

**Annual Development Plan for Brickell Biotech, Inc.**

[\*\*\*]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT NO. 1 TO  
LICENSE AGREEMENT**

**THIS AMENDMENT NO. 1 TO LICENSE AGREEMENT** (“Amendment No. 1”) is made effective October 21, 2013 (the “Effective Date”) by and among **BODOR LABORATORIES, INC.**, a Florida corporation, having an office located at 4400 Biscayne Boulevard, Suite 980, Miami, FL 33137 (“BLI”) and **NICHOLAS S. BODOR**, a Florida resident residing at 10225 Collins Ave., Apt 1002, Bal Harbour, FL, USA 33154 (“Bodor”) (collectively BLI and Bodor are referred to herein as “Licensor”), and **BRICKELL BIOTECH, INC.**, a Delaware corporation having an office located at 2600 Southwest Third Avenue, Suite 350, Miami, Florida 33129, and any Affiliates (collectively, “Licensee”).

WITNESSETH:

**WHEREAS**, Licensor and Licensee entered into an exclusive license agreement dated December 15, 2012 (the “License Agreement”); and

**WHEREAS**, Licensee and Licensor desire to amend Exhibit A of the License Agreement to [\*\*\*].

**NOW, THEREFORE**, Licensee and Licensor, in consideration of the mutual covenants and agreements and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, do hereby agree as follows:

1. Amendments. The License Agreement is hereby amended as follows:
  - a. *Exhibit A of the License Agreement*. Exhibit A is hereby amended and restated in its entirety as set forth in the revised “Exhibit A” attached hereto and made part of this Amendment No. 1 as **Attachment A**.
2. Capitalized Terms. Capitalized terms herein shall, unless otherwise provided for in this Amendment No. 1 have the same meaning as set forth in the License Agreement.
3. Term and Termination. This Amendment No. 1 shall be effective and shall run concurrently with the License Agreement. In the event that the License Agreement shall be terminated for any reason, this Amendment No. 1 shall also be terminated.
4. Counterparts. This Amendment No. 1 may be executed in any number of counterparts, with the same effect as if all had signed the same document. All counterparts shall be construed together and shall constitute one agreement.

5. Full Force and Effect. Except as specifically set forth herein, all other terms and provisions of the License Agreement shall remain in full force and effect. In the event of a conflict between this Amendment No. 1 and the License Agreement, this Amendment No. 1 shall govern.

IN WITNESS WHEREOF, the Parties hereto executed this Amendment No. 1 to the License Agreement as of the Effective Date.

**BODOR LABORATORIES, INC.**

By: /s/ Erik T. Bodor

Its: VP Research and CFO

Date: October 29, 2013

By: /s/ Nicholas Bodor  
Nicholas Bodor, Individually

Date: October 29, 2013

**BRICKELL BIOTECH, INC.**

By: /s/ Andrew Sklawer  
Andrew Sklawer, Vice President

Date: October 29, 2013

**ATTACHMENT A**

**List of Patents and Patent Applications**

[\*\*\*]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT NO. 2 TO  
LICENSE AGREEMENT**

**THIS AMENDMENT NO. 2 TO LICENSE AGREEMENT** (“Amendment No. 2”) is made effective [March 31], 2015 (the “Effective Date”) by and among **BODOR LABORATORIES, INC.**, a Florida corporation, having an office located at 4400 Biscayne Boulevard, Suite 980, Miami, FL 33137 (“BLI”) and **NICHOLAS S. BODOR**, a Florida resident residing at 10225 Collins Ave., Apt 1002, Bal Harbour, FL, USA 33154 (“Bodor”) (collectively BLI and Bodor are referred to herein as “Licensor”). and **BRICKELL BIOTECH, INC.**, a Delaware corporation having an office located at 2600 Southwest Third Avenue, Suite 350, Miami, Florida 33129, and any Affiliates (collectively, “Licensee”).

WITNESSETH:

**WHEREAS**, Licensor and Licensee entered into an exclusive license agreement dated December 15, 2012 as amended by Amendment No. 1 to License Agreement, effective as of October 21, 2013 (the “License Agreement”); and

**WHEREAS**, Licensee and Licensor desire to make certain amendments to the License Agreement.

**NOW, THEREFORE**, Licensee and Licensor, in consideration of the mutual covenants and agreements and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, do hereby agree as follows:

1. Addition of Defined Term. The following shall be added immediately after Section 1.1 of the License Agreement as a new Section 1.2 (and the remaining defined terms shall be renumbered accordingly):

1.2 “*Asia*” shall mean Japan, China (including Hong Kong), South Korea, Taiwan, Malaysia, Cambodia, Singapore, Thailand, Indonesia and Vietnam.

2. Amendment to Section [\*\*\*] of the License Agreement. [\*\*\*]:

2.2.1 *Diligence Events*. Licensee shall use [\*\*\*] at its own cost and expense to [\*\*\*].

[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

3. Amendment to Section 3.2.2 of the License Agreement. Section 3.2.2 of the License Agreement is hereby amended and restated as follows:

3.2.2 [\*\*]:

3.2.2.1 [\*\*]:

[**]	[**]
[**]	[**]
[**]	[**]

[\*\*].

3.2.2.2 [\*\*].

4. Amendment to Exhibit A of the License Agreement. Exhibit A of the License Agreement is hereby amended and restated as set forth on Attachment A.

5. Capitalized Terms. Capitalized terms herein shall, unless otherwise provided for in this Amendment No. 2 have the same meaning as set forth in the License Agreement.

6. Term and Termination. This Amendment No. 2 shall be effective and shall run concurrently with the License Agreement. In the event that the License Agreement shall be terminated for any reason, this Amendment No. 2 shall also be terminated.

7. Counterparts. This Amendment No. 2 may be executed in any number of counterparts, with the same effect as if all had signed the same document. All counterparts shall be construed together and shall constitute one agreement.

8. Full Force and Effect. Except as specifically set forth herein, all other terms and provisions of the License Agreement shall remain in full force and effect. In the event of a conflict between this Amendment No. 2 and the License Agreement, this Amendment No. 2 shall govern.

**IN WITNESS WHEREOF**, the Parties hereto executed this Amendment No. 2 to the License Agreement as of the Effective Date.

**BODOR LABORATORIES, INC.**

By: /s/ Erik T. Bodor

Its: CFO

By: /s/ Nicholas Bodor

Nicholas Bodor, Individually

**BRICKELL BIOTECH, INC.**

By: /s/ Andrew Sklawer

Andrew Sklawer, Vice President

**ATTACHMENT A**

**List of Patents and Patent Applications**

[\*\*\*]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED  
BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**[\*\*\*] LICENSE AGREEMENT**  
**BETWEEN**  
**THE UAB RESEARCH FOUNDATION**  
**AND**  
**BRICKELL BIOTECH, INC.**

**DATED JUNE 26, 2012**

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## TABLE OF CONTENTS

		Page
ARTICLE 1	DEFINITIONS	1
ARTICLE 2	GRANT OF LICENSE	4
ARTICLE 3	DEVELOPMENT AND COMMERCIALIZATION	6
ARTICLE 4	PROTECTION OF THE LICENSED PATENTS; PATENT PROSECUTION	7
ARTICLE 5	FINANCIAL TERMS	8
ARTICLE 6	RECORDKEEPING AND AUDIT RIGHTS	11
ARTICLE 7	INFRINGEMENT; ENFORCEMENT	12
ARTICLE 8	OTHER COVENANTS AND AGREEMENTS	14
ARTICLE 9	TERM AND TERMINATION	17
ARTICLE 10	COVENANTS; REPRESENTATIONS AND WARRANTIES; LIMITATIONS ON UABRF'S OBLIGATIONS	18
ARTICLE 11	LIABILITY AND INDEMNIFICATION	20
ARTICLE 12	MISCELLANEOUS	20
EXHIBIT A	LICENSED PATENTS	25
EXHIBIT B	DEVELOPMENT AND COMMERCIALIZATION PLAN AND [***]	26
EXHIBIT C	FORM OF [***] REPORT	31

## [\*\*\*] LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made and is effective as of the 26th day of June, 2012 (the "Effective Date") between THE UAB RESEARCH FOUNDATION, an Alabama not-for-profit corporation ("UABRF") and BRICKELL BIOTECH, INC., a Delaware corporation (the "Licensee").

### RECITALS:

WHEREAS, UABRF owns all right, title and interest in and to those patented and patent pending advances developed by [\*\*\*] (the "Inventors") outlined in UABRF Intellectual Property disclosures [\*\*\*] and [\*\*\*] referenced and made a part of this Agreement as set forth in Exhibit A ("**Exhibit A**");

WHEREAS, UABRF desires to have the intellectual property developed and commercialized to benefit the public; and WHEREAS, the Licensee, a pharmaceutical company specializing in the field of dermatology pharmaceuticals, desires to obtain a license to the Licensed Patents upon the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the premises described above and the mutual promises and agreements set forth in this Agreement, the Parties agree as set forth below.

### **ARTICLE I DEFINITIONS**

The Definitions used in this Agreement are set forth below.

- 1.1 "Affiliate" means any Person that directly or indirectly controls, is controlled by, or is under common control with a Party. "Control" means (i) the beneficial ownership of at least fifty percent (50%) of the voting securities of a Person with voting equity, or (ii) the power to direct or cause the direction of the management or policies of a Person.
- 1.2 "Agreement" means this agreement, as amended from time to time in accordance with the terms and conditions set forth in this agreement.
- 1.3 "Applicable Law" means all laws, statutes and regulations promulgated by all Regulatory Authorities and all Governmental Authorities.
- 1.4 "Development and Commercialization Plan" or "Plan" means a report of those development, manufacturing, marketing and commercialization activities proposed or undertaken by the Licensee with respect to the Licensed Patents as further detailed in **Section 3.1** and in a form similar to **Exhibit B**.
- 1.5 [\*\*\*].
- 1.6 "First Commercial Sale" means the first sale of a Licensed Product to a Third Party.

- 1.7 “For Value” means any consideration, remuneration or benefit of any kind, whether received directly or indirectly, including, but not limited to, cash, equity, debt, preferential treatment, including waiver, rebate, discount, etc.
- 1.8 “Governmental Authorities” means, with respect to each country or jurisdiction, all legislative and governmental authorities, bodies, commissions, agencies or other instrumentalities of such country or jurisdiction.
- 1.9 “Infringement Notice” is defined in **Section 7.1** of this Agreement.
- 1.10 “Inventors” are defined in the first recital of this Agreement.
- 1.11 “Licensed Field of Use” means the [\*\*\*].
- 1.12 “Licensed Patents” means (a) the patents and/or patent applications set forth in **Exhibit A**, (b) any foreign patent applications based thereon, (c) all patents proceeding from such domestic and foreign patent applications, (d) all claims of continuations-in-part that are entitled to the benefit of the priority date of the parent Licensed Patent and are enabled by subject matter that is disclosed in the parent Licensed Patent, (e) any patent or patent application jointly developed by the Parties and or their Representatives arising from the Licensed Patents (“New Patents”) as described in **Section 4** below and (f) all divisionals, continuations, reissues, reexaminations and extensions of any patent or patent application described in (a) - (e) above. Licensed Patents specifically excludes [\*\*\*].
- 1.13 “Licensed Product” means any product or part thereof, process or service, the development, manufacture, use, import, export, offer for sale or sale of which is covered by, or which cannot be undertaken or completed without infringing, a Valid Patent Claim set forth in any Licensed Patent.
- 1.14 “Licensed Territory” means [\*\*\*].
- 1.15 “Management Activities” means any and all Protection Activities and any other steps deemed necessary and reasonable to commercialize the Licensed Patents.
- 1.16 “Net Sales” means the gross revenue and other consideration paid to Licensee or its Affiliates or Sublicensees for [\*\*\*], which are sold, leased or otherwise commercialized by or for Licensee or any of its Affiliates or Sublicensees; however, sales or other transfers of [\*\*\*] between Licensee and its Affiliates or Sublicensees shall be excluded from the computation of Net Sales, and no payments will be payable to UABRF on such sales or transfers except where such Affiliates or Sublicensees are end users or consumers; invoiced amounts shall be reduced by the following deductions, directly attributable to the [\*\*\*] and specifically identified in writing, and borne by the seller to the extent they are included in such gross revenue or other consideration:

[\*\*\*]

A Licensed Product shall be considered sold when it is shipped, delivered, or invoiced, whichever is earlier. No deductions shall be made from Net Sales for commission paid to individuals whether they are with independent sales agencies or are regularly employed by Licensee or its Affiliates or Sublicensees and are on its or their payroll, or for the cost of collections. In the event Licensee transfers a Licensed Product to a Third Party in a bona fide arm's length transaction, for consideration, in whole or in part, other than cash, then the Net Sales price for such Licensed Product shall be deemed to be the standard invoice price then being invoiced by Licensee in an arm's length transaction with similar companies, and in the absence of such standard invoice price, then the reasonable Fair Market Value of the Licensed Product, shall be determined in the ordinary course of business using the accrual method of accounting in accordance with generally accepted accounting principles.

- 1.17 "Non-Commercial Research Purposes" means any use and practice for academic research and educational purposes, including research sponsored by commercial, for-profit Third Parties, but excluding any disclosure of Proprietary Information of Licensee to such commercial, for-profit Third Parties.
- 1.18 [\*\*\*].
- 1.19 "Parties" means each of UABRF and the Licensee, and each of them individually is a "Party."
- 1.20 "Person" means an individual, corporation, partnership, trust, business trust, association or any other entity with a separate legal identity, including the Parties.
- 1.21 "Proprietary Information" is defined in **Section 8.4**.
- 1.22 "Protection Activities" means taking all actions deemed commercially necessary and desirable to protect the Licensed Patents, including, but not limited to, obtaining, filing for, securing, pursuing, prosecuting, continuing or maintaining, the Patents and patent application(s).
- 1.23 "Protection Expenses" means all legal fees, costs and expenses reasonably incurred by either Party in the performance of the Protection Activities, with such fees, costs and expenses to be documented by written invoice.
- 1.24 "Regulatory Authority" means, with respect to any particular country or jurisdiction, the Governmental Authority with the primary responsibility for the evaluation or approval of pharmaceutical products before such products can be tested, marketed, promoted, distributed or sold in such country, including Governmental Authorities that have jurisdiction over the pricing of such products. The term Regulatory Authority shall include the U.S. Food and Drug Administration.
- 1.25 "Representative(s)" means, with respect to each Party and their Affiliates, all trustees, directors, officers, employees, agents and professional advisors.

- 1.26 “Sublicensee” means a Person to whom the Licensee has granted a sublicense pursuant to **Section 2.5** of this Agreement.
- 1.27 “Term” is defined in **Section 10.1**.
- 1.28 “Third Party” means any Person other than the Parties and their Affiliates.
- 1.29 “United States” means the United States of America.
- 1.30 “Valid Patent Claim” means (i) a pending patent claim included within the Licensed Patents or (ii) an issued and unexpired patent claim included within the Licensed Patents which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, to which an appeal has not or cannot be taken within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

## ARTICLE 2 GRANT OF LICENSE

- 2.1 Grant of License. Subject to the terms and upon the conditions set forth in this Agreement, UABRF hereby grants to the Licensee [\*\*\*] to (i) practice the [\*\*\*] and (ii) make, have made, develop, use, license, offer to sell, sell, import and export [\*\*\*], within the [\*\*\*] in the [\*\*\*] during the Term. The Licensee may transfer its rights under this Agreement to an Affiliate, provided such Affiliate assumes all of the obligations of the Licensee under this Agreement.
- 2.2 Rights of the United States Government. It is understood that a United States Governmental Authority (NIH, Grant Nos. P01 CA034968 and P01 CA089019) has funded research, during the course of or under which any of the Licensed Patents were conceived or made, The United States Government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200-212 and applicable regulations of Chapter 37 of the Code of Federal Regulations, to [\*\*\*]. The Licensee acknowledges that the rights and license granted to it pursuant to this Agreement are subject to any and all rights of the United States Government.
- 2.3 Reservation of Rights by UABRF and its Affiliates. UABRF reserves the right, for itself and for its Affiliates, to:
- (a) practice and use, and to permit its Representatives to practice and use, the Licensed Patents within the Licensed Field of Use for Non-Commercial Research Purposes;
  - (b) grant to non-profit academic, educational or research institutions and Governmental Authorities, [\*\*\*];
  - (c) permit their respective Representatives to disseminate and publish scientific findings from research related to the Licensed Patents provided that in the event of any prospective New Patent, Licensee shall be provided advance notice and a reasonable time and opportunity for Protection Activities prior to any disclosure; and

- (d) practice, use and otherwise commercialize, including licensing, the Licensed Patents to Third Parties for applications and uses outside of the Licensed Field of Use.
- 2.4 Title Remains with UABRF. All right, title and interest in and to the [\*\*\*] remains with UABRF. Except as provided in this Agreement, no express or implied licenses with respect to the Licensed Patents or any other rights are transferred or granted to the Licensee by implication, estoppel or otherwise.
- 2.5 Right to Grant [\*\*\*]. The Licensee has the right to grant [\*\*\*] under this Agreement on the following terms and conditions:
- (a) the execution of a [\*\*\*] shall not in any way diminish, reduce or eliminate any of the Licensee's obligations under this Agreement, and the Licensee shall remain primarily liable for such obligations and any breach of any provision of this Agreement [\*\*\*];
  - (b) [\*\*\*] who are not Affiliates of the Licensee, or who are not otherwise immediate family members of, or controlled by the immediate family members of, Persons who control the Licensee;
  - (c) the Licensee shall obtain UABRF's prior written consent of all [\*\*\*], which consent shall not be unreasonably withheld;
  - (d) any [\*\*\*] so granted shall be subject and subordinate to, and consistent with, the terms of this Agreement;
  - (e) the Licensee may not [\*\*\*];
  - (f) any [\*\*\*] shall also provide that, in the event this Agreement is terminated or upon the expiration of the Term, [\*\*\*] on the terms stated therein;
  - (g) [\*\*\*] are to be [\*\*\*] and the Licensee shall not receive f[\*\*\*] under this Agreement without the prior written consent of UABRF;
  - (h) the Licensee shall provide UABRF with [\*\*\*] under this Agreement within thirty (30) days after the [\*\*\*];
  - (i) all such [\*\*\*] confidential scientific information and other information required by [\*\*\*] to be kept confidential, provided that all relevant financial terms and information shall be retained [\*\*\*]; the disclosure of [\*\*\*] to UABRF shall be subject to the confidentiality obligations set forth in this Agreement;
  - (j) UABRF is [\*\*\*], and each agreement evidencing a [\*\*\*] shall include a statement and an acknowledgement [\*\*\*] to this effect; and
  - (k) [\*\*\*].

**ARTICLE 3**  
**DEVELOPMENT AND COMMERCIALIZATION**

- 3.1 Development and Commercialization Plan. During the Term, the Licensee shall [\*\*\*] to develop, manufacture, commercialize and market the Licensed Patents through a diligent program designed to accomplish the commercial exploitation of the technology in the Licensed Patents in accordance with the usual and customary practices for the pharmaceutical and cosmetics industry. The Parties acknowledge that the Licensee has developed a written disclosure setting forth its development and commercialization objectives (the "Plan") as set forth in Exhibit "B" ("**Exhibit B**"). The Parties further acknowledge and agree that the Development and Commercialization Plan is intended to achieve [\*\*\*] in **Section 5.3** and to accomplish the commercialization of the Licensed Products. Accordingly, such Plan is a dynamic arrangement that sets forth prospective activities that may change over time in accordance with research results, market opportunities and business conditions. The Licensee shall consult with UABRF in the design and implementation of its Development and Commercialization Plan to ensure a clear understanding of its proposed activities. However, the Licensee shall have the sole responsibility and control over business objectives and activities.
- 3.2 Amendment of the Plan. All material variations and deviations from and changes to the Plan shall be promptly communicated in writing to UABRF.
- 3.3 Plan Report. The Licensee shall provide UABRF with written progress reports detailing the activities of the Licensee relating to the Plan, each January and July for a period of six (6) years from the Effective Date, or until the First Commercial Sale. As a general guide, each such report shall provide information regarding the accomplishments and progress made by the Licensee during the prior reporting period and the objectives and goals to be reached during the forthcoming reporting period. Subsequent to the foregoing development period and for the balance of this Term of this Agreement, the Licensee shall provide UABRF with annual reports outlining the status of the commercialization activities of the Licensed Products.
- 3.4 Regulatory Approvals. With respect to each Licensed Product, and to the extent regulatory approval is required, the Licensee shall [\*\*\*] to obtain the approval of each applicable Regulatory Authority prior to the First Commercial Sale in each country/jurisdiction in which the Licensee intends to sell Licensed Products.
- 3.5 Patent Markings. The Licensee shall ensure that each Licensed Product manufactured and/or sold in the United States shall bear patent markings that meet all applicable requirements of 35 U.S.C. §287, as amended from time to time. All Licensed Products manufactured and/or sold outside of the United States shall be marked in such a manner as to conform to the Applicable Law of such country/jurisdiction.
- 3.6 Manufacturing in the United States. The Licensee shall use [\*\*\*] any Licensed Products sold in the United States that incorporate any invention or intellectual property owned by

UABRF and licensed to the Licensee under this Agreement that was developed using funds provided by a United States Governmental Authority.

- 3.7 Information Sharing. Within fifteen (15) days of the Effective Date, UABRF shall use reasonable effort to provide Licensee with all information in its immediate possession related to or involving (i) the Licensed Patents and (ii) any and all concepts or data arising from or related to potential further protectable advances in the Licensed Field of Use only. Additionally, UABRF shall make available to Licensee any and all publications that are within UABRF's possession as of the Effective Date.

#### **ARTICLE 4 PROTECTION OF THE LICENSED PATENTS; PATENT PROSECUTION**

4.1 Protection Activities.

- (a) Shared Responsibility. Subject to the terms and conditions set forth in this Agreement, UABRF and Licensee shall work cooperatively to undertake Protection Activities relating to the Licensed Patents. UABRF shall select legal counsel to manage Protection Activities for patents and patent applications existing as of the Effective Date of this Agreement. Licensee anticipates that it will initiate the filing of [\*\*\*]. Licensee shall be permitted to use its own legal counsel in undertaking Protection Activities at its sole cost, provided all such activities shall be coordinated with UABRF legal counsel to secure existing patent rights without conflict. New Patents shall be assigned to UABRF and shall automatically be included in Licensed Patents upon date of filing. Exhibit A shall be amended accordingly to reflect the New Patents.
- (b) Consultation with the Licensee. UABRF, Licensee and their designated legal counsel shall consult with the one another in connection with Protection Activities and neither party will authorize or instruct counsel on prosecution matters without first informing the other of such.
- (c) Foreign Protection Requested by the Licensee. The Licensee must identify those jurisdictions, if any, where the Licensee seeks to undertake Protection Activities with respect to any Licensed Patents. UABRF shall be responsible for coordinating all Protection Activities at Licensee's cost in connection with the specific Licensed Patent in the relevant jurisdictions. Exhibit A shall be amended accordingly to reflect these revised jurisdictions.
- (d) Disclaimed Licensed Patent Rights. The Licensee may, at any time during the Term, provide written notice to UABRF that it no longer wishes to be responsible for the Protection Expenses in connection with one or more Licensed Patents. In such cases, (i) the Licensee shall continue to be responsible for all Protection Expenses incurred in connection therewith until the expiration of sixty (60) days and thereafter shall not be responsible for such expenses, and (ii) the Licensed Patents so affected shall no longer be deemed to be licensed to the Licensee in that specific jurisdiction and

shall be deemed to have been disclaimed by the Licensee (each, a “Disclaimed Licensed Patent Right”), (iii) the Licensee shall forfeit and shall no longer have any rights or obligations with respect thereto and (iv) Exhibit A shall be amended accordingly to delete the affected Licensed Patents.

## ARTICLE 5 FINANCIAL TERMS

- 5.1 Protection Expenses. During the Term and with respect to each Licensed Patent, other than Disclaimed Licensed Patent Rights, the Licensee will be financially responsible for the payment of all Protection Expenses incurred after the Effective Date. The Licensee shall pay such amounts to UABRF within thirty (30) days of receipt of an invoice for the same from UABRF. UABRF shall be responsible for all Protection Expenses incurred in connection with each Disclaimed Licensed Patent Rights in jurisdictions specifically disclaimed by the Licensee upon the expiration of the sixty (60) day notice period referred to in **Section 4.1**.
- 5.2 License Fee. On or before the Effective Date, the Licensee shall pay to UABRF [\*\*\*].
- 5.3 Milestone Payments. During the Term, the Licensee shall pay to UABRF the [\*\*\*] in this **Section 5.3**. Each [\*\*\*]. The Licensee shall provide written notice to UABRF to accompany the payment [\*\*\*].
- [\*\*\*]
- [\*\*\*]
- 5.4 [\*\*\*] Payments. During the Term and with respect to each country or jurisdiction within the Licensed Territory, the Licensee shall pay to UABRF [\*\*\*] arising in such country/jurisdiction until the expiration of the last Valid Patent Claim in that country/jurisdiction. All amounts owing to UABRF under this section shall be paid on a quarterly basis, on or before the thirtieth (30<sup>th</sup>) day following the end of the calendar quarter in which such amounts were earned.
- 5.5 [\*\*\*] Reports. Commencing with the first day of the calendar quarter following the calendar quarter in which the obligation of the Licensee to pay [\*\*\*] is triggered, the Licensee shall provide to UABRF a written report setting forth all applicable information specified in Exhibit “C” (“**Exhibit C**”), which such report shall accompany the [\*\*\*] to UABRF by the Licensee with respect to the preceding calendar quarter. Reports furnished must include the [\*\*\*] by Licensed Product and by country/jurisdiction and must include the rate of currency conversion and the date such conversion was calculated as described in **Section 5.10** of this Agreement, in substantially the format set forth in **Exhibit C**.
- 5.6 [\*\*\*] Income. The Licensee shall pay to UABRF the amounts, as laid out in the chart below [\*\*\*] during the Term with such payments being made to UABRF on or before the thirtieth (30<sup>th</sup>) day of receipt by the Licensee. All such payments shall be accompanied by a written

notification of the nature and origin of the payment, the identity of the original maker of the payment and, if the original payment was made in a foreign currency, must include the rate of currency conversion and the date such conversion was calculated as described in **Section 5.10** of this Agreement. In the event that the Licensee [\*\*\*].

[\*\*\*]

- 5.7 Payments from [\*\*\*]. During the Term, [\*\*\*] arising in the applicable country/jurisdiction until the expiration of the last Valid Patent Claim in that country/jurisdiction. Where sales or other transfers of Licensed Products shall occur between Licensee and/or its Affiliates [\*\*\*], such sales or other transfers shall be [\*\*\*]. For the avoidance of doubt, a [\*\*\*] shall only be payable to UABRF [\*\*\*].
- 5.8 Address for Payments. Except as otherwise directed by UABRF, all amounts due to be paid by the Licensee to UABRF pursuant to this Agreement shall be paid to UABRF at the address set forth below its signature on the signature page of this Agreement.
- 5.9 Late Payment Penalty. The balance of any amount which remains unpaid more than thirty (30) days after it is due to UABRF shall accrue interest until paid at the rate equal to the lesser of [\*\*\*] or the maximum amount allowed under Applicable Law. However, in no event shall this interest provision be construed as a grant of permission for payment delays.
- 5.10 Currency Conversion. All amounts due to be paid to UABRF pursuant to this Agreement shall be made [\*\*\*]. Any and all amounts received by the Licensee or generated in foreign currency shall be [\*\*\*] at the rate quoted in the Wall Street Journal (United States edition) for the last business day of the calendar quarter in which [\*\*\*] are due and payable to UABRF or on a business day no earlier than five (5) business days before payment is made to UABRF.
- 5.11 Taxes. UABRF is exempt from [\*\*\*]; therefore, all payments made by Licensee under this Agreement shall be made without deduction for taxes, assessments or other charges of any kind that are [\*\*\*]. Any tax required to be withheld by the Licensee under the laws of any foreign country or jurisdiction for the account of UABRF shall be promptly paid by the Licensee for and on behalf of UABRF to the appropriate Governmental Authority, and the Licensee shall use [\*\*\*] to furnish UABRF with proof of payment of such tax, together with official or other appropriate evidence issued by the applicable Governmental Authority. Any such amounts actually paid on UABRF's behalf shall be deducted from any amounts due to be paid to UABRF under this Agreement.

## **ARTICLE 6 RECORDKEEPING AND AUDIT RIGHTS**

- 6.1 Books and Records. The Licensee shall keep complete and accurate books, accounts and other records and documentation necessary to ascertain all transactions and events pursuant to which payments due to UABRF pursuant to this Agreement arise and are accrued and to verify the accuracy and completeness of such amounts. All such books, accounts and other records and documentation shall be kept at the Licensee's principal place of business for a

period of not less than six (6) years following the end of the calendar year to which they pertain.

- 6.2 Right to Audit. UABRF shall have the right to have the Licensee's books and records audited by a qualified, independent accounting firm of its choosing, under appropriate confidentiality provisions such as those set forth in Section 8.4 of this Agreement, to ascertain the accuracy of the reports and payments due to UABRF under this Agreement and compliance by the Licensee, its Affiliates and its Sublicensees with their obligations pursuant to this Agreement and any sublicense. Such audit shall be conducted during normal business hours and in a manner that does not interfere unreasonably with the Licensee's business but not more than once in any twelve (12) month period. If any such examination reveals that the Licensee has underpaid or underreported any amount due under this Agreement to UABRF for any calendar quarter examined, the Licensee shall promptly pay to UABRF the amount so underpaid or underreported.
- 6.3 Reimbursement of Cost of Audit. If any such examination reveals that the Licensee has underpaid or underreported any amount due under this Agreement to UABRF by more than five percent (5%) for any calendar quarter examined, the Licensee shall immediately reimburse UABRF the full costs and expenses incurred by it with respect to the audit.

## **ARTICLE 7 INFRINGEMENT; ENFORCEMENT**

- 7.1 Notification of Infringement. During the Term, each Party shall provide prompt written notice to the other Party of any actual infringement or suspected/potential infringement of the Licensed Patents of which such Party is or becomes aware and shall provide, to the extent reasonable and practicable, any available evidence of such infringement by a Third Party (an "Infringement Notice").
- 7.2 Licensee Right to Pursue/Prosecute. During the Term, the Licensee shall have the right to resolve, in the Licensed Field of Use and in the Licensed Territory, any suspected/potential infringement and prosecute any infringement of any Licensed Patents, in its own name and at its own expense, provided:
- (a) the affected Licensed Patents [\*\*\*] and are not a Disclaimed Licensed Patent Right;
  - (b) the claim relates to a Valid Patent Claim;  
and
  - (c) the Licensee remains in compliance in all material respects with its obligations under this Agreement.

The Licensee shall [\*\*\*] to abate or terminate such infringement without resorting to litigation, which may include negotiating and executing a sublicense agreement that complies with the terms of Section 2.5 of this Agreement. Before the Licensee commences an action with respect to any infringement or potential infringement, it shall give careful consideration to the views of UABRF and the potential effects on the public interest in making its decision whether or not to sue. UABRF

shall use reasonable efforts to cooperate with the Licensee in connection with any remedial action undertaken by the Licensee and shall be responsible for the costs and expenses incurred by it and for those costs and expenses incurred by it at the reasonable request of the Licensee with respect to such cooperation.

7.3 Control of Suit; Joinder; Expenses.

- (a) Initiated by the Licensee. If the Licensee wishes to commence a lawsuit, it must do so within ninety (90) days following the date of the relevant Infringement Notice, and it shall bear all costs and expenses incurred by it in connection with such lawsuit. UABRF shall co-operate fully with the Licensee in connection with such lawsuit and shall be responsible for the costs and expenses incurred by it and for those costs and expenses incurred by it at the reasonable request of the Licensee with respect to such co-operation.
- (b) Initiated by UABRF. If the Licensee elects not to exercise its right to commence, or fails to commence, an action within ninety (90) days of the date of the relevant Infringement Notice, UABRF may do so at its own expense, and shall retain sole control over the direction of such lawsuit. The Licensee shall cooperate fully with UABRF in connection with such lawsuit and shall be responsible for the costs and expenses incurred by it with respect to such cooperation. If UABRF files an infringement lawsuit, the Licensee may not thereafter commence a lawsuit against the same infringing party with respect to the same acts of infringement which are the subject of UABRF's lawsuit or with respect to which settlement is reached by the infringing party and UABRF.
- (c) Joinder by UABRF. UABRF, to the extent permitted by Applicable Law, may elect to join in as a party to any infringement lawsuit initiated by the Licensee, in which case, both Parties shall jointly control the lawsuit and shall equally share the responsibility of all legal fees, costs and expenses, unless otherwise agreed to by the Parties. The Licensee may not join UABRF in as a party to any lawsuit initiated by it without the prior written consent of UABRF, which such consent shall not be unreasonably withheld, and without prior written agreement between the Parties as to the responsibility between the Parties for all costs and expenses incurred by the Parties. If UABRF is involuntarily joined as a party to a lawsuit initiated by the Licensee, the Licensee shall pay all legal fees, costs and expenses incurred by UABRF arising out of such joinder and participation, including, but not limited to legal fees, costs and expenses reasonably incurred by legal counsel selected and retained by UABRF to represent it in such lawsuit. While UABRF remains a party to any infringement lawsuit initiated by the Licensee, UABRF may not thereafter commence a lawsuit against the same infringing party with respect to the same acts of infringement which are the subject of the Licensee's lawsuit or with respect to which settlement is reached by the infringing party, the Licensee and UABRF.

7.4 Settlement. The Licensee may not settle, enter into a consent judgment or other voluntary final disposition of any lawsuit initiated by it or to which it is a party without the prior written

consent of UABRF, which consent shall not be unreasonably withheld. Neither Party may settle or otherwise dispose of any lawsuit to which it is a party, which admits liability on the part of the other Party or which requires the other Party to pay money damages or issue a formal statement without such other Party's prior written consent.

7.5 Recoveries.

- (a) Lawsuit initiated by the Licensee and in which only the Licensee is a party. With respect to any lawsuit commenced by the Licensee pursuant to **Section 7.3(a)** above and in which UABRF is not a party, any recovery of damages shall first be applied in satisfaction of the costs and expenses incurred by the Licensee in bringing such lawsuit, including attorneys' fees, provided they are reasonably incurred, and any balance shall be treated in accordance with **Section 5.4**. [\*\*\*].
- (b) Lawsuit initiated by the Licensee and in which UABRF joins.
  - (i) With respect to any lawsuit commenced by the Licensee pursuant to **Section 7.3(a)** above and in which UABRF is involuntarily joined as a party, any recovery of damages (whether compensatory or punitive in nature) shall first be applied, pro rata, in satisfaction of the costs and expenses incurred by the Licensee and UABRF in bringing such lawsuit, including attorneys' fees, provided they are reasonably incurred (which such costs and expenses shall include all costs and expenses incurred by UABRF arising out of such joinder and participation, including, but not limited to legal fees and expenses reasonably incurred by legal counsel selected and retained by UABRF to represent it in such lawsuit), and any balance shall be treated in accordance with Section 5.4 of this Agreement.
  - (ii) With respect to any lawsuit commenced by the Licensee pursuant to **Section 7.3(a)** above and in which UABRF voluntarily joins as a party, any recovery of damages (whether compensatory or punitive in nature) shall first be applied, pro rata, in satisfaction of the costs and expenses incurred by the Parties in bringing such lawsuit, including attorneys' fees, provided they are reasonably incurred, and any balance shall be treated in accordance with **Section 5.4** of this Agreement.
- (c) Lawsuit initiated by UABRF and in which only UABRF is a party. With respect to any lawsuit commenced by UABRF pursuant to **Section 7.3(b)** above, all recoveries of damages [\*\*\*]. Furthermore, the Licensee [\*\*\*] under any existing or future sublicense authorizing Licensed Products, [\*\*\*].
- (d) Lawsuit initiated by UABRF and in which Licensee Joins. With respect to any lawsuit commenced by the UABRF pursuant to **Section 7.3(a)** above and in which Licensee voluntarily joins as a party, any recovery of damages (whether compensatory or punitive in nature) shall first be applied, pro rata, in satisfaction of the costs and expenses incurred by the Parties in bringing such lawsuit, including attorneys' fees,

provided they are reasonably incurred, and any balance shall be treated in accordance with **Section 5.4** of this Agreement.

- 7.6 Inapplicability of Licensee's Rights. Notwithstanding **Sections 7.1 - 7.5** above, the rights and obligations of the Licensee under this article shall not apply to (a) any Licensed Patents in which there are no Valid Patent Claims remaining or (b) any Disclaimed Licensed Patent Rights.

## ARTICLE 8 OTHER COVENANTS AND AGREEMENTS

- 8.1 Use of Names. No Party may, without the prior written consent of the other Party: use (a) the name of the other Party or its Affiliates, if applicable, (b) the name or image of any Representative of the other Party, or (c) any trade-name, trademark, trade device, service mark, symbol, image, icon, abbreviation, contraction or simulation thereof owned by the other Party in any publication, advertising or sales promotional material, press release or in any marketing or advertising documentation or material; or represent, either directly or indirectly, that any product or service of the other Party is a product or service of the representing Party or that it is made in accordance with or utilizes the information or documents of the other Party. Notwithstanding the foregoing, the Licensee may disclose that it has received a license from UABRF in connection with any Licensed Product, and either Party may use the name of the other Party to the extent such use is reasonably necessary for complying with Applicable Law.
- 8.2 Publications. In furtherance of **Section 2.3(c)** of this Agreement, UABRF or its Affiliates shall submit a copy of any proposed publication or disclosure containing Proprietary Information to the Licensee at least sixty (60) days prior to submission or disclosure. The Licensee shall have sixty (60) days from its receipt to provide written notice to UABRF or its disclosing Affiliate as to (i) specific edits to remove Licensee's Proprietary Information prior to publication or disclosure or (ii) the need to delay such publication or disclosure for a reasonable period of time to undertake Protection Activities. If the Licensee does not provide written notice of such request to UABRF or its Affiliate within sixty (60) days, UABRF or its Affiliate shall be free to publish or disclose to third parties the proposed publication or disclosure without further obligation to the Licensee.
- 8.3 Insurance Coverage. Prior to commencing any clinical trial and during the Term, the Licensee shall cause to be in effect through purchase from a reputable insurance company or, upon the consent of UABRF, through a self-insurance program, at its sole expense, shall maintain "occurrence based type" liability insurance coverage or, if the Licensee is unable to obtain "occurrence based type" liability insurance, a "claims made type" liability insurance coverage ([\*\*\*]). Such insurance coverage shall include a contractual endorsement providing coverage for all liability which may be incurred in connection with this Agreement, including, but not limited to general liability and products liability, and such other type of insurance coverage required by Applicable Law or which it deems necessary to enable the Licensee to perform its obligations under this Agreement. All such insurance coverage shall list UABRF and its Affiliates as additional insureds. The Licensee shall provide evidence

of such insurance coverage to UABRF within ten (10) business days of commencing any clinical trial and at least annually thereafter. All such insurance coverage shall require the insurance provider, or in the case of a self-insurance program, the Licensee, to provide UABRF with at least thirty (30) days prior written notice of any change in the terms or cancellation of coverage.

#### 8.4 Confidentiality.

- (a) Exchange of Proprietary Information. The Parties acknowledge that during the Term they are likely to share information with each other that they each consider to be confidential and proprietary (“Proprietary Information”). For the purposes of this Agreement, the Party that discloses Proprietary Information shall be referred to as the “Disclosing Party” and the Party receiving the Proprietary Information, the “Receiving Party.”
- (b) Nature of Proprietary Information. The Parties agree that all information that is provided to the other Party shall be deemed to be Proprietary Information. All information must be disclosed in writing or in another tangible medium and must be clearly marked “Proprietary” or “Confidential”. Information disclosed orally must be summarized and reduced to writing and identified as “Proprietary” or “Confidential” in writing to the other Party within thirty (30) days of such disclosure. Notwithstanding the above, the Parties specifically agree that any reports provided by the Licensee pursuant to this Agreement shall be considered Proprietary Information.
- (c) Restrictions. With respect to all Proprietary Information disclosed to it, the Receiving Party (i) shall keep it confidential (other than as permitted by this Agreement), (ii) shall store and maintain it with the same diligence and care as its own proprietary information, but no less than reasonable diligence and care, (iii) may only use it for the purpose for which it was disclosed by the Disclosing Party, (iv) may not disclose it (other than as permitted by this Agreement), (v) may not deconstruct, modify or copy it (other than as permitted by this Agreement), and (vi) may not transfer or assign it to any Third Party without the prior written consent of the Disclosing Party.
- (d) Access to the Proprietary Information. The Proprietary Information may be used by, and disclosed to, on an “as-needed” basis, the Receiving Party’s Representatives. The Licensee may disclose Proprietary Information relating to the Licensed Patents to investors, prospective investors, consultants, collaborators and other Third Parties in the chain of manufacturing and distribution, if and only if, the Licensee obtains from such recipient a written confidentiality agreement, the provisions of which are at least as protective of UABRF’s Proprietary Information as these set forth in this section 8.4. Each Party will promptly notify the other Party of any unauthorized use of or access to the Proprietary Information of which it becomes aware.
- (e) Exceptions to Confidentiality Obligation. The restrictions of confidentiality described above shall not apply to Proprietary Information (i) which as of the

Effective Date or subsequent thereto is or becomes available to the public without breach of this Agreement, (ii) if it is lawfully obtained from a Third Party not bound by similar confidentiality and use restrictions and obligations, (iii) if it is known by the Receiving Party prior to disclosure as evidenced by contemporaneous records, or (iv) if it is at any time developed by the Receiving Party independently of any disclosure made pursuant to this Agreement. In addition, the confidentiality obligations shall not apply to the Receiving Party if the Receiving Party is legally required by applicable law, court order or Governmental Authority to disclose the Information, provided the Receiving Party discloses only the minimum to comply and, if possible and in light of the circumstances, provides reasonable prior notice to the Disclosing Party to enable it to contest the requirement or to seek a protective order.

- (f) Termination or Expiration of this Agreement. Upon the expiration of the Term, or the earlier termination of this Agreement, each Receiving Party shall, at the Disclosing Party's option and upon written notice thereof to the Receiving Party, return all Proprietary Information, copies and other tangible expressions thereof, to the Disclosing Party or provide the Disclosing Party with written notice that the Proprietary Information in its possession, or in the possession of its Representatives, has been destroyed within thirty (30) days after receipt of the Disclosing Party's written notice to the Receiving Party requiring the Receiving Party to destroy the Proprietary Information in its possession. The Receiving Party may retain one archival copy of the Information for purposes of compliance of its obligations under this Agreement.
- (g) Continuing Obligations after Termination/Expiration. The restrictions and obligations set forth in Section 8.4(c) above shall continue for seven (7) years from the termination or expiration of this Agreement.

## ARTICLE 9 TERM AND TERMINATION

- 9.1 Term. This Agreement shall commence on the Effective Date and shall continue, unless terminated sooner in accordance with the terms of this Agreement, until [\*\*\*] (the "Term").
- 9.2 Termination by the Licensee. The Licensee may terminate this Agreement at any time, in its sole discretion, by giving not less than [\*\*\*] prior written notice to UABRF. Upon the reasonable request of UABRF, the Licensee shall provide assistance, at its expense, to UABRF to enable UABRF to facilitate and effect the transfer of applicable information and documents regarding the Licensed Patents to a new licensee.
- 9.3 Termination by UABRF. UABRF shall have the right to immediately terminate this Agreement upon the occurrence of any one or more of the following events:

- (a) if the Licensee is in material default of any provision of this Agreement or its obligations under this Agreement and such default has not been remedied within sixty (60) days after receipt of a notice to cure from UABRF;
- (b) if the Licensee fails to make a payment due under this Agreement and fails to cure such non-payment within forty-five (45) days of receipt of a non-payment notice from;
- (c) if the Licensee fails to diligently undertake development and commercialization activities as set forth in the Plan, provided however, Licensee shall be deemed to have demonstrated sufficient diligence through the expenditure of time, money or effort in planning, working, and undertaking objectives in accordance with the Plan;
- (d) if an examination by UABRF pursuant to Section 6.2 shows an underreporting or underpayment by the Licensee in excess of ten percent (10%) of any amounts due to UABRF under this Agreement in any twelve (12) month period, provided however, any disputed reporting or payment obligations by Licensee shall not be considered a breach of this provision;
- (e) if the Licensee shall become insolvent, shall make an assignment for the benefit of its creditors, or shall have a petition in bankruptcy filed for or against it.

9.4 Effect of Termination or Expiration. Upon the termination of this Agreement or the expiration of the Term, all payments then or thereafter [\*\*\*] shall, immediately and automatically, become owed directly to UABRF. Upon the natural expiration of each Licensed Patent, Licensee shall receive [\*\*\*].

**ARTICLE 10**  
**COVENANTS; REPRESENTATIONS AND WARRANTIES; LIMITATIONS ON UABRF'S OBLIGATIONS**

10.1 The Licensee. The Licensee makes the following representations and warranties to UABRF.

- (a) The Licensee is a corporation, duly incorporated, validly existing and in good standing under the laws of the State of Delaware.
- (b) The Licensee has all necessary corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby.
- (c) The execution, delivery and performance of this Agreement by the Licensee will not conflict with or result in a breach of, or entitle any party thereto to terminate, an agreement or instrument to which the Licensee is a party, or by which any of the Licensee's assets or properties are bound.
- (d) This Agreement has been duly authorized, executed and delivered by the Licensee and constitutes a legal, valid and binding agreement of the Licensee, enforceable against the Licensee in accordance with its terms, except as such enforceability may

be limited by bankruptcy, insolvency, moratorium, reorganization or other similar laws affecting creditors' rights generally.

- (e) The Licensee possesses the necessary expertise and skill in the technical areas pertaining to the Licensed Patents, to make Licensed Products, and to make its own evaluation of the capabilities, safety, utility and commercial application of the Licensed Patents.
- (f) Any activity undertaken with the Licensed Patents and the Licensed Products will be conducted in compliance with all Applicable Laws.

10.2 UABRF. UABRF makes the following representations and warranties to the Licensee.

- (a) UABRF is a non-profit corporation, duly incorporated, validly existing and in good standing under the laws of the State of Alabama.
- (b) UABRF has all necessary corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby.
- (c) The execution, delivery and performance of this Agreement by UABRF does not conflict with or contravene its governing documentation, nor will the execution, delivery and performance of this Agreement by UABRF conflict with or result in a breach of, or entitle any party thereto to terminate, an agreement or instrument to which UABRF is a party, or by which any of UABRF's assets or properties are bound.
- (d) This Agreement has been duly authorized, executed and delivered by UABRF and constitutes a legal, valid and binding agreement of UABRF, enforceable against UABRF in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, moratorium, reorganization or other similar laws affecting creditors' rights generally.
- (e) UABRF has the right to grant the license under this Agreement.
- (f) To UABRF's best knowledge and based upon information and representations and warranties made to it by the Inventors, UABRF owns all right, title and interest in the Licensed Patents and there have been no claims made against UABRF asserting the invalidity or non-enforceability, and with respect to the Licensed Patents, UABRF is not aware that any such claims exist.
- (g) The performance of Management Activities with respect to Disclaimed Licensed Patent Rights will not conflict with or result in a breach of any of the terms, conditions, or provisions of, or constitute a default under, this Agreement, and no Third Party shall have any right of claim against the Licensee, with respect to this Agreement or any rights remaining therein.

10.3 Limitations on UABRF's Representations and Warranties. Except as set forth in this Agreement, UABRF makes no other representations or warranties of any kind. In particular, UABRF makes no express or implied warranties regarding merchantability, fitness for a particular purpose, non infringement of the intellectual property rights of third parties, validity and scope of any Licensed Patents, the capability, safety, efficacy, utility or commercial application or usefulness for any purpose of any Licensed Patents, or that UABRF will not grant licenses to one or more Third Parties to make, use or sell products or perform processes that may be similar to and/or compete with any Licensed Product.

10.4 No Obligation of UABRF. UABRF has no obligation to:

- (a) supervise, monitor, review or otherwise assume responsibility for the production, manufacture, testing, marketing, sale or disposition of any Licensed Product;
- (b) furnish any knowhow or other information relating to the Licensed Patents, other than as specifically provided in this Agreement; or
- (c) bring or prosecute legal action against any Person for infringement of the Licensed Patents.

**ARTICLE 11**  
**LIABILITY AND INDEMNIFICATION**

11.1 No Liability of UABRF. Neither UABRF nor any of its Representatives have any liability whatsoever to the Licensee or any Sublicensee or any Person for or on account of any injury, loss or damage of any kind or nature, sustained by, assessed or asserted against, or any other liability incurred by or imposed upon the Licensee, or any Sublicensee or any Person, arising out of or in connection with or resulting from:

- (a) the use of the Licensed Patents during the Term;
- (b) the production, use, practice, lease, or sale of any Licensed Product;
- (c) any advertising or other promotional activities with respect to (a) and/or (b) above; or
- (d) the Licensee's compliance with, and performance of the Licensee's representations and warranties given under, and the Licensee's obligations pursuant to, this Agreement.

11.2 Indemnification by the Licensee. The Licensee agrees to indemnify and hold UABRF and its Representatives harmless from and against any and all claims, demands, losses, costs, expenses, deficiencies, liabilities or causes of action of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) based upon, arising out of or otherwise relating to:

- (a) the use of the Licensed Patents during the Term;

- (b) the production, use, practice, lease, or sale of any Licensed Product;
- (c) any advertising or other promotional activities with respect to (a) and/or (b) above;  
or
- (d) the Licensee's compliance with, and performance of the Licensee's representations and warranties given under, and the Licensee's obligations pursuant to, this Agreement.

**ARTICLE 12  
MISCELLANEOUS**

- 12.1 Entire Agreement. This Agreement is the sole and entire agreement by and between the Parties regarding the subject matter set forth in this Agreement, and this Agreement supersedes all prior agreements and understandings with respect thereto. All previous negotiations, statements and preliminary instruments by the Parties with respect to the subject matter hereof are merged in this Agreement.
- 12.2 No Inducement. Each Party hereby acknowledges that in executing this Agreement, such Party has not been induced, persuaded or motivated by any promise or representation made by any other Party, unless expressly set forth in this Agreement.
- 12.3 Independent Contractors. The relationship between the Parties is that of independent contractors. No Party has the authority to bind or act on behalf of the other Party without obtaining such other Party's prior written consent. The Parties do not intend to create an employer/employee relationship.
- 12.4 No Third Party Beneficiaries. This Agreement is entered into by and among the Parties for the exclusive benefit of the Parties and their successors and permitted assignees. This Agreement is expressly not intended for the benefit of any creditor of a Party, or any other person. Except and only to the extent provided by applicable statute, no such creditor or Third Party shall have any rights under this Agreement or any other agreement between the Parties.
- 12.5 Assignment. Neither Party shall sell, assign, transfer or otherwise dispose of this Agreement including by operation of law to a Third Party without the prior written consent of the other, which consent shall not be unreasonably withheld except that Licensee shall be permitted to assign this Agreement in the case of: (i) an assignment to a wholly owned Affiliate of Licensee, (ii) the sale of substantially all of the stock or assets of Licensee, or (iii) any merger or acquisition or business combination resulting in a change of control of Licensee, provided that any assignee (a) shall have the wherewithal to perform this Agreement and (b) shall ratify this Agreement and abide by all of its terms and conditions provisions. Any attempted assignment of this Agreement not in compliance with the terms of this subsection will be null and void. No assignment will relieve any Party of the performance of any accrued obligation that such Party may then have pursuant to this Agreement.

- 12.6 Amendments. Any and all modifications to this Agreement shall only be effective and binding if in writing and signed by a duly authorized representative of each Party.
- 12.7 Notices. Any notice, request, approval or consent required to be given under this Agreement will be sufficiently given if in writing and delivered to a Party in person, by recognized overnight courier or mailed in the United States Postal Service, postage prepaid to the address appearing below such Party's signature on the last page of this Agreement, or at such other address as each Party so designates in accordance with these criteria. Notice shall be deemed effective upon receipt if delivered in person or by overnight courier or five (5) business days after mailing with the United States Postal Service.
- 12.8 Disputes.
- (a) Equitable Relief. Either Party may seek equitable and injunctive relief in a court of competent jurisdiction in the event of a breach or threatened breach by the other Party of its obligations under this Agreement, without the requirement to post a bond.
  - (b) Internal Resolution. In the event of any dispute arising out of or relating to this Agreement or to a breach thereof, including its interpretation, performance or termination, the Parties shall try to settle such conflicts amicably between themselves. In the event that the conflict is not resolved within sixty (60) days after one Party notifies the other Party in writing concerning a dispute or conflict, then the dispute or conflict shall be referred to executive officers of each Party involved for resolving by negotiation in good faith as soon as practicable but no later than sixty (60) days after its referral.
  - (c) Mediation. In the event the Parties are still unable to resolve the dispute or conflict by negotiation, the dispute or conflict may then be submitted by a Party to a mediator, mutually agreed to by the Parties, for nonbinding mediation. The Parties shall cooperate with the mediator in an effort to resolve such dispute.
  - (d) Arbitration. If the dispute is not resolved within sixty (60) days of its submission to the mediator, either Party may submit the dispute for binding arbitration. The arbitration shall be conducted by three (3) arbitrators, one to be appointed by UABRF, one to be appointed by the Licensee and the third to be appointed by the other two arbitrators. The arbitration shall be conducted in accordance with the commercial rules of the American Arbitration Association, which shall administer the arbitration. The arbitration, including the rendering of the award, shall take place in [\*\*\*] and shall be the exclusive forum for resolving such dispute. The decision of the arbitrators shall be final and binding upon the Parties and the expense of the arbitration, including, without limitation, the award of attorneys' fees to the prevailing Party, shall be paid as the arbitrators determine.
- 12.9 Rights and Remedies. The rights and remedies provided by this Agreement are cumulative, and the use of any one right or remedy by any Party shall not preclude or waive the right to

use any or all other remedies. Such rights and remedies are given in addition to any other rights the Parties may have by law, statute, ordinance or otherwise.

- 12.10 Waiver. No waiver of a provision, breach or default shall apply to any other provision or subsequent breach or default or be deemed continuous, nor will any single or partial exercise of a right or power preclude any other further exercise of any rights or remedies provided by law or equity.
- 12.11 Severability. In the event that any covenant, condition, or other provision contained in this Agreement is determined to be invalid, void or illegal, such covenant, condition or other provision shall be deemed deleted from the Agreement and shall not affect the validity of the remaining provisions of this Agreement.
- 12.12 Force Majeure. Neither Party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such Party's control, including, without limitation, labor disturbances or labor disputes of any kind; accidents; acts, omissions or delays in acting by any Governmental Authority; civil disorders; insurrections; riots; war; acts of war (whether war be declared or not); terrorism; acts of aggression; acts of God; fire; floods; earthquakes; natural disasters; energy or other conservation measures imposed by law or regulation; explosions; failure of utilities; mechanical breakdowns; material shortages; disease or other such occurrences; provided that the affected Party uses reasonable efforts to overcome or avoid the effects of such cause and continues to perform its obligations to the extent possible.
- 12.13 Survivability. All rights and obligations of the Parties which by intent or meaning have validity beyond or by their nature apply or are to be performed or exercised after the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement for the period so specified, if any, or for perpetuity.
- 12.14 Governing Law. This Agreement, and the application or interpretation hereof, shall be governed exclusively by its terms and by [\*\*\*].
- 12.15 Interpretation. Whenever used in this Agreement and when required by the context, the singular number shall include the plural and the plural the singular. Pronouns of one gender shall include all genders, masculine, feminine and neuter.
- 12.16 Captions. The captions as to contents of particular sections or paragraphs contained in this Agreement are inserted for convenience and are in no way to be construed as part of this Agreement or as a limitation on the scope of the particular sections or paragraphs to which they refer.
- 12.17 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which shall constitute one and the same instrument.

[The remainder of this page intentionally left blank]

**IN WITNESS WHEREOF**, the Licensee and UABRF have each caused its duly authorized representative to execute this Agreement, effective as of the Effective Date.

**UABRF:**  
**The UAB Research Foundation**

**LICENSEE:**  
**Brickell Biotech, Inc.**

By: /s/ David Winwood  
Name: David Winwood, Ph.D.  
Title: CEO, UABRF

By: /s/ Andy Sklawer  
Name: Andy Sklawer  
Title: Vice President, Operations, BBI.

<i>Address For Notices:</i>	<i>Address For Notices:</i>
<i>Via Courier:</i> [***]	[***]

**EXHIBIT A**  
**LICENSED PATENTS**

[\*\*\*]

**EXHIBIT B**  
**DEVELOPMENT AND COMMERCIALIZATION PLAN**

**DEVELOPMENT AND COMMERCIALIZATION PLAN**

[\*\*\*]

*Below is a summary of the planned development activities for [\*\*\*]:*

**I. Manufacturing of API:**

Multiple manufacturing campaigns will be required during the development program. [\*\*\*]. The manufacturing of the initial batches to support pharmacology activities will be initiated as soon as feasible upon the execution of the license agreement. This activity includes the assessment and transfer of analytical methods.

**II. API stability studies:**

The stability program of the drug substance will be initiated upon manufacturing of the first batch and will continue with representative samples from subsequent manufacturing campaigns. The stability of GMP batches will conform to ICH guidelines.

**III. Drug product Development and manufacturing:**

Upon availability of drug substance, drug product development activities will be initiated.

A suitable formulation for topical use will be developed along with all analytical methods needed for characterization. Manufacturing campaigns to support preclinical and clinical trials will be scheduled as needed and will include manufacturing of product suitable to support GLP and GMP activities.

**IV. Drug product stability studies:**

The stability program of the drug product will be initiated upon manufacturing of the first batch and will continue with representative samples from subsequent manufacturing campaigns. The stability of GMP batches will conform to ICH guidelines.

**V. Pharmacology assessments:**

To better define the pharmacological activities of [\*\*\*], a series of studies will be conducted. Information gained from initial studies may indicate the need for subsequent assessments. At this point, the following [\*\*\*] are planned:

[\*\*\*]

**VI. Toxicology assessments to enable up to 28 days of dosing:**

Topical toxicology studies will be required to enable opening an IND for topical use. The following studies are being considered:

[\*\*\*]

**VII. Clinical evaluation Phase 1/2a:**

The clinical evaluation will start with an assessment of the tolerability and bioavailability of [\*\*\*] in healthy volunteers under maximum use conditions.

Assuming no relevant findings from topical toxicology studies and minimum bioavailability after topical application, subsequent studies will be planned in the intended to treat population:

[\*\*\*]

Information from these clinical trials will be informative of the potential of BBI-3000 to provide a clinically meaningful effect on the indication tested.

**VIII. Toxicology assessments to enable 12 weeks of dosing:**

The indications intended require longer [\*\*\*] for demonstration of maximum efficacy. To enable [\*\*\*] in clinical trials, the following toxicology studies are being considered:

[\*\*\*]

**IX. Clinical Evaluation Phase 2b studies:**

To determine safety, tolerability, dose ranging and magnitude of treatment effect that will be needed to demonstrate the [\*\*\*] will be conducted. The final design of these studies will be informed by the [\*\*\*]. Phase 2b studies will be [\*\*\*].

**X. Comprehensive [\*\*\*] and reproductive/development toxicology studies:**

Considering the intended indication a more comprehensive toxicology assessment of [\*\*\*] as well as reproductive and development toxicity will be needed. The design of these studies will be informed from previous toxicology studies.

**XI. Clinical Evaluation Phase 3 studies:**

[\*\*\*]. Final design of the studies will be informed from the Phase 2b study results. Typically, [\*\*\*]

**XII. Dermal safety studies:**

[\*\*\*] are to be conducted with the to be marketed formulation. These studies are typically conducted along with the Phase 3 clinical studies, however, depending on findings from preliminary phases of development some of these studies, may need to be conducted sooner.

**XIII. [\*\*\*]:**

For indications that will require recurrent treatment periods within a year, [\*\*\*]. This study typically includes [\*\*\*] to ensure sufficient study population at 1-year time point. Contingent upon the safety findings during the development program, the data from this study may be provided after NDA submission.

**XIV. Carcinogenicity assessment:**

Current data appears to indicate low risk for carcinogenicity. However, [\*\*\*] may be required, upon discussion with regulatory agencies.

**XV. NDA submission**

[\*\*\*]

[\*\*\*]

**EXHIBIT C**  
**FORM OF [\*\*\*]**

Licensee: \_\_

**Agreement No.:** \_\_

Inventor: \_\_

**P# :**  P

Period Covered: From  //20

Through:  //20

Prepared By: \_\_

**Date:** \_\_

Approved By: \_\_

**Date:** \_\_

If license covers several major product lines, please prepare a separate report for each line. Then combine all product lines into a summary report.

**Report Type: Single Product Line Report:** \_\_

**Multiproduct Summary Report.** Page 1 of \_\_\_\_ Pages

**Product Line Detail.** Line: \_\_\_\_\_ Trade name: \_\_\_\_\_ Page: \_\_\_\_\_

**Report Currency:** U. S. Dollars Other \_\_

Country	[***]	[***]	[***]	[***]	[***]	[***]
					[***]	[***]
[***]						
[***]						
[***]						
[***]						
Other:						
<b>TOTAL:</b>						

[\*\*\*]

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**AMENDMENT NO. 1 TO [\*\*\*] LICENSE AGREEMENT**

This Amendment No. 1 to the [\*\*\*] License Agreement (this “**Amendment**”) is made as of October 29, 2015 (the “**Amendment Effective Date**”), by and between The UAB Research Foundation, an Alabama not-for-profit corporation (“**UABRF**”) and Brickell Biotech Inc., a Delaware corporation (“**Licensee**”), and amends the [\*\*\*] License Agreement between the parties, effective as of June 26, 2012 (the “**Agreement**”).

The parties agree as follows:

1. Effective as of June 26, 2012, Section 1.18 ([\*\*\*]) is hereby amended and replaced in its entirety with the following:

“[\*\*\*]” means anything [\*\*\*].

2. All other provisions of the Agreement shall remain unchanged and effective. All capitalized terms used but not defined in this Amendment will have the meaning given to such terms in the Agreement. This Amendment may be executed in identical counterparts, each of which will be deemed an original and all of which together will constitute one instrument.

IN WITNESS WHEREOF, duly authorized representatives of each of the parties have executed this Amendment as of the Amendment Effective Date.

UAB RESEARCH FOUNDATION

BRICKELL BIOTECH TNC.

By: /s/ Kathy Nugent

By: /s/ Andy Sklawer

Name: Kathy Nugent, PhD

Name: Andy Sklawer

Title: Executive Director

Title: COO

Date: 10/28/15

Date: 11/2/15

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

Dated the 20th day of May, 2011

- (1) THE UNIVERSITY OF MANCHESTER
- (2) BRICKELL BIOTECH, INC

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Licence Agreement

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**THIS AGREEMENT** is made on the 20th day of May, 2011

**BETWEEN**

1. The University of Manchester (a Royal Charter corporation registered under number RC 000797, an exempt charity) of Oxford Road, Manchester, M13 9PL (“the University”)
2. Brickell Biotech, Inc. a corporation organized under the laws of the State of Delaware USA whose principal place of business is located at 612 SE 5<sup>th</sup> Avenue, Suite 1, Fort Lauderdale, Florida, United States of America 33301 (“the Licensee”)

**OPERATIVE PROVISIONS**

**1. INTERPRETATION**

- 1.1 In this Agreement the following expressions have the following meanings unless inconsistent with the context:

“Academics”	[***] and [***]
“Affiliate”	any company or other entity which Controls, is Controlled by, or is under common Control with another company or other entity
“Business Day”	any day other than Saturday and Sunday or a bank or public holiday in England
“Commencement Date”	the date of this Agreement
“Confidential Information”	all secret or not generally known information or information which is not easily accessible to others or of a commercially sensitive nature disclosed or made available in any way by one party or any of its Affiliates (“Discloser”) to the other party or, in the case of the University, to UMIP or any of its Affiliates (“Recipient”) in connection with this Agreement (including Know-How of the Discloser)
“Control”	direct or indirect ownership of 50% (or, outside a company’s home territory, such lesser percentage as is the maximum permitted level of foreign investment) or more of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of that company. “Controls” and “Controlled” shall be construed accordingly
“Expert”	has the meaning set out in <b>clause 4.4</b>
“Field”	[***].

“Improvements”	any technological advance in the Field made by either of the Academics at the University that infringes, or would infringe any of the Licensed IP.
“Intellectual Property”	patents, trademarks, copyright, database rights, design rights, registered designs, know-how, and all other intellectual property rights, in each case whether registered or unregistered and including applications or rights to apply for them and together with all extensions and renewals of them, and in each case all rights and forms of protection having equivalent and similar effect anywhere in the world
“Know-How”	the unpatented technical information in the Field developed prior to the Commencement Date by the University which is set out in <b>Schedule 1</b>
“Licensed IP”	Patents and Know-How
“Licensed Products”	any and all products and services that are manufactured, performed, sold or otherwise supplied by the Licensee or any of its sub-licensees using any of the Licensed IP
“Milestones”	those milestones to be achieved by the Licensee which are set out in <b>clause 4.5</b>
“Net Receipts”	[***].
“Net Sales Value”	[***].
“Patents”	<p>(a) the patents and applications for patents in the Territory short particulars of which are set out in <b>Schedule 2</b>;</p> <p>(b) all patents granted in the Territory pursuant to the patent applications mentioned in paragraph (a) of this definition;</p> <p>(c) any continuations, divisionals, reissues, re-examinations, extensions, substitutions and continuations in part in respect of any of the patent applications and patents mentioned in paragraph (a) or (b) of this definition</p>
“Related IP”	any technological advance in the Field made at the University by the Academics which functions similarly to the Licensed IP and does not infringe, or would not infringe any of the Licensed IP
“Territory”	[***]

“UMIP”

The University of Manchester Intellectual Property Limited

“Year”

the period of 12 consecutive months ending on 31 December (such dates being “**Year Days**”) or any shorter period either commencing on the Commencement Date and ending on the next Year Day or commencing on the day after a Year Day and ending on the expiration or termination of this Agreement.

- 1.2 References in this Agreement to a statute or statutory provision shall, unless the context otherwise requires include any statute or statutory provision which the referred to provision amends, re-enacts, extends, consolidates or replaces. References to a statutory provision also extend to any subordinate legislation made under it.
- 1.3 References in this Agreement to persons includes bodies corporate, unincorporated associations and partnerships.
- 1.4 References in this Agreement to the words “include” “includes”, “including” and “included” will be construed without limitation unless inconsistent with the context.
- 1.5 References in this Agreement to clauses and Schedules are to clauses of and Schedules to this Agreement.
- 1.6 The headings to the clauses are for ease of reference only and shall not be taken into account in its interpretation.

## 2. GRANT OF LICENCE

- 2.1 The University grants to the Licensee [\*\*\*] licence, [\*\*\*], in each case to develop, manufacture, have manufactured, use and sell [\*\*\*], but only in the Field and only in the Territory.
- 2.2 The Licensee may not assign this licence in whole or in part without the prior written consent of University, such consent not unreasonably withheld or delayed, provided however, no consent of University shall be required for [\*\*\*].
- 2.3 Additionally, Licensee may [\*\*\*] with any such [\*\*\*] to be contingent upon (i) [\*\*\*] (ii) [\*\*\*] and (iii) [\*\*\*], and further provided that:
  - 2.3.1 the Licensee must provide the University with [\*\*\*];
  - 2.3.2 obligations and conditions matching those in this Agreement (save as set out below), and sufficient to protect the security of the Patents, and the interests of the University, [\*\*\*];
  - 2.3.3 the [\*\*\*];

- 2.3.4 the [\*\*\*] for any reason;
- 2.3.5 the [\*\*\*] must be [\*\*\*] and [\*\*\*];  
and
- 2.3.6 the Licensee must indemnify the University and keep the University indemnified against any and all loss, damages, costs, claims or expenses which are awarded against or suffered by the University as a result of [\*\*\*].
- 2.4 The Licensee will ensure that [\*\*\*] are marked suitably with any relevant patent or patent application numbers to satisfy the laws of each of the countries in which [\*\*\*] and in which they are protected by any of the Licensed IP.
- 2.5 The Licensee will comply fully with all relevant import, export and free movement of goods laws and regulations of the United Kingdom and the European Union and of other applicable countries to ensure that the Licensed IP is not imported or exported, directly or indirectly, in violation of such laws or regulations.
- 2.6 No licence is granted to the Licensee other than as expressly stated in this **clause 2**. The University reserves all other rights under the Licensed IP.
- 2.7 Notwithstanding the licence granted by **clause 2.1**, the University reserves rights for its employees and students to use the Licensed IP in any way for any bona fide research or teaching purposes and to sub-license such rights to the University's Affiliates for any bona fide research or teaching purposes. The University shall notify Licensee of any proposed submission for publication of any research containing information arising from, related to or associated with the Patents, along with a copy of any proposed submission at least 30 days prior to the submission of any publication to any third party. The University shall refrain from communicating or publishing any material that in the reasonable opinion of the University may compromise the patentability of the rights conveyed hereby, for a period of time sufficient for the University and Licensee to assess and undertake legal protections to preserve the commercial value of any such advances.
- 2.8 The Licensee will use [\*\*\*] to develop and commercialise [\*\*\*], including but not limited to [\*\*\*], in order to maximise the potential for financial return for both parties.
- 2.9 Within 60 days of the execution date of this Agreement, the Licensee shall prepare and deliver a written development plan to the University outlining the Licensee's plans for the commercialisation of the Licensed IP ("Development Plan") herein set forth as **Schedule 3**. The Development Plan shall be: (i) solely determined by the Licensee with input from the University; (ii) alterable by Licensee during the year in response to activities, obstacles, progress and market conditions; (iii) annually updated as to activities and status by the Licensee and delivered to the University no later than the 31<sup>st</sup> day of January; and (iv) considered "[\*\*\*]" for purposes of evaluating the Licensee's diligence in commercializing the Licensed IP.

- 2.10 If the University believes that the Licensee has failed to properly act to commercialise the Licensed IP in accordance with the Development Plan as required pursuant to **clause 2.9**, the University may, within 20 Business Days of any such report being received, issue a notice to the Licensee detailing its basis for such belief ("**Discussion Notice**"). Where a Discussion Notice has been issued by the University the parties shall enter into good faith negotiations to reach mutual agreement as to changes to the Development Plan that should be undertaken to remedy this deficiency within 20 Business Days of the date of any request. If the parties cannot reach agreement as to changes to the Development Plan to remedy any deficiency, the parties agree to [\*\*\*].
- 2.11 Where the Licensee fails to reasonably act to commercialise the Licensed IP in accordance with the Development Plan, and fails to diligently undertake actions to remedy any such deficiency, and where [\*\*\*], the University may consider such failure to be a material breach under this Agreement and shall have the right to terminate this Agreement pursuant to **clause 7.2.1**.
- 2.12 Subject to the Licensee complying with its obligations under this Agreement, if the Licensee so requires, the Licensee may engage the University and its personnel for consultancy services from time to time pursuant to the provisions as set forth in **Schedule 4**.
- 2.13 The University will provide to the Licensee all of the Know-How in its possession or control that the University is free to disclose and that is necessary for [\*\*\*], subject to the Licensee complying with **clauses 2.1 and 3**.
- 2.14 Subject to any pre-existing third party rights, the University grants [\*\*\*] under this Agreement subject to the provisions of **clauses 2.15 to 2.17**.
- 2.15 From the date of the disclosure by the University of [\*\*\*] the Licensee shall have 30 Business Days in which to notify the University in writing of its wish to [\*\*\*] under this Agreement.
- 2.16 In the event that the Licensee notifies the University in writing that it wishes to [\*\*\*], the University and the Licensee shall execute an appropriate instrument to [\*\*\*].
- 2.17 If the Licensee fails to notify the University in writing that it wishes to [\*\*\*] or notifies the University in writing that it no longer wishes to [\*\*\*], then the University shall be free [\*\*\*] in any way that it chooses.
- 2.18 Subject to any pre-existing third party rights, the University grants the Licensee [\*\*\*] subject to the provisions of **clauses 2.19 to 2.21**.
- 2.19 From the date of the disclosure by the University of [\*\*\*] the Licensee shall have 20 Business Days in which to notify the University in writing of its wish to [\*\*\*] and thereafter within 3 months of [\*\*\*] with the University.
- 2.20 The parties agree to [\*\*\*] and if such [\*\*\*] incorporating the agreed terms within 3 months of [\*\*\*].

- 2.21 If the Licensee fails to notify the University in writing that it wishes to [\*\*\*] or [\*\*\*] or notifies the University in writing that it [\*\*\*], then the University shall be free to deal with [\*\*\*] in any way that it chooses.
- 2.22 The University will use [\*\*\*] to inform the Licensee in writing of any [\*\*\*] within 30 days of disclosure of such Improvements or Related IP to the University by the Academics. For the avoidance of doubt, the [\*\*\*] shall commence upon the receipt of that written notice provided by University to Licensee.

### 3. CONFIDENTIALITY

- 3.1 The Recipient agrees to keep and agrees to ensure that its Affiliates keep secret and confidential all Confidential Information, to use and agrees to ensure that its Affiliates use such Confidential Information only for the purposes of this Agreement, and only to disclose such Confidential Information so far as is necessary as follows:
- 3.1.1 (in the case of the Licensee) to its licensees on such terms as are equivalent in effect to the Licensee's obligations of confidentiality under this Agreement; and
- 3.1.2 to the Recipient's directors and employees concerned in carrying out or administering this Agreement provided that such individual is bound by obligations of confidentiality and use equivalent to those set out in this Agreement.
- 3.2 The Recipient will not be in breach of any obligation to keep any information confidential or not to disclose it to any third party to the extent that the Recipient can show that it:
- 3.2.1 was known to it before its receipt from the Discloser, and not already subject to any obligation of confidentiality to the Discloser or has become publicly known without any breach of this Agreement or any other undertaking to keep it confidential;
- 3.2.2 has it from a third party in circumstances where the Recipient has no reason to believe that there has been a breach of an obligation of confidentiality owed to the Discloser;
- 3.2.3 has independently developed it;
- 3.2.4 is required to disclose pursuant to an obligation under statute or to a statutory or governmental body (including the Freedom of Information Act 2000) but then only to the extent of making such required disclosure; *provided*, that prior to making any such legally required disclosure, the Recipient shall give the Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances; or
- 3.2.5 has express consent from the Discloser to disclose,
- 3.3 If the University receives a request under the Freedom of Information Act 2000 to disclose any information that is the Licensee's Confidential Information, it will notify the Licensee

and will consult with the Licensee. The Licensee will respond to the University within 5 Business Days after receiving the University's notice if that notice requests the Licensee to provide information to assist the University to determine whether or not an exemption to the Freedom of Information Act applies to the information requested under that Act.

- 3.4 Upon the expiration or termination of this Agreement or earlier request from the Discloser (save in the latter case in relation to licensed Know-How), the Recipient will cease its use and, upon request, within 30 days either return or destroy (and certify as to such destruction) all Confidential Information of the Discloser, including any copies of it provided Recipient shall be entitled to keep an archival copy for purposes of compliance with provisions of confidentiality.
- 3.5 The provisions of this **clause 3** will remain in force for 10 years from expiration or termination of this Agreement.

#### 4. PAYMENTS

- 4.1 In consideration of the rights granted under **clause 2**, the Licensee agrees to pay to the University:
  - 4.1.1 on the signature of this Agreement, the [\*\*\*]  
and
  - 4.1.2 [\*\*\*]
  - 4.1.3 [\*\*\*]
- 4.2 If [\*\*\*]  
are:
  - 4.2.1 rented, leased, let out or hired or otherwise disposed of to a customer other than by way of sale by the Licensee or [\*\*\*];
  - 4.2.2 used by the Licensee or any of its Affiliates or [\*\*\*] for its own commercial purposes;
  - 4.2.3 supplied to an Affiliate of the Licensee or [\*\*\*];
  - 4.2.4 supplied in conjunction with [\*\*\*] or in any way as part of an [\*\*\*],then the [\*\*\*] will be deemed to be equivalent to the [\*\*\*] which would have been applicable under this Agreement had such [\*\*\*].
- 4.3 [\*\*\*].
- 4.4 Any dispute between the parties about [\*\*\*] or monetary value of any [\*\*\*] will, at the request of either party, be referred to an expert under **clause 4.4**. The expert will be a single, independent chartered accountant to be agreed between the parties, or in default of agreement between the parties within 5 Business Days, to be selected at the request of either of them by the President for the time being of the Institute of Chartered Accountants [\*\*\*]

**(“Expert”).** Any dispute to be referred to the Expert will be decided upon in a final and binding manner by the Expert acting as a technical expert [\*\*\*]. Any actions, decisions, awards or payments to be made or taken pursuant to the determination of the Expert will be made or taken within 20 Business Days of notification of the same to the relevant parties. The costs of the Expert will be borne by the parties as determined by the Expert.

4.5 [\*\*\*].

4.6 All sums due under this Agreement:

4.6.1 will be made in [\*\*\*]

4.6.2 are exclusive of any value added tax which will be payable in addition by the Licensee on the rendering by the University of an appropriate value added tax invoice. The Licensee will pay any costs, interest and penalties due and incurred by the University whether directly or indirectly by reason of late payment of any such value added tax; and

4.6.3 will be made in full without deduction of taxes, charges and other duties (including any withholding or other income taxes) that may be imposed, except where the Licensee is required by law to make such deduction or withholding, in which event the Licensee will:

4.6.3.1 ensure that the deduction or withholding does not exceed the minimum amount legally required;

4.6.3.2 pay to the applicable taxation or other authorities within the period for payment permitted by law the full amount of the deduction or withholding (including, but without prejudice to the generality of the foregoing, the full amount of any deduction or withholding from any additional amount paid pursuant to this **clause 4.6.3**);

4.6.3.3 furnish to the University, within the period for payment permitted by law, either an official receipt of the applicable taxation or other authorities for all amounts deducted or withheld as aforesaid or, if such receipts are not issued by the taxation or other authorities concerned on payment to them of amounts so deducted or withheld, a certificate of deduction or equivalent evidence of the relevant deduction or withholding.

4.7 Payments due will be made within 30 days of the end of each Year in respect of [\*\*\*] Year.

4.8 The Licensee will send the University a report within 30 days of the end of each Quarter showing the [\*\*\*] and the [\*\*\*] in such Year, and [\*\*\*] for that Year.

4.9 If any sum payable under this Agreement is not paid when due, then that sum shall bear interest from the due date until payment is made at [\*\*\*] over LIBOR, where “LIBOR” means the three month Sterling BBA LIBOR as quoted on page 3750 of the Telerate screen

or if such page is unavailable the interest rate at which Sterling deposits are perceived to be generally available by leading banks in the London Interbank Market at or about 11.00 a.m. on the first day of that period for delivery on that day.

- 4.10 The Licensee will keep, and will ensure that each of its Affiliates [\*\*\*] keeps, complete and accurate records and accounts of [\*\*\*] manufactured and supplied and [\*\*\*] and will permit, and will ensure that each of its Affiliates [\*\*\*] permits, the University or its agents during the Agreement and for 12 months afterwards to audit and take copies of those records and accounts solely for the purpose of determining the accuracy of the [\*\*\*]. If any audit reveals a discrepancy of more than 5<sup>0</sup>/0 in any report supplied under **clause 4.8** to the detriment of the University, the Licensee will reimburse the University for the costs of that audit and pay any accrued underpayment together with any interest accrued under **clause 4.9**.

## 5. INTELLECTUAL PROPERTY

- 5.1 The University gives no warranty and makes no representation that any applications compromised within the Licensed IP will proceed to grant or that any registration compromised within the Licensed IP is valid, or that the manufacture, use, sale, supply, or performance of any of the Licensed Products does not or will not infringe the rights (including but not limited to intellectual property rights) of any third party in the Territory.
- 5.2 The Licensee agrees that it will not obtain any right, title or interest in or to the Licensed IP, Improvements and Related IP other than such as may be granted to it under this Agreement and that the Licensee will not knowingly do or permit anything to be done in its use of any of the Licensed IP which would or could jeopardise its validity or any part of it.
- 5.3 The University shall be obligated to protect and manage the intellectual property rights of the Licensed IP whilst this Agreement remains in force and shall maintain final authority in all decisions regarding the preparation, prosecution and maintenance of the Licensed IP and any Improvements and any Related IP under this Agreement. The Licensee shall work closely with the University in the development of a suitable strategy for the prosecution and maintenance of Licensed IP and Improvements and Related IP. The University will request that copies of all documents prepared by the selected patent counsel be provided to Licensee for information following filing. The Licensee will bear all future legal and filing costs associated with the preparation, prosecution, and maintenance of the Licensed IP and Improvements with effect from the Commencement Date. In the event that any additional licence shall be granted by University for the Licensed IP, the Licensee's financial responsibility for costs arising from the preparation, maintenance, prosecution and protection of the Licensed IP shall be pro-rated and apportioned among all the licence holders.
- 5.4 If either party becomes aware of any infringement or any misuse of any of the Licensed IP, it will promptly notify the other party and provide all details within its knowledge and the parties will consult with each other to decide the best way to respond to such infringement provided that the University may at all times take such action as it sees fit in respect of such infringement or misuse. The Licensee will also provide the University with all assistance

required by the University for the purposes of any infringement or misuse action which the University may bring.

- 5.5 The University will be under no obligation to take any action regarding any infringements or misuse of any of the Licensed IP whether through the institution of legal proceedings or otherwise, but should the University in its absolute discretion decide to take any such action, it will do so at its own cost and the Licensee will have no claim to any sums recovered by the University.
- 5.6 In the event the University shall choose not to act against any identified infringer, then Licensee, at its sole option, shall be permitted to undertake legal action at its own responsibility, cost and expense, with any resulting recovery to first offset any and all Licensee costs of prosecution and recovery, and thereafter, any remaining sum shall be apportioned in accordance with standard royalty payments. University agrees to cooperate in any such action at the expense of the Licensee.

## 6. WARRANTIES AND LIABILITY

- 6.1 The University warrants as follows:
- 6.1.1 it is the owner of and applicant for or the registered proprietor (as the case may be) of the Patents;
  - 6.1.2 it has not previously licensed any of the Patents pursuant to a licence which remains in force;
  - 6.1.3 it has the sole right, power and authority to enter into this Agreement and to grant the [\*\*\*] licences granted hereunder.
- 6.2 Each of the parties acknowledges that, in entering into this Agreement, it has not relied on any warranty, representation or undertaking except those expressly set out in this Agreement and each party waives any claim for breach of any representation (unless made fraudulently) which is not specifically contained in this Agreement as a warranty.
- 6.3 Except as set forth In **clause 6.1**, the University does not give any warranty, representation or undertaking:
- 6.3.1 as to the efficacy or usefulness of any of the Licensed IP;  
or
  - 6.3.2 that any of the Licensed IP is or will be valid or subsisting or (in the case of an application) will proceed to grant;  
or
  - 6.3.3 that the use of any of the Licensed IP in, the manufacture, sale, supply, use or performance of any or the Licensed Products or the exercise of any of the rights granted under this Agreement will not infringe any intellectual property or other rights of any other person; or

- 6.3.4 that the Know-How or any other information communicated by the University to the Licensee under or in connection with this Agreement will produce Licensed Products of satisfactory quality or fit for the purpose for which the Licensee intended; or
  - 6.3.5 imposing any obligation on the University to bring or prosecute actions or proceedings against third parties for infringement or to defend any action or proceedings for revocation of any of the registered intellectual property comprised within the Licensed IP; or
  - 6.3.6 imposing any liability on the University in the event that any third party supplies Licensed Products to customers located in the Territory.
- 6.4 The Licensee will indemnify the University, and keep it fully and effectively indemnified, against each and every claim made against the University as a result of the Licensee's manufacture, use, sale or performance of, or other dealing in any of the Licensed Products except where such claim results directly from the University's negligence, provided that the University must:
- 6.4.1 promptly notify the Licensee of details of the claim;
  - 6.4.2 not make any admission in relation to the claim; and
  - 6.4.3 give the Licensee all reasonable assistance (at the Licensee's expense) in dealing with the claim.
- 6.5 Subject to **clause 6.8**, and except for third party claims made under any provision of indemnification, the liability of either party to the other for any breach of this Agreement, for any negligence or liability arising in any other way out of the subject matter of or in connection with this Agreement will not extend to any indirect damages or losses, or any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity, whether direct or indirect, even if the party bringing the claim has advised the other of the possibility of those losses or if they were within the other party's contemplation.
- 6.6 Subject to **clause 6.8**, except for third party claims made under any provision of indemnification, the aggregate liability of each party to the other for all and any breaches of this Agreement, any negligence or liability arising in any other way out of the subject matter of or in connection with this Agreement, will not exceed in total the payments received by the University from the Licensee under **clause 4.1** aggregate (excluding VAT) during the 12 months preceding the date upon which the claim is first notified to the University.
- 6.7 Subject to **clause 6.8**, any claim under or arising in any other way out of the subject matter of or in connection with this Agreement must be notified in writing by the party making the claim ("**Claimant**") within 12 months of the date when the Claimant became aware or ought reasonably to have become aware of such claim and in any event within 2 years of the

Commencement Date and proceedings in respect of such claim must be issued and served on the other party within 12 months of the date of such notification.

- 6.8 Nothing in this Agreement limits or excludes either party's liability for:
- 6.8.1 death or personal injury caused by its negligence;  
or
  - 6.8.2 any fraud or for any sort of liability that, by law, cannot be limited or excluded.

## 7. DURATION AND TERMINATION

- 7.1 This Agreement will take effect on the Commencement Date and, unless terminated earlier under the provisions of this Agreement, will continue in force until the date when all the Patents have expired, lapsed or been declared invalid by a final judgment of a court of competent jurisdiction or by any other institution, regulatory body or relevant registry which has authority to make such a ruling and from which no appeal can be made or is taken. Unless this license is terminated prior to the natural expiration of each patent, then upon the natural expiration of each patent, Licensee shall [\*\*\*].
- 7.2 Either party may terminate this Agreement with immediate effect by giving notice to the other party if;
- 7.2.1 the other party is in material breach of any provision of this Agreement and (if it is capable of remedy) the breach has not been remedied within 60 days after receipt of written notice specifying the breach and requiring its remedy; or
  - 7.2.2 the other party becomes insolvent, or if an order is made or a resolution is passed for its winding up (except voluntarily for the purpose of solvent amalgamation or reconstruction), or if an administrator, administrative receiver or receiver is appointed over the whole or any part of the other party's assets, or if the other party makes any arrangement with its creditors.
- 7.3 Licensee may terminate this Agreement at its sole option within 120 days of the execution of this Agreement should Licensee determine that the Licensed IP shall not satisfactorily permit the attainment of Licensee's commercial objectives. In such instance, Licensee shall notify University, shall convey back its licensed interest, and absent fraud, University shall retain [\*\*\*]. Each receiving party shall return all confidential information and materials to the disclosing party. Thereafter, this Agreement shall be null and void with neither party having any additional financial obligation to the other party.
- 7.4 If at any time during the term of this Agreement the Licensee or any of its Affiliates directly or indirectly opposes or assists any third party to oppose the grant of a Patent or disputes or directly or indirectly assists any third party to dispute or challenge the validity of any Licensed IP or any claim of any Patent then the University may at any time thereafter terminate this Agreement by notice to the Licensee.

- 7.5 Upon the expiration or termination of this Agreement prior to the natural expiration of any patent, the Licensee and its Affiliates [\*\*\*] may use or dispose of their then existing stocks of Licensed Products for a period of 3 months after the effective date of termination (subject to [\*\*\*]) but will no longer be licensed under the Licensed IP,
- 7.6 **Clauses 3, 4** (in relation to any accrued payments), **4.10, 5.1, 5.2, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7** and **6.8, 7.3, 7.4 7.5** and **7.6** and any provisions required for their interpretation will survive the expiry or termination of this Agreement for any reason and will continue indefinitely.

## 8. NOTICES

- 8.1 Any demand, notice or other communication given or made under or in connection with this Agreement shall be in writing and shall be given to the University or to the Licensee, as the case may be, either personally, by post or, by facsimile appropriately addressed as follows:

### University Licensee

The University of Manchester Brickell Biotech, Inc.

[\*\*\*] [\*\*\*]

For the attention of: Chief Executive For the attention of : President

or to such other destination as either party may from time to time designate by notice to the other.

- 8.2 Notices and communications so designated, shall be deemed to have been duly given or made:
- 8.2.1 if delivered by hand, upon delivery at the address of the relevant party;
- 8.2.2 if sent by prepaid ,first class post, 2 Business Days after posting;
- 8.2.3 if sent by fax, at the time of transmission (provided a confirmatory letter is sent by prepaid, first class post).
- 8.3 Where in accordance with the above provisions any notice or communication would otherwise be deemed to be given or made on a day which is not a Business Day or after 4.00 pm on a Business Day such notice or other communication shall be deemed to be given or made at 9.00 am on the next Business Day.

## 9. MISCELLANEOUS

- 9.1 The University may at any time assign the benefit (including any present, future or contingent interest or the right to any sums or damages payable by the Licensee under or in connection

with this Agreement) or delegate the burden of this Agreement or otherwise sub-contract, mortgage, charge or otherwise transfer or hold on trust any or all of its rights and obligations under this Agreement.

- 9.2 Neither party may use the other's name or logo in any press release or product advertising, or for any other promotional purpose, without first obtaining the other's written consent.
- 9.3 Nothing contained in this Agreement, and no action taken by the parties pursuant to this Agreement shall imply that there is any relationship between the parties of partnership or of principal/agent or of employer/employee, nor are the parties engaging in a joint venture, association or other co-operative venture and accordingly neither of the parties shall have any right or authority to act on behalf of the other nor to bind the other by contract or otherwise, unless expressly permitted by the terms of this Agreement.
- 9.4 If any of the provisions of this Agreement is judged to be illegal or unenforceable, the continuation in full force and effect of the remaining provisions will not be prejudiced unless the substantive purpose of this Agreement is then frustrated, in which case either party may terminate this Agreement on written notice.
- 9.5 This Agreement and all of its exhibits constitutes the entire agreement between the parties relating to the subject matter of this Agreement and supersedes all prior communications, drafts, agreements, representations, warranties, stipulations, undertakings and agreements of whatsoever nature, whether oral or written, between the parties and all implied conditions and warranties are excluded so far as permitted by law.
- 9.6 No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of each of the parties.
- 9.7 The failure to exercise or delay in exercising a right or remedy under this Agreement shall not constitute a waiver of the right or remedy or a waiver of any other rights or remedies, and no single or partial exercise of any right or remedy under this Agreement shall prevent any further exercise of the right or remedy or the exercise of any other right or remedy.
- 9.8 This Agreement may be executed in any number of counterparts, and by the parties on separate counterparts, each of which so executed and delivered shall constitute an original, but all the counterparts shall together constitute one and the same instrument.
- 9.9 The parties to this Agreement do not intend that any of its items will be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 by any person not a party to it.
- 9.10 If the parties are unable to reach agreement on any material issue relating to this Agreement within 10 Business Days after one party has notified the other of that issue, they will refer the matter to the CEO of UMIP or his or her nominee in the case of the University, and to **President** of Brickell Biotech, Inc. or his or her nominee in the case of the Licensee in an attempt to resolve the issue within 20 Business Days after the referral. Either party may bring proceedings in accordance with **clause 9.11** if the matter has not been resolved within

those 20 Business Days. Notwithstanding the foregoing, either party may apply to any court of competent jurisdiction for injunctive relief whether or not any issue has been escalated under this **clause 9.10**.

- 9.11 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by and construed in accordance with the [\*\*\*]. Subject to **clause 9.10**, the [\*\*\*] will have [\*\*\*] jurisdiction to settle any disputes which may arise out of or in connection with this Agreement.

**SCHEDULE 1**

**Know-How**

[\*\*]

**SCHEDULE 2**

**Patents**

[\*\*\*]

**SCHEDULE 3**

**The Development Plan**

For period beginning \_\_\_\_\_ and ending \_\_\_\_\_ (“Period”)

Date: \_\_\_\_\_

Contact Person: \_\_\_\_\_ Phone: \_\_\_\_\_ Email: \_\_\_\_\_

The initial Development Plan and each update to the Development Plan will include, at a minimum, the following information:

- a. Identification and nature of each active relationship between Company and its Affiliates, sublicensees or subcontractors in the research, development or commercialization of Licensed Products or Patent Rights.
- b. Significant projects completed during the reporting period by Company or its Affiliates, sublicensees or subcontractors in the research, development or commercialization of Licensed Products or Patent Rights,
- c. Significant projects currently being performed by Company or its Affiliates, sublicensees or subcontractors in the research, development or commercialization of Licensed Products or Patent Rights.
- d. Future projects expected to be undertaken during the next reporting period by Company or its Affiliates, sublicensees or subcontractors in the research, development or commercialization of Licensed Products or Patent Rights.
- e. Projected timelines to product launch of each Licensed Product prior to first Sale.
- (i) The Corporation will [\*\*\*] to achieve each of the diligence events by the applicable completion date listed in the table below for the Licensed Product. This table will be updated, when necessary, during each respective development plan update.

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

- f. Significant changes to the current Development Plan since the previous Development Plan and the reasons for the changes.

- g. Significant assumptions underlying the Development Plan and the future variables that may cause significant changes to the Development Plan.

## SCHEDULE 4

### Consultancy

- S2.1 Subject to the Licensee complying with its obligations under this Agreement, should the Licensee require, the University will use reasonable endeavours to make available [\*\*\*] for up to two Person Days per month for consultancy services during the first Year of this Agreement to facilitate the Licensee's development of Licensed Products. Such assistance will be provided at mutually acceptable times and locations and the Licensee will pay to the University up to [\*\*\*], payable in quarterly installments upon receipt of an invoice from the University.
- S2.2 The Licensee will be responsible for all disbursements on travel, accommodation and subsistence incurred by the University's or the Licensee's staff, together with the cost to the University of providing such staff with such insurance cover as the University may reasonably consider appropriate in connection with any facilitation or training under **S2.1**.
- S2.3 All payments under **S2.1** or **S2.2** will be made monthly in arrears to the credit of such bank account as is designated in writing from time to time by the University.
- S2.4 The Licensee acknowledges to the University that neither the University nor any of the University's staff involved in any way in connection with this Agreement will be under any liability whatsoever (whether in contract, tort (including negligence), breach of statutory duty, restitution or otherwise) for any injury, damage or direct, indirect or consequential loss (all three of which terms include pure economic loss, loss of profits, loss of business, depletion of goodwill and like loss) howsoever caused arising out of or in connection with or resulting from any actual or alleged advice or assistance of such staff. Notwithstanding anything else in this Agreement nothing in this Agreement shall exclude or limit the liability of the University or its staff for any liability which it or they are not permitted by law to so exclude or limit.
- S2.5 The Licensee will indemnify, keep indemnified and hold harmless the University from and against all costs (including the cost of enforcement), expenses, liabilities (including any tax liability), injuries, direct, indirect or consequential loss (all three of which terms include pure economic loss, loss of profits, loss of business, depletion of goodwill and like loss), damages, claims, demands, proceedings or legal costs (on a full indemnity basis) and judgements which the University incurs or suffers against all or any costs claims and expenses or other liability arising in connection with such consultancy given under **S2.1** (whether such consultancy was negligent or otherwise).

SIGNED by \_\_\_\_\_ ) /s/ Jane Shelton  
for and on behalf of \_\_\_\_\_ )  
THE UNIVERSITY OF MANCHESTER \_\_\_\_\_ )  
in the presence of: \_\_\_\_\_ )

Witness signature: /s/ Peter Welsh

Name: Peter Welsh

Address: UMIP, CTF (which stands for Core Technology Facility – see below), 46 Grafton Street, Manchester M13 9NT, UK

Occupation: Legal Executive

SIGNED by \_\_\_\_\_ ) /s/ Reginald Hardy  
for and on behalf of \_\_\_\_\_ )  
BRICKELL BIOTECH, INC. \_\_\_\_\_ ) Reginald Hardy  
in the presence of: \_\_\_\_\_ ) President

Witness signature: /s/ Andrew Sklawer

Name: Andrew Sklawer

Address: 612 SE 5<sup>th</sup> Avenue, Suite 1, Ft. Lauderdale, FL 33301

Occupation: Vice President, Operations, Brickell Biotech, Inc.

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

Execution Copy

SECOND RESTATED LICENSE AGREEMENT

This Restated License Agreement (this “Agreement”), effective as of June 6, 2013 (the “Effective Date”) and first amended as of 28 January 2015 (the “License Restatement Effective Date”), and subsequently amended as of 23 November 2015 (the “Second License Restatement Effective Date”) is by and between:

NEW YORK UNIVERSITY (hereinafter “NYU”), a corporation organized and existing under the laws of the State of New York and having a place of business at 70 Washington Square South, New York, New York, 10012.

AND

ORCA PHARMACEUTICALS LLC (hereinafter “CORPORATION”), a limited liability company organized and existing under the laws of the State of Delaware having its principal office at 3605 Warrensville Center Rd., MSC 2394, Cleveland, OH 44122.

RECITALS

WHEREAS, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member at NYU; and [\*\*\*], an employee of NYU (hereinafter “the NYU Scientists”) have made certain inventions relating to [\*\*\*], all as more particularly described in pending U.S. patent applications and counterpart foreign patent applications owned by NYU, identified in annexed Appendix I.A and forming an integral part hereof (hereinafter “the NYU Pre-Existing Inventions”);

WHEREAS, the NYU Scientists and researchers of the National Institutes of Health (hereinafter “NIH”) have made certain inventions relating to [\*\*\*], all as more particularly described in pending U.S. patent applications and counterpart foreign patent applications jointly owned by NYU and the NIH, identified in annexed Appendix I.B and forming an integral part hereof (hereinafter “the NYU/NIH Pre-Existing Inventions”);

WHEREAS, the [\*\*\*] with NYU dated 05/13/2013, 07/23/2012 and 06/26/2012 attached hereto as Appendix IV under which [\*\*\*] (the “Inter-Institutional Agreements”);

WHEREAS, HHMI has assigned its rights in the NYU Pre-Existing Inventions and NYU/NIH Pre-Existing Inventions to NYU, subject to an HHMI License (as hereinafter defined).

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WHEREAS, the parties entered into a license agreement dated June 7, 2013 for the NYU Pre-Existing Inventions, the NYU/NIH Pre-Existing Inventions and the NYU Know-How (as defined below) (the "Original License");

WHEREAS, the parties have previously re-stated the Original License in two agreements: a Restated License Agreement dated January 28, 2015 (the "Restated Agreement") and a separate know-how license to the NYU Know-How dated January 28, 2015; and WHEREAS, subject to the terms and conditions hereinafter set forth, NYU and CORPORATION are willing to restate the Restated Agreement to provide that NYU grants to CORPORATION and CORPORATION accepts from NYU the license to the NYU Pre-Existing Inventions, the NYU/NIH Pre-Existing Inventions and the NYU Know-How on the terms set out below;

NOW, THEREFORE, in consideration of the mutual promises and agreements contained herein, the parties hereto hereby agree as follows:

**1. Definitions.**

1.01 "Affiliate" shall mean any company or other legal entity which controls, or is controlled by, or is under common control with, CORPORATION; control for purposes of this definition means the holding of (i) fifty percent (50%) or more of the capital and/or the voting rights and/or (H) the right to elect or appoint fifty percent (50%) or more of the directors.

1.02 "Agreement Year" shall mean the yearly period beginning on the License Restatement Effective Date and each succeeding year thereafter for the term of the Agreement.

1.03 "Date of First Commercial Sale" shall mean, [\*\*\*], the date on which a Licensed Product is first sold by CORPORATION or an Affiliate or sublicensee of CORPORATION.

1.04 "Field" shall mean all fields and uses.

1.05 "License" shall mean (i) the [\*\*\*] the NYU/NIH Patents (as hereinafter defined), and (ii) the [\*\*\*] the NYU Patents and the NYU Know-How (as hereinafter defined); in each case [\*\*\*].

1.06 "Licensed Patents" shall mean the NYU Patents and the NYU/NIH Patents.

1.07 "Licensed Products" shall mean Licensed Compound Products and Licensed Know-How Products.

1.08 "Licensed Compound Products" shall mean all products which in the absence of the License would infringe any Valid Claim.

1.09 "Licensed Know-How Products" shall mean all products that are (i) not Licensed Compound Products, and (ii) which also are not Series 2 Licensed Products (as hereinafter defined), and (Hi) which either incorporate or are discovered or developed using NYU Know-How.

1.10 “Licensed Technology” shall mean all [\*\*\*].

1.11 “Net Sales” shall mean the total amount invoiced by CORPORATION, its Affiliates, and its sublicensees in connection with sales of the Licensed Products to any person or entity that is not an Affiliate or a sublicensee of CORPORATION under the License, after deduction of all the following to the extent applicable to such sales;

- i) all trade, case and quantity credits, discounts, refunds or rebates, including Medicaid, managed care and other such rebates;
- ii) allowances or credits for returns and recalls;
- iii) sales taxes (including value-added tax), custom duties and other governmental charges levied on sales of Licensed Product; and
- iv) amounts for transportation, transportation insurance, handling and shipping.

If CORPORATION, a CORPORATION Affiliate, or any sublicensee sells any Licensed Product in [\*\*\*] containing [\*\*\*], Net Sales of such [\*\*\*] for the purpose of determining [\*\*\*] to NYU pursuant to Section 6.01(c) will be calculated by [\*\*\*]. If, on a country-by-country basis, such other [\*\*\*] are not sold separately in such country, but the Licensed Product component of [\*\*\*] in such country, Net Sales for the purpose of [\*\*\*] shall be [\*\*\*]. If, on a country-by-country basis, such Licensed Product component is not sold separately in such country, Net Sales of [\*\*\*] for the purposes of [\*\*\*] for the [\*\*\*] shall be [\*\*\*] of CORPORATION and NYU, based upon [\*\*\*] and available market information. Notwithstanding anything above to the contrary, in no event shall the [\*\*\*].

1.12 “NYU Know-How” shall mean any information that was discovered, developed or acquired by, or on behalf of the NYU Scientists as of the Effective Date and, in each case, provided by NYU to CORPORATION, including but not limited to the information listed in Appendix II.

1.13 “NYU Patents” shall mean the patent applications listed in Appendix I.A and any divisions, continuations or claims of foreign counterparts thereof, or patents issuing thereon, or reissues, renewals and extensions thereof which are directed to subject matter specifically described in the patent applications listed in Appendix I.A.

1.14 “NYU/NIH Patents” shall mean the patent applications listed in Appendix I.13 and any divisions, continuations, continuations-in-part (but only to the extent that such continuations-in-part claim inventions specifically described in, and are directed to subject matter specifically described in, the patent applications listed in Appendix 1.B) or claims of foreign counterparts thereof, or claims of patents issuing thereof which are directed to subject matter specifically described in the patent applications listed in Appendix 1.B, or reissues, renewals and extensions thereof which are directed to subject matter specifically described in the patent applications listed in Appendix I.B.

1.15 "Series 2 Licensed Products" shall mean the series of compounds generated solely by Orca Pharmaceuticals Limited or on Orca Pharmaceuticals Limited's behalf and which [\*\*\*] as filed, [\*\*\*].

1.16 "Valid Claim" shall mean on a territory by territory basis, any claim of any issued unexpired Licensed Patent or any pending patent application within Licensed Patents which has been pending for less than five (5) years from the earliest date to which it claims priority, in each case which has not been disclaimed, permitted to lapse or held invalid by a court of competent jurisdiction or patent office from which no appeal can be taken or is taken within the time limits provided for such an appeal.

## **2. Effective Date.**

This Agreement shall be effective as of the Effective Date and shall remain in full force and effect until it expires or is terminated in accordance with Section 13 hereof.

## **3. Title.**

3.01 Subject to the License granted to CORPORATION hereunder, and the HHMI License, it is hereby agreed that all right, title and interest, in and to the (i) NYU Patents and NYU Know-How, and in and to any drawings, plans, diagrams, specifications, and other documents containing any of the NYU Patents and NYU Know-How shall [\*\*\*] and (ii) NYU/NIH Patents, and in and to any drawings, plans, diagrams, specifications, and other documents containing any of the NYU/NIH Patents shall [\*\*\*]. At the request of NYU, CORPORATION shall take [\*\*\*] as may be [\*\*\*] to give full effect to said right, title and interest of NYU and NIH including, but not limited to, the execution of any documents that may be required to record such right, title and interest with the appropriate agency or government office.

3.02 For so long as each of the NYU Scientists is employed by NYU or HHMI, any and all inventions made by such NYU Scientist and relating to the Field shall be owned [\*\*\*] (as hereinafter defined).

3.03 NYU shall not terminate [\*\*\*] without CORPORATION's prior written consent. If NYU receives any notice pursuant to Section 10.3 of one or more of [\*\*\*], NYU shall provide CORPORATION with a copy of such notice [\*\*\*], shall permit CORPORATION to control the content of and approve the response [\*\*\*] with respect to such notice, in consultation with NYU, and shall permit CORPORATION to participate in any discussions or other communication [\*\*\*] regarding any potential termination of [\*\*\*] thereof.

## **4. Patents and Patent Applications.**

4.01 [\*\*\*]

4.02 At the initiative of CORPORATION or NYU, the parties shall consult with each other regarding the prosecution of all patent applications with respect to the NYU/NIH Patents. Copies of all such patent applications, patent office actions and proposed responses shall be

forwarded to each of NYU and CORPORATION sufficiently prior to filing to allow for review and comment by each party, and the comments of each party shall be reasonably considered.

4.03 Subject to Section 4.02, all applications and proceedings with respect to the NYU/NIH Patents shall be filed, prosecuted and maintained by CORPORATION at the expense of CORPORATION. CORPORATION may select patent counsel, NYU may object to appointment of patent counsel where it believes such patent counsel are not qualified to file, prosecute and maintain the NYU/NIH Patents on behalf of CORPORATION. Where such objection is received, CORPORATION shall select alternative counsel reasonably acceptable to NYU, such acceptance not to be unreasonably withheld. CORPORATION shall file and prosecute the NYU/NIH Patents in good faith to obtain as broad a protection as reasonably possible, based on advice received from its patent counsel on obtaining such broad protection. The final decision in relation to any prosecution shall vest with CORPORATION.

4.04 If at any time during the term of this Agreement CORPORATION decides that it is undesirable, as to one or more countries, to prosecute or maintain any patents or patent applications within the NYU/NIH Patents, it shall give prompt written notice thereof to NYU at least 60 days in advance of any deadline, and upon receipt of such notice CORPORATION shall be released from its obligations to bear all of the expenses to be incurred thereafter as to such countries in conjunction with such patent(s) or patent application(s) and such patent(s) or application(s) shall be deleted from the Licensed Technology and NYU shall be free to prosecute such patents or patent applications at its sole discretion and expense, and to grant rights in and to such patent(s) or patent application(s) in such countries to third parties, without further notice or obligation to CORPORATION, and the CORPORATION shall have no rights whatsoever to exploit such patent(s) or patent application(s) in such countries.

4.05 NYU shall prosecute the NYU Patents at its sole discretion and expense and may abandon any NYU Patents at NYU's sole discretion.

4.06 Subject to Section 16, Nothing herein contained shall be deemed to be a warranty by NYU, NIH, or HHMI that

- i) NYU can or will be able to obtain any patent or patents on any patent application or applications in the Licensed Patents or any portion thereof, or that any of the Licensed Patents will afford adequate or commercially worthwhile protection, or
- ii) that the manufacture, use, or sale of any element of the Licensed Technology or any Licensed Product will not infringe any patent(s) of a third party.

4.07 CORPORATION and any Affiliates and sublicensees of CORPORATION shall insure that they apply patent markings that meet all requirements of U.S. law, 35 U.S.C. § 287, with respect to all Licensed Products.

## **5. Grant of License.**

5.01 Subject to the terms and conditions hereinafter set forth, NYU hereby grants to CORPORATION and CORPORATION hereby accepts from NYU the License.

5.02 NYU reserves [\*\*\*].

5.03 The parties acknowledge that the United States government retains rights in intellectual property funded under any grant or similar contract with a Federal agency. The License is expressly subject to all applicable United States government rights, including, but not limited to, any applicable requirement that products, which result from such intellectual property and are sold in the United States, must be substantially manufactured in the United States. NYU will take all actions reasonably requested by CORPORATION, at CORPORATION's expense, to obtain a waiver from the United States government of such substantial manufacture requirement.

5.04 The parties acknowledge that the Licensed Technology was developed, at least in part, by [\*\*\*].

5.05 The License granted to CORPORATION in Section 5.01 hereto shall commence upon the Effective Date and shall remain in force [\*\*\*], if not previously terminated under the terms of this Agreement for [\*\*\*] or until the expiration date of the last to expire of the NYU Patents and the NYU/NIH Patents that cover such Licensed Product [\*\*\*], whichever shall be later (the "License Term"). CORPORATION shall inform NYU in writing of the Date of First Commercial Sale with respect to each Licensed Product [\*\*\*] as soon as practicable after the making of each such first commercial sale. Following the expiration of the License Term, [\*\*\*].

5.06 CORPORATION shall be entitled to [\*\*\*] under the License on terms and conditions in compliance and not inconsistent with the terms and conditions of this Agreement (except that [\*\*\*]) (i) to an Affiliate or (H) to other third parties for consideration and in an arms-length transaction. The NYU Patents may only be [\*\*\*]. All [\*\*\*] shall only be granted by CORPORATION under a written agreement, a copy of which shall be provided by CORPORATION to NYU and NIH as soon as practicable after the signing thereof; provided, that, (a) the copy of the [\*\*\*] may be redacted by CORPORATION with respect to obligations that are not relevant to this Agreement and (b) the terms of each such sublicense agreement shall be Confidential Information of CORPORATION for purposes of this Agreement. Each [\*\*\*] granted by CORPORATION hereunder shall be subject and subordinate to the terms and conditions of this Agreement and shall contain (inter-alia) the following provisions:

- (1) [\*\*\*];
- (2) [\*\*\*];
- (3) [\*\*\*];
- (4) [\*\*\*];
- (5) [\*\*\*];  
and
- (6) [\*\*\*].

**6. Payments for License.**

6.01 In consideration for the grant and during the term of the License with respect to each Licensed Product, CORPORATION shall pay to NYU:

- (a) [\*\*\*];  
and
- (b) Within [\*\*\*] after [\*\*\*], with respect to each Licensed Compound Product and each Licensed Know-How Product, the payments as indicated below:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

The foregoing [\*\*\*], with respect to the [\*\*\*], regardless of how many times [\*\*\*]. If a particular above [\*\*\*] is achieved by a sublicensee of CORPORATION, and if CORPORATION receives a [\*\*\*], for which a payment is due to NYU under Section 6.01(d) below, then NYU shall [\*\*\*]. For example, if [\*\*\*] shall fully satisfy CORPORATION's obligations to NYU pursuant to this Section 6.01(b) and Section 6.01(d).

- (c) [\*\*\*];  
and
- (d) A [\*\*\*] under the terms of, or as a consideration for the grant of, a sublicense of any rights hereunder or for [\*\*\*] such a sublicense, based upon the development stage of the [\*\*\*] included in such grant at the time of the grant other than [\*\*\*]:
  - (I) [\*\*\*];
  - (II) [\*\*\*];
  - (III) [\*\*\*];  
or
  - (IV) [\*\*\*].

6.02 For the purpose of [\*\*\*] hereunder, the year shall be divided into four parts ending on March 31, June 30, September 30, and December 31. Not later than sixty (60) days after each December, March, June, and September in each Agreement Year during the term of the License, CORPORATION shall submit to NYU a full and detailed report [\*\*\*] NYU under the terms of this Agreement for the preceding quarter year (hereinafter "the Quarter-Year Report"), setting forth the [\*\*\*] including:

- i) [\*\*\*];

- ii) [\*\*\*];
- iii) [\*\*\*];  
and
- iv) [\*\*\*].

If no [\*\*\*] payments are due, a statement shall be sent to NYU stating such fact. Payment of the full amount of [\*\*\*] for the preceding quarter year shall accompany each Quarter-Year Report on [\*\*\*]. CORPORATION shall keep for a period of at least [\*\*\*], full, accurate and complete books and records consistent with sound business and accounting practices and in such form and in such detail as to enable [\*\*\*] to NYU from CORPORATION pursuant to the terms of this Agreement.

6.03 Within sixty (60) days after the end of each Agreement Year, commencing on the Date of First Commercial Sale CORPORATION shall furnish NYU with a report (hereinafter “the Annual Report”), relating to [\*\*\*] pursuant to this Agreement in respect of the Agreement Year covered by such Annual Report and containing the same details as those specified in Section 6.02 above in respect of the Quarter-Year Report.

6.04 On [\*\*\*] notice and during regular business hours and not more than once per calendar year, NYU or the authorized representative of NYU shall each have the right to designate an independent, certified public accountant reasonably acceptable to CORPORATION to inspect the books of accounts, records and other relevant documentation of CORPORATION or of any Affiliate of CORPORATION insofar as they relate to the production, marketing and sale of the Licensed Products, in order to [\*\*\*] hereunder, and the accuracy of the information provided to NYU in the aforementioned reports. The cost of such inspection shall be borne by NYU, unless it is determined in such inspection that NYU has been underpaid in any period by more than [\*\*\*] of the amount which NYU should have been paid, in which case the cost of such inspection shall be reimbursed to NYU by CORPORATION.

## **7. Method of Payment.**

7.01 [\*\*\*] hereunder shall be paid to NYU in [\*\*\*]. Any such [\*\*\*] based on the closing buying rate listed at [\*\*\*] on the last business day of the accounting period for which such royalty or other payment is due.

7.02 CORPORATION shall be responsible for payment to NYU of [\*\*\*] by each Affiliate of CORPORATION.

7.03 Any amount payable hereunder by one of the parties to the other, which has not been paid by the date on which such payment is due, shall bear interest from such date until the date on which such payment is made, at the rate of [\*\*\*] per annum in excess of the prime rate prevailing at the Citibank, N.A., in New York,

during the period of arrears and such amount and the interest thereon may be set off against any amount due, whether in terms of this Agreement or otherwise, to the party in default by any non-defaulting party.

## **8. Development and Commercialization.**

8.01 CORPORATION undertakes to use [\*\*\*] to carry out the Development Plan (annexed hereto as Appendix III and which is an integral part of this Agreement, as such Development Plan may be updated from time-to-time by mutual agreement of the parties), including but not limited to, the performance of all efficacy, pharmaceutical, safety, toxicological and clinical tests, trials and studies and all other activities necessary in order to obtain the approval of the FDA for the production, use and sale of the Licensed Products, all as set forth in the Development Plan (as updated from time-to-time by mutual agreement of the parties) and within all timetables set forth therein. CORPORATION further undertakes to exercise [\*\*\*], and to include in each sublicense agreement an obligation of such sublicensee, to [\*\*\*], to obtain the appropriate approvals of the health authorities for the production, use and sale of the Licensed Products, [\*\*\*] in which CORPORATION or its sublicensees intend to produce, use, and/or sell Licensed Products.

8.02 Provided that applicable laws, rules and regulations require that the performance of the tests, trials, studies and other activities specified in Paragraph 8.01 above shall be carried out in accordance with FDA Good Laboratory Practices and in a manner acceptable to the relevant health authorities, CORPORATION shall carry out such tests, trials, studies and other activities in accordance with FDA Good Laboratory Practices and in a manner acceptable to the relevant health authorities. Furthermore, the Licensed Products shall be produced in accordance with FDA Good Manufacturing Practice (“GMP”) procedures in a facility which has been certified by the FDA as complying with GMP, provided that applicable laws, rules and regulations so require.

8.03 CORPORATION agrees to [\*\*\*] to begin the regular commercial production, use, and sale of the Licensed Products [\*\*\*] in accordance with the Development Plan and to continue diligently thereafter to commercialize the Licensed Products.

8.04 CORPORATION shall provide NYU with written reports on all activities and actions undertaken by CORPORATION to develop and commercialize the Licensed Products; such reports shall be made within sixty (60) days after each six (6) months during the term of this Agreement, commencing six (6) months after the Effective Date. CORPORATION shall include sufficient details in such reports for NYU to ascertain CORPORATION’s progress in developing and commercializing Licensed Products.

## **9. CONFIDENTIAL INFORMATION.**

9.01 “Confidential Information” shall mean non-public information provided by one party (a “Disclosing Party”) to the other party (“Recipient”). Except as otherwise provided in Section 9.02 and 9.03 below, each Recipient shall maintain any and all of the Confidential Information in confidence and shall not release or disclose any tangible or intangible component

thereof to any third party without first receiving the prior written consent of, the Disclosing Party to said release or disclosure.

9.02 The obligations of confidentiality set forth in Sections 9.01 shall not apply to any Confidential Information that (i) is or becomes publicly available through no wrongful act of Recipient; (ii) was known by Recipient prior to disclosure by the Disclosing Party, as evidenced by tangible records; (iii) becomes known to Recipient after disclosure from a third party having an apparent bona fide right to disclose it; (iv) is independently developed or discovered by Recipient without use of the Disclosing Party's Confidential Information, as evidenced by tangible records; or (v) is disclosed to another party by the Disclosing Party without restriction on further disclosure.

9.03 Recipient shall have the right to, and agrees that it will, use the Disclosing Party's Confidential Information solely as provided under this Agreement, except a Recipient may disclose Confidential Information of the Disclosing Party to (x) its Affiliates, and to its and their directors, employees, consultants, and agents in each case who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use, (y) any bona fide actual or prospective collaborators, sublicensees, underwriters, investors, lenders or other financing sources who are obligated to keep such information confidential, to the extent reasonably necessary to enable such actual or prospective collaborators, sublicensees, underwriters, investors, lenders or other financing sources to determine their interest in collaborating with, sublicensing, underwriting or making an investment in, or otherwise providing financing to, the Recipient, and (z) the extent such disclosure is required to comply with applicable law or regulation or the order of a court of competent jurisdiction or to defend or prosecute litigation; provided, however, that the Recipient provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure. Notwithstanding any other provision of this Agreement, each Recipient may disclose and use Confidential Information of the Disclosing Party as necessary to file or prosecute patent applications, prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, or to submit regulatory filings.

#### **10. Infringement of NYU and NYU/NIH Patents.**

10.01 In the event a party to this Agreement acquires information that a third party is infringing one or more of the NYU Patents or NYU/NIH Patents, the party acquiring such information shall promptly notify the other party to the Agreement in writing of such infringement.

10.02 In the event of an infringement of an NYU/NIH Patent, CORPORATION shall have the right but not the obligation to bring suit against the infringer. Should CORPORATION elect to bring suit against an infringer and NYU is joined as a party plaintiff in any such suit, NYU shall have the right to approve the counsel selected by CORPORATION to represent CORPORATION and NYU. The expenses of such suit or suits that CORPORATION elects to bring, including the reasonable expenses of NYU incurred in conjunction with the prosecution of such suit or the settlement thereof, shall be paid for entirely by CORPORATION and

CORPORATION shall reimburse NYU, NIH, and HHMI for their reasonable costs and expenses incurred in connection with such litigation, including attorneys' fees. CORPORATION shall not compromise or settle such litigation without the prior written consent of NYU which shall not be unreasonably withheld.

10.03 In the event CORPORATION exercises the right to sue herein conferred, it shall have the right to first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys' fees, necessarily involved in the prosecution of any such suit, and if after such reimbursement, any funds shall remain from said recovery, CORPORATION shall promptly pay to NYU an amount as follows: (i) in the case of damages representing lost profits of CORPORATION, lost sales shall be calculated based on such lost profits and CORPORATION's profit margin, and [\*\*\*], (ii) in the case of damages representing [\*\*\*], then such damages shall be deemed to be consideration for the grant of a sublicense, and [\*\*\*] and [\*\*\*]; and, in each case, CORPORATION shall be entitled to receive and retain the balance of the remainder of such recovery.

10.04 If CORPORATION does not bring suit against said infringer pursuant to Section 10.02 herein, or has not commenced negotiations with said infringer for discontinuance of said infringement, within ninety (90) days after receipt of such notice, NYU shall have the right, but shall not be obligated, to bring suit for such infringement. Should NYU elect to bring suit against an infringer and CORPORATION is joined as a party plaintiff in any such suit, CORPORATION shall have the right to approve the counsel selected by NYU to represent NYU and CORPORATION, and NYU shall reimburse CORPORATION for its reasonable costs and expenses incurred in connection with such litigation, including attorneys' fees. If CORPORATION has commenced negotiations with an alleged infringer of the NYU/NIH Patent for discontinuance of such infringement within such 90-day period, CORPORATION shall have an additional ninety (90) days from the termination of such initial 90-day period to conclude its negotiations before NYU may bring suit for such infringement. In the event NYU brings suit for infringement of any NYU/NIH Patent, NYU shall not compromise or settle any such suit by licensing the alleged infringer without the prior consent of CORPORATION, which shall not be unreasonably withheld. In the event NYU brings suit for infringement of any NYU/NIH Patent, NYU shall have the right to first reimburse itself out of any sums recovered in such suit or settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys' fees necessarily involved in the prosecution of such suit, and if after such reimbursement, any funds shall remain from said recovery, [\*\*\*] and NYU shall be entitled to receive and retain the balance of the remainder of such recovery.

10.05 Each party shall always have the right to be represented by counsel of its own selection in any suit for infringement of the NYU/NIH Patents instituted by the other party to this Agreement under the terms hereof. The expense of such counsel shall be borne by the party initiating such infringement suit.

10.06 CORPORATION agrees to cooperate fully with NYU at the request of NYU, including, by giving testimony and producing documents lawfully requested in the prosecution

of any suit by NYU for infringement of the NYU/NIH Patents; provided, NYU shall pay all reasonable expenses (including attorneys' fees) incurred by CORPORATION in connection with such cooperation. NYU shall cooperate and shall endeavor to cause the NYU Scientists to cooperate with CORPORATION at the request of CORPORATION, including by giving testimony and producing documents lawfully requested, in the prosecution of any suit by CORPORATION for infringement of the NYU/NIH Patents; provided, that CORPORATION shall pay all reasonable expenses (including attorneys' fees) incurred by NYU in connection with such cooperation.

10.07 NYU shall have the sole right, but not the obligation to take any action with regard to infringement of the NYU Patents, and to retain any recovery therefrom.

#### **11. Liability and Indemnification.**

11.01 CORPORATION shall indemnify, defend and hold harmless NYU and NIH and their trustees, officers, medical and professional staff, employees, students and agents and their respective successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments (i) arising out of the design, production, manufacture, sale, use in commerce or in human clinical trials, lease, or promotion by CORPORATION or by a licensee, Affiliate or agent of CORPORATION of any Licensed Product, process or service relating to, or developed pursuant to, this Agreement or (ii) arising out of any other activities to be carried out pursuant to this Agreement.

11.02 With respect to an Indemnitee, CORPORATION's indemnification under subsection 11.01(i) shall apply to any liability, damage, loss or expense whether or not it is attributable to the negligent activities of such Indemnitee. CORPORATION's indemnification obligation under subsection 11.01(i) shall not apply to any liability, damage, loss or expense to the extent that it is attributable to the negligent activities of any such Indemnitee.

11.03 An Indemnitee or HHMI Indemnitee (as hereinafter defined) shall provide CORPORATION with notice of any Claim or HHMI Claim (as hereinafter defined) for which indemnification may be sought pursuant to this Agreement. Such notice shall be given reasonably promptly following actual receipt of written notice thereof. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of any Indemnitee or HHMI Indemnitee to give reasonably prompt notice to CORPORATION of any such Claim or HHMI Claim shall not affect the rights of such Indemnitee or HHMI Indemnitee, as applicable, unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects CORPORATION. CORPORATION shall, at its own expense, provide attorneys reasonably acceptable to the Indemnitee to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought. NYU or NIH, as relevant, shall cooperate as reasonably requested (at the expense of CORPORATION) in the investigation and defense of any Claim. NYU, HHMI, or NH-I, as relevant, shall permit CORPORATION to

assume direction and control of the defense of the Claim or HHMI Claim (including the right to settle the Claim solely for monetary consideration); provided, however, that CORPORATION shall not settle any Claim or HHMI Claim without the prior written consent of NYU, HHMI or NIH, as relevant, where such settlement (a) would include any admission of liability on the part of the relevant Indemnitee or HHMI Indemnitee, (b) would impose any restriction on the relevant Indemnitee's or HHMI Indemnitee's conduct of any of its activities or (c) would not include an unconditional release of the relevant Indemnitee or HHMI Indemnitee from all liability for claims that are the subject matter of the settled Claim or HHMI Claim. CORPORATION agrees to keep each affected Indemnitee informed of the progress in the defense and disposition of such Claim.

11.04 HHMI, and its trustees, officers, employees, and agents (collectively, "HHMI Indemnitees"), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by CORPORATION from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "HHMI Claims"), based upon, arising out of, or otherwise relating to this Agreement or any other sublicense, including without limitation any cause of action relating to product liability. The previous sentence will not apply to any HHMI Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee. Notwithstanding any other provision of this Agreement, CORPORATION's obligation to defend, indemnify and hold harmless the HHMI Indemnitees under this paragraph will not be subject to any limitation or exclusion of liability or damages or otherwise limited in any way.

## **12. Insurance.**

12.01 At such time as any Licensed Product, process or service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold or tested in clinical trials by CORPORATION or by a licensee, Affiliate or agent of CORPORATION, CORPORATION shall at its sole cost and expense, procure and maintain policies of comprehensive general liability insurance in amounts not less than (i) [\*\*\*] during the period that such [\*\*\*], and (ii) [\*\*\*] as additional insureds. Such comprehensive general liability insurance shall provide (i) product liability coverage and (H) broad form contractual liability coverage for CORPORATION's indemnification under Section 11 of this Agreement. If CORPORATION elects to self-insure all or part of the limits described above (including deductibles or retentions [\*\*\*]) such self-insurance program shall include assets or reserves which have been actuarially determined for the liabilities associated with this Agreement and must be acceptable to NYU.

The minimum amounts of insurance coverage required under this Section 12 shall not be construed to create a limit of CORPORATION's liability with respect to its indemnification under Section 11 of this Agreement.

12.02 CORPORATION shall provide NYU with written evidence of such insurance upon request of NYU. If insurance is cancelled, not renewed or a material change is made to such insurance; if CORPORATION does not obtain replacement insurance providing comparable coverage within such sixty (60) day period, NYU shall have the right to terminate this

Agreement effective at the end of such sixty (60) day period without notice or any additional waiting periods.

12.03 CORPORATION shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold or tested in clinical trials by CORPORATION or by a sublicensee, Affiliate or agent of CORPORATION and (H) a reasonable period after the period referred to in (i) above.

### **13. Expiry and Termination**

13.01 Unless earlier terminated pursuant to this Section 13 this Agreement shall expire upon the expiration of the period of the License in all countries as set forth in Section 5.05 above.

13.02 At any time prior to expiration of this Agreement, either party may terminate this Agreement forthwith for cause, as “cause” is described below, by giving written notice to the other party. Cause for termination by one party of this Agreement shall be deemed to exist if the other party materially breaches or materially defaults in the performance or observance of any of the provisions of this Agreement and such breach or default is not cured within sixty (60) days or, in the case of failure to pay any amounts due hereunder, thirty (30) days (unless otherwise specified herein) after the giving of notice by the other party specifying such breach or default, or if either NYU or CORPORATION discontinues its business or becomes insolvent or bankrupt.

13.03 Upon termination of this Agreement for any reason and prior to expiration as set forth in Section 13.01 hereof, all rights in and to the Licensed Technology shall revert to NYU, and CORPORATION shall not be entitled to make any further use whatsoever of the Licensed Technology; provided, that, for a period of up to ninety (90) days from the effective date of termination, CORPORATION will have the right to sell any existing inventory of Licensed Products, subject to its payment of the royalty applicable thereto and the provision of royalty reports pursuant to Sections 6 and 7.

13.04 In the event that this Agreement is terminated, any granted sublicenses shall remain in full force and effect and each sublicensee shall become a direct license of NYU; provided, that, (i) the sublicensee is not then in breach of its sublicense agreement, (ii) the scope of such sublicensee’s rights with respect to the Licensed Technology shall remain unchanged and the sublicensee agrees to be bound to NYU as a licensee under the non-financial terms and conditions of this Agreement that apply to such scope, and (iii) the sublicensee agrees to pay to NYU all annual license fees due pursuant to Section 6.01(a) and all amounts that CORPORATION would have been obligated to pay to NYU under this Agreement as a result of the activities of such sublicensee.

13.05 Termination of this Agreement shall not relieve either party of any obligation to the other party incurred prior to such termination.

13.06 Sections 3.01, 3.02, 4.01, 9, 11, 12, 13, 17, 18 and 19.01 hereof shall survive and remain in full force and effect after any termination, cancellation or expiration of this Agreement.

Following termination for any reason prior to expiration as set forth in Section 13.01 hereof, should CORPORATION continue to sell Licensed Know-How Products or develop Licensed Know-How Products after such termination despite Section 13.03 above, in each case where NYU Know-How was used to discover or develop such Licensed Know-How Product prior to termination but no NYU Know-How is needed to develop or sell such Licensed Know-How Product after termination, then termination shall not relieve the CORPORATION from payment of milestones and royalties in accordance with Sections 6.01(b) and 6.01(c) of this Agreement and Sections 6.02-6.04 and 7.01-7.03 shall survive and remain in full force and effect after such termination of this Agreement solely with respect to the development and sales of such Licensed Know-How Products and solely for the period of time that such payments would have been owed if the Agreement had not terminated early. Following termination, royalty reports under clause 6.02 shall only be due where CORPORATION does in fact sell such Licensed Know-How Products.

13.07 CORPORATION may at any time terminate this Agreement by providing 30 days prior written notice to NYU.

13.08 NYU may terminate this Agreement by providing 30 days prior written notice to CORPORATION if CORPORATION or its Affiliate institutes a legal proceeding that challenges the validity of the Licensed Patents.

**14. Representations and Warranties by CORPORATION.**

CORPORATION hereby represents and warrants to NYU as follow:

- (1) CORPORATION is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. CORPORATION has been granted all requisite power and authority to carry on its business and to own and operate its properties and assets. The execution, delivery and performance of this Agreement have been duly authorized by the Board of Directors of CORPORATION.
- (2) There is no pending or, to CORPORATION's knowledge, threatened litigation involving CORPORATION which would have an adverse effect on this Agreement or on CORPORATION's ability to perform its obligations hereunder; and
- (3) There is no indenture, contract, or agreement to which CORPORATION is a party or by which CORPORATION is bound which prohibits or would prohibit the execution and delivery by CORPORATION of this Agreement or the performance or observance by CORPORATION of any term or condition of this Agreement.

**15. Representations and Warranties by NYU.**

NYU hereby represents and warrants to CORPORATION as follows:

- (1) NYU is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. NYU has been granted all requisite power and authority to carry on its business and to own and operate its properties and assets. The execution, delivery and performance of this Agreement have been duly authorized by the Board of Trustees of NYU.
- (2) There is no pending or, to NYU's knowledge, threatened litigation involving NYU which would have any effect on this Agreement or on NYU's ability to perform its obligations hereunder; and
- (3) There is no indenture, contract, or agreement to which NYU is a party or by which NYU is bound which prohibits or would prohibit the execution and delivery by NYU of this Agreement or the performance or observance by NYU of any term or condition of this Agreement.
- (4) it is the owner by assignment and/or the co-owner with NIH of all Licensed Patents listed on Appendix I.A and LB and the inventions described and claimed therein, and it has the right to grant the licenses to CORPORATION under this Agreement;
- (5) NYU has not received any notice from any third party that any third party patent, patent application or other intellectual property rights would be infringed (i) by practicing any method covered by the Licensed Patents or by making, using or selling any composition covered by the Licensed Patents, or (ii) by making, using, offering for sale, selling or importing Licensed Products; and
- (6) NYU is not aware of any infringement or misappropriation by any third party of the Licensed Patents.

**16. Limitation of Liability.**

IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES OR ANY OF THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, MEDICAL AND PROFESSIONAL STAFF, EMPLOYEES AND AGENTS BE LIABLE TO CORPORATION OR ANY OF ITS AFFILIATES, SUBLICENSEES OR DISTRIBUTORS FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE LICENSE RIGHTS GRANTED HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION ECONOMIC DAMAGES OR INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL BE

ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

**17. No Assignment.**

17.01 Neither CORPORATION nor NYU shall have the right to assign, delegate or transfer at any time to any party, in whole or in part, any or all of the rights, duties and interest herein granted without first obtaining the written consent of the other to such assignment, [\*\*\*].

17.02 NYU hereby consents to [\*\*\*]. Effective upon such assignment, all references to CORPORATION in this Agreement shall be deemed, with respect to time periods after such assignment, to be references to Brickell (or in the event one or more subsequent assignments pursuant to Section 17.01, the then current direct or indirect assignee of Brickell). Also effective upon the assignment from ORCA to Brickell described above, the contact information for CORPORATION for the purposes of Section 19.05 shall be [\*\*\*]. Brickell and its direct and indirect assignees are intended third party beneficiaries of this Section 17.02.

**18. Use of Name.**

18.01 Without the prior written consent of the other party, neither CORPORATION nor NYU shall use the name of the other party or any adaptation thereof or of any staff member, employee or student of the other party:

- i) in any product labeling, advertising, promotional or sales literature;
- ii) in connection with any public or private offering or in conjunction with any application for regulatory approval, unless disclosure is otherwise required by law, in which case either party may make factual statements concerning the Agreement or file copies of the Agreement after providing the other party with an opportunity to comment and reasonable time within which to do so on such statement in draft.

Except as provided herein, neither NYU nor CORPORATION will issue public announcements about this Agreement without prior written approval of the other party.

18.02 CORPORATION acknowledges that under HHMI policy, CORPORATION may not use the name of HHMI or of any HHMI employee ([\*\*\*]) in a manner that could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference to the name of HHMI or any HHMI employee in press releases or similar materials intended for public release is approved by HHMI in advance.

**19. Miscellaneous.**

19.01 HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party

beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

19.02 In carrying out this Agreement the parties shall comply with all local, state and federal laws and regulations including but not limited to, the provisions of Title 35 United States Code §200 et seq. and 15 CFR §730-774.

19.03 If any provision of this Agreement is determined to be invalid or void, the remaining provisions shall remain in effect.

19.04 This Agreement shall be governed by and construed in accordance with the [\*\*\*], without regard to principles relating to conflicts of law. The courts of the [\*\*\*] shall have exclusive jurisdiction over the parties with respect to any dispute or controversy between them arising under or in connection with this Agreement and, by execution and delivery of this Agreement, the parties to this Agreement submit to the jurisdiction of those courts, including, but not limited to, the in personam and subject matter jurisdiction of those courts, waive any objection to such jurisdiction on the grounds of venue or forum non conveniens, the absence of in personam or subject matter jurisdiction and any similar grounds, consent to service of process by mail in accordance with paragraph 19.05 or any other manner permitted by law and irrevocably agree to be bound by any such judgment rendered thereby in connection with this Agreement. These consents to jurisdiction shall not be deemed to confer rights on any person other than the parties to this Agreement.

19.05 All payments or notices required or permitted to be given under this Agreement shall be given in writing and shall be effective when either personally delivered or deposited, postage prepaid, in the United States registered or certified mail, or sent via a recognized national overnight delivery service (such as Federal Express or DHL), addressed as follows:

To NYU: [\*\*\*]

To CORPORATION:

[\*\*\*]

or such other address or addresses as either party may hereafter specify by written notice to the other. Such notices and communications shall be deemed effective on the date of delivery or fourteen (14) days after having been sent by registered or certified mail, whichever is earlier.

19.06 This Agreement (and the annexed Appendices) constitute the entire Agreement between the parties and no variation, modification or waiver of any of the terms or conditions hereof shall be deemed valid unless made in writing and signed by both parties hereto. This Agreement supersedes any and all prior agreements or understandings, whether oral or written, between CORPORATION and NYU.

19.07 No waiver by either party of any non-performance or violation by the other party of any of the covenants, obligations or agreements of such other party hereunder shall be deemed

to be a waiver of any subsequent violation or non-performance of the same or any other covenant, agreement or obligation, nor shall forbearance by any party be deemed to be a waiver by such party of its rights or remedies with respect to such violation or non-performance.

19.08 The descriptive headings contained in this Agreement are included for convenience and reference only and shall not be held to expand, modify or aid in the interpretation, construction or meaning of this Agreement.

19.09 It is not the intent of the parties to create a partnership or joint venture or to assume partnership responsibility or liability. The obligations of the parties shall be limited to those set out herein and such obligations shall be several and not joint.

**[Remainder of page intentionally left blank.]**

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the Second License Restatement Effective Date.

NEW YORK UNIVERSITY

By: /s/ Abram M. Goldfinger  
Abram M. Goldfinger  
Executive Director,  
Industrial Liaison/Technology Transfer

Date: 11/23/15

ORCA PHARMACEUTICALS LLC

By: /s/ Baiju Shah  
Name: Baiju Shah  
Title: Manager

**Appendix I.A**

**[\*\*\*] Patents and Applications**

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

**Appendix I.B**

**[\*\*\*] Patents and Applications**

[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]

**Appendix II**

NYU Know-How

[\*\*\*]

Appendix II-1

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**Appendix III**  
**Development Plan**

***	***
***	***
***	***
***	***
***	***
***	***

**Initial plan for selection of lead compound:**

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Appendix III-1

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**Appendix IV**

**Inter-Institutional Agreements with NIH**

Appendix IV-1

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**PUBLIC HEALTH SERVICE**  
**PHS INTERINSTITUTIONAL AGREEMENT**  
**INSTITUTION-LEAD**

This Agreement is entered into between the National Institutes of Health (“NIH”) or the Food and Drug Administration (“FDA”), hereinafter singly or collectively referred to as “PHS”, agencies of the United States Public Health Service within the Department of Health and Human Services (“HHS”) through the Office of Technology Transfer, NIH, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and New York University School of Medicine a not for profit education corporation, hereinafter referred to as the “Institution”, having an address at One Park Avenue, 6<sup>th</sup> Floor, New York, New York 10016, U.S.A.

**BACKGROUND**

- 1.1 In the course of fundamental research programs at the PHS and by the Institution, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member of the Institution, [\*\*\*] (Institution), [\*\*\*] (PHS), [\*\*\*] (PHS) (Inventor(s)) made or reduced to practice certain inventions which are included within the Patent Rights, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the Institution and the PHS that their respective undivided interests in the Patent Rights be administered in a manner to ensure the rapid commercialization of the Patent Rights and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 C.F.R. §401.10, PHS is granting an [\*\*\*] to PHS’ rights in the Patent Rights to the Institution under the conditions set forth herein.
- 1.3 The Institution and HHMI are parties to a Collaboration Agreement under which (i) HHMI employees at the Institution, including [\*\*\*], assign their rights in inventions to the Institution, (ii) the Institution seeks patent protection for such inventions and seeks to license them to companies to be developed into products to benefit the public, (iii) the Institution shares any revenues from such licensing with HHMI, and (iv) the Institution grants HHMI a license to such inventions for its non-commercial purposes, and inserts certain language in license agreements with companies for HHMI’s benefit.

**2. DEFINITIONS**

- 2.1 “Patent Rights” means:
    - (a) Patent applications (including provisional patent applications and PCT patent applications) or patents as follows:  
[\*\*\*];
    - (b) [\*\*\*];  
and
-

(c) [\*\*\*];  
and

(d) Patent Rights shall  
[\*\*\*].

- 2.2 “Net Revenues” means all consideration received by the Institution [\*\*\*], less (a) Expenses and then (b) [\*\*\*]. It is contemplated that Patent Rights may be licensed together with other patent rights solely owned by the institution, or owned jointly by the Institution and a third party. In such instance, the portion of consideration from such licensing allocated to the Patent Rights shall be determined on a pro rata basis, based upon the number of patent families. Payments for the overall license, such as license fees, shall be allocated based upon the total number of patent families included in the license at the time the payment was received. Product-specific payments, such as royalties and milestone payments, shall be allocated based upon the total number of patent families covering the product generating the payments, at the time the payment was received.
- 2.3 “Expenses” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, paid by the Institution for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.
- 2.4 “Research License” means a nontransferable, nonexclusive license to make and to use any tangible embodiment of the Patent Rights and to practice any process(es) included within the Patent Rights for purposes of internal research and not for purposes of commercial manufacture or distribution or in lieu of purchase.
- 2.5 “Practical Application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the Government of the United States of America (hereinafter referred to as “Government”), available to the public on reasonable terms.

### 3. GRANT AND RESERVATION OF RIGHTS

- 3.1 PHS hereby grants and the Institution accepts, subject to the terms and conditions of this Agreement, an [\*\*\*].
- 3.2 The Government shall [\*\*\*]. Any license granted by the Institution under the terms of this Agreement shall be subject to [\*\*\*].
- 3.3 PHS reserves the right to require the Institution, or its licensees, to [\*\*\*].
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- 3.4 In addition to the reserved right of Paragraph 3.3, PHS reserves the right to [\*\*\*]. The purpose of these [\*\*\*] is to encourage basic research, whether conducted at an academic or corporate facility.
- 3.5 PHS acknowledges that Institution is required to, and that Institution may, include in any license for the Patent Rights granted by institution provisions which comply with the HHMI licensing provisions set forth on Appendix B.

#### 4. PATENT PROSECUTION AND PROTECTION

- 4.1 The Institution shall file, prosecute, and maintain patent application(s) relating to the Patent Rights and shall promptly provide to PHS all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the Institution, shall file with Patent Offices, a Power of Attorney, that names both the Institution and PHS. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to Patent Rights. The Institution shall consult with PHS, when so requested, prior to communicating with any Patent Office with respect to the Patent **Rights**.
  - 4.2 The Institution shall make an election with respect to foreign filing, upon consultation with PHS, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the Institution shall promptly provide to PHS all serial numbers and filing dates. The Institution also shall provide PITS copies of foreign patent applications and Patent Office actions. The Institution shall consult with PHS, when so requested, prior to communication with any Patent Office with respect to the Patent Rights.
  - 4.3 The Institution shall promptly record Assignments of domestic Patent Rights in the United States Patent and Trademark Office and shall promptly provide PHS with the original of each recorded Assignment with respect to PHS.
  - 4.4 Notwithstanding any other provision of this Agreement, the Institution shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this Agreement, without prior written notice to PHS. Upon receiving the written notice, PHS may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.
  - 4.5 The Institution shall promptly provide PHS with copies of all issued patents under this Agreement.
  - 4.6 In the event that the Institution anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement,
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including, without limitation, interferences, reexaminations, reissues and oppositions, the Institution shall provide PHS with all relevant information, and these extraordinary expenditures shall be included as Expenses only upon written agreement of PHS, provided that if such extraordinary expenses are necessary to preserve or to avoid abandonment of the Patent Rights, PHS shall not unreasonably withhold its approval of such extraordinary expenses. The Institution and PHS shall agree on a mutually acceptable course of action prior to incurring these expenditures.

## 5. LICENSING

- 5.1 The Institution shall diligently seek licensees for the commercial development of the Patent Rights and shall administer the Patent Rights for the mutual benefit of the parties and in the public interest. The Institution shall ensure that any license granted for the Patent Rights is subject to the provisions of 22 C.F.R. Part 401 and the rights retained by the Government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.
- 5.2 The Institution [\*\*\*], notwithstanding any other provision of this Agreement, without the prior written consent of PHS; provided, however, that PHS hereby agrees that HHMI [\*\*\*]. The Institution shall consult with PHS in the negotiation of [\*\*\*], notwithstanding any other provision of this Agreement, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of PHS.
- 5.3 Before licensing of the Patent Rights or any part thereof by the Institution, the Institution shall first notify and confer with PHS regarding any research funding related to the Patent Rights so as to determine PHS' interest in participating in any funded collaborative research project.
- 5.4 The Institution shall promptly provide PHS with complete copies of all licenses and sublicensees granted for the Patent Rights.
- 5.5 Institution agrees that its licensees shall supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the licensed products or licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

## 6. ROYALTIES AND EXPENSES

- 6.1 [\*\*\*].
  - 6.2 All payments to PHS, required under this Agreement, shall be in [\*\*\*] and payment options are listed in Appendix A.
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- (a) Institution shall submit to MS annual statements of itemized Expenses as defined in Paragraph 2.3 and shall deduct the Expenses as provided for in Paragraph 2.2, except where PITS has identified discrepancies in billing by Institution, in which case, deduction of the contested item(s), as a part of Expenses as provided for in Paragraph 2.2, from Net Revenues shall be delayed pending resolution thereof.

6.3 In no event shall PHS be obligated to bear any costs for Expenses under this Agreement.

6.4 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the Patent Rights any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

## 7. RECORDS AND REPORTS

7.1 The institution shall keep complete, true, and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the Patent Rights and shall permit PHS or PHS' designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.

7.2 Upon request by PHS, the Institution shall submit to PHS an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the Patent Rights for the preceding calendar year.

## 8. PATENT INFRINGEMENT

8.1 In the event PHS or the Institution, including its licensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The Institution and its licensees, in cooperation with PHS, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by the Institution, the Institution shall have the right, after consulting with PHS, to commence suit on its own account or to permit the Institution's licensee to commence suit on the licensee's own account. PITS may join the Institution's suit or commence its own suit.

8.2 If neither the Institution nor its licensee (i) bring suit within one (1) year after the parties are formally notified of the existence of an infringement, or (ii) are in negotiations with the infringing party to abate the infringement within such one (1) year period and either abate the infringement or bring suit within an additional

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one (1) year period; then PHS may bring suit to abate the infringement at PHS' sole expense.

- 8.3 Neither a licensee nor the Institution shall take action to compel PHS either to initiate or to join in any suit for patent infringement. Should the Government be made a party to any suit by motion or ally other action of a licensee or the Institution, the licensee or the Institution shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of the motion or other action, including any and all costs incurred by PHS in opposing any joinder action.
- 8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered Net Revenues.
- 8.5 Each party agrees to cooperate with the other in litigation proceedings. PHS may be represented, at its expense, by counsel of its choice in any suit.

#### 9. GOVERNING LAWS. SETTLING DISPUTES

- 9.1 This Agreement shall be construed in accordance with [\*\*\*]. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this Agreement. The Institution agrees to be subject to the jurisdiction of [\*\*\*].
- 9.2 Any controversy or any disputed claim by either party against the other arising under or related to this Agreement shall be submitted jointly to the Institution's President or designee and to the Director of the NIH or designee for resolution. The Institution and PHS shall be free after written decisions are issued by those officials to pursue all administrative or judicial remedies which may be available.

#### 10. TERM AND TERMINATION

- 10.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 11.10 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the Patent Rights unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.
  - 10.2 The Institution may terminate this Agreement upon at least sixty (60) days written notice to PHS, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.
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10.3 In the event the Institution has made no commitments to any third party for exclusive license rights relating to the Patent Rights, PHS may terminate this Agreement for any reason upon thirty (30) days written notice to the Institution. During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the Patent Rights between the Institution and an option= or licensee, PHS may terminate this Agreement when:

- (a) it is determined by PHS' Office of Technology Transfer that:
  - (i) The Institution or its licensee has not taken and is not expected to take effective steps to achieve Practical Application of the Patent Rights;
  - (ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the Institution or its licensee;
  - (iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the Institution or its licensees; or
  - (iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the Patent Rights in the United States is in breach of its agreement obtained pursuant to Section 204;
- (b) the Institution or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and
- (c) the Institution's or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.

10.4 PHS may terminate this Agreement in whole or in part if:

- (a) the Institution fails to make any payment or periodic reports required by this Agreement;
  - (b) the Institution has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the Agreement or in any report required by the Agreement;
  - (c) the Institution has committed a substantial breach of a covenant or duty contained in *this* Agreement;  
or
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- (d) PHS and the Institution are involved in a dispute under this Agreement which cannot be resolved under the procedures specified in Paragraph 9.2.

If the Agreement is terminated under this Paragraph 10.4, PHS agrees, subject to the restrictions of 37 C.F.R. Part 404, that any licenses that have been granted by the Institution shall remain in effect and Institution obligations to PHS including, paying royalties shall survive termination of this Agreement.

- 10.5 Following termination by PHS, PHS shall have no further rights or obligations under this Agreement, except that the Institution shall be obligated to administer subsequent gross proceeds from licensing the Patent Rights according to the Institution policy, and to distribute royalties to PHS for PHS Inventor(s) as though they were Inventor(s) of the Institution under that policy with respect to royalties and payment schedules.

## 11. GENERAL

- 11.1 [\*\*\*].
- 11.2 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 11.3 This Agreement shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this Agreement shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.
- 11.5 This Agreement is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this Agreement may not be assigned by either party without the prior written consent of the other party.
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- 11.6 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the PBS other than the Patent Rights regardless of whether such patents are dominant or subordinate to the Patent Rights.
- 11.7 Any modification to this Agreement must be in writing and agreed to by both parties.
- 11.8 It is understood and agreed by the Institution and PBS that this Agreement constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 11.9 HHMI is not a party to this Agreement and has no liability to any party, but HHMI is an intended third- party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.
- 11.10 The terms and conditions of this Agreement shall, at PHS' sole option, be considered by PHS to be withdrawn from Institution's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Institution and a fully executed original is received by PHS within sixty (60) days from the date of PHS signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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PHS INTERINSTITUTIONAL AGREEMENT-- INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For PHS:

/s/ Richard U. Rodriguez    6/19/12 \_\_\_\_\_  
Richard U. Rodriguez    Date  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

[E-mail: LicenseNotices\\_Reports@mailmil.gov](mailto:LicenseNotices_Reports@mailmil.gov)

For the Institution:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Institution made or referred to in this Agreement are truthful and accurate.

/s/ Abram M. Goldfinger    6/26/12 \_\_\_\_\_  
Signature of Authorized Official    Date

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Official and Mailing Address for Agreement notices:

Abram M. Goldfinger  
Printed Name

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Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University  
Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

And:

Annette Johnson, Esq.  
Name

Vice Dean and Senior Counsel for Medical School Affairs  
Title

Mailing Address:

550 First Avenue, HCC 15  
New York, New York 10016 U.S.A.

Email Address: [annettejohnson@nyumc.org](mailto:annettejohnson@nyumc.org)

Phone: 212-263-7921

Fax: 212-263-3235

Official and Mailing Address for Financial notices (Institution's contact person for royalty payments)

Abram M. Goldfinger  
Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University

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Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. 03801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

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**APPENDIX A — ROYALTY PAYMENT OPTIONS**

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## APPENDIX B — HHMI LICENSING PROVISIONS

Any licenses granted by the Institution under this Agreement shall include the following HI•IMI licensing provisions, where University shall mean Institution:

### 1. **Identification of HHMI Investigators**

If inventors are named in the license, HHMI investigators and HHMI inventor/employees should be properly identified as employees of the Howard Hughes Medical Institute doing research at the HHMI laboratory at the University.

*Example:* The invention was made by Dr. \_\_\_\_\_, an employee of the Howard Hughes Medical Institute and a faculty member at the University.

### 2. **Scope of Rights**

HI-IMI requires that the scope of rights in future technology granted under a license not go beyond the following:

“Patent rights” shall mean and include all of the following intellectual property of the University:

The United States patents and/or patent applications listed in Appendix A [to the license]; United States patents issued from the applications listed in Appendix A and from divisionals and continuations of these applications and any reissues of such United States patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the applications listed in Appendix A; and claims of all foreign patent applications, patents, and other intellectual property which are directed to subject matter specifically described in the United States patents and/or patent applications listed in Appendix A.

### 3. **HHMI Research Use License**

The license must reflect the fact that HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use the intellectual property for its research purposes (without the right to sublicense or assign) by including the following:

Licensee acknowledges that it has been informed that the [licensed technology] was developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable license to use the [licensed technology] for HHMI’s research purposes, but with no right to assign or sublicense (the “HHMI License”). This license is explicitly made subject to the HHMI License.

When exclusive licenses are being negotiated, HHMI’s research tools policies must be considered. If research tools developed in an HHMI laboratory (including software) are to be licensed on an exclusive basis, unless otherwise agreed by HHMI, HHMI requires that the

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University establish a licensing plan acceptable to HHMI showing how the research tools will be made available to the research community on reasonably acceptable terms.

#### 4. **Indemnification**

HHMI requires that it and its trustees, officers, employees and agents be indemnified and held harmless by licensees against claims based on or arising out of the license. The following is the indemnification provision that MIMI requires in licenses.

Howard Hughes Medical Institute (“HHMI”), and its trustees, officers, employees, and agents (collectively, “HHMI Indemnitees”), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by [the licensee, sublicensee, or other contracting party] from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) (collectively, “Claims”), based upon, arising out of, or otherwise relating to this [license, sublicense, or other contract or agreement], including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee.

HHMI’s indemnification must survive termination indefinitely.

HHMI’s required indemnification language does not provide a right to receive notice of claims or to settle claims. If the licensee requires the right to settle claims against HHMI and/or to receive notice of claims, then the following provisions should be added.

An indemnified party shall provide Licensee with prompt notice of any claim for which indemnification may be sought pursuant to this Agreement. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of [any indemnified party] [ally HHMI Indemnitee] to give reasonably prompt notice to Licensee of any such claim shall not affect the rights of such [HHMI Indemnitee] [indemnified party) unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Licensee.

Licensee agrees not to settle any Claim against an HHMI Indemnitee without HHMI’s written consent, where (a) such settlement would include any admission of liability on the part of any HHMI Indemnitee, (b) such settlement would impose any restriction on any HHMI indemnitee’s conduct of any of its activities, or (c) such settlement would not include an unconditional release of all HHMI Indemnitees from all liability for claims that are the subject matter of the settled Claim.

#### 5. **Insurance**

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HHMI asks for the same insurance protection as the University receives in any license. This insurance protection should survive termination.

Licensee shall have the insurance coverage set forth below. Such coverage shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name the University and HHMI as additional insureds.

6. **HHMI Third-Party Beneficiary Status**

The license should describe HHMI's status and rights as a third-party beneficiary as follows:

HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

7. **Arbitration**

HHMI does not permit the provisions in the license governing its rights to be subject to binding arbitration. Accordingly, if the licensee requires that all parties submit to binding arbitration, disputes relating to HHMI's rights must be carved out of the requirements. The following is model language to exclude HHMI's rights from a binding arbitration provision.

Notwithstanding the foregoing, no dispute affecting the rights or property of HHMI shall be subject to the arbitration provisions set forth above.

8. **Sublicenses**

HHMI requires that sublicensees be bound by the obligations in the sections of the License on indemnification, insurance and HHMI's third party beneficiary status, in accordance with the following:

Licensee shall have the right to grant sublicenses consistent with this Agreement, which sublicenses shall include, without limitation, a provision binding sublicensees to all terms hereof intended for the protection of the University and other indemnified parties, including HHMI, against liability or loss.

9. **Use of Name Provision**

The University shall include one of the two following provisions:

LICENSEE acknowledges that under HHMI policy, LICENSEE may not use the name of HHMI or of any HHMI employee (including Dr. [Investigator Name]) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference

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to the name of HHMI or any MIMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

LICENSEE may use Dr. \_\_\_\_\_'s name so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of LICENSEE or of any LICENSEE program, product or service. However, LICENSEE shall not use Dr. \_\_\_\_\_'s name or the Institute's name in any press release, or quote Dr. \_\_\_\_\_ in any company materials, or otherwise use Dr. \_\_\_\_\_'s name or the Institute's name in a manner not specifically permitted by the preceding sentence, unless in each case LICENSEE obtains in advance the written consent of the Institute, and, in the case of the use of Dr. \_\_\_\_\_'s name, Dr. \_\_\_\_\_'s consent as well.

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**PUBLIC HEALTH SERVICE**  
**PITS INTERINSTITUTIONAL AGREEMENT**  
**INSTITUTION-LEAD**

This Agreement is entered into between the National Institutes of Health (“NIH”) or the Food and Drug Administration (“FDA”), hereinafter singly or collectively referred to as “PHS”, agencies of the United States Public Health Service within the Department of Health and Human Services (“HHS”) through the Office of Technology Transfer, NIH, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and New York University School of Medicine a not for profit education corporation, hereinafter referred to as the “Institution”, having an address at One Park Avenue, 6<sup>th</sup> Floor, New York, New York 10016, U.S.A.

**BACKGROUND**

- 1.1 In the course of fundamental research programs at the PHS and by the Institution, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member of the Institution, [\*\*\*] (Institution), [\*\*\*] (PHS), [\*\*\*] (PHS) and [\*\*\*] (PHS) (Inventor(s)) made or reduced to practice certain inventions which are included within the Patent Rights, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the Institution and the PHS that their respective undivided interests in the Patent Rights be administered in a manner to ensure the rapid commercialization of the Patent Rights and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 C.F.R. §401.10, PHS is granting an exclusive license to PHS’ rights in the Patent Rights to the Institution under the conditions set forth herein.
- 1.3 The Institution and HHMI are parties to a Collaboration Agreement under which (i) HHMI employees at the Institution, including Daniel Littman, assign their rights in inventions to the institution, (ii) the institution seeks patent protection for such inventions and seeks to license them to companies to be developed into products to benefit the public, (iii) the Institution shares any revenues from such licensing with HHMI, and (iv) the Institution grants HHMI a license to such inventions for its non-commercial purposes, and inserts certain language in license agreements with companies for HHMI’s benefit.

**2. DEFINITIONS**

- 2.1 “Patent Rights”  
means:
    - (a) [\*\*\*];
    - (b) [\*\*\*];  
and
-

(c) [\*\*\*];  
and

(d) [\*\*\*].

2.2 “Net Revenues” means all consideration received by the institution from the licensing of the Patent Rights pursuant to this Agreement, less (a) Expenses and then (b) [\*\*\*]. It is contemplated that Patent Rights may be licensed together with other patent rights solely owned by the institution, or owned jointly by the Institution and a third party. In such instance, the portion of consideration from such licensing allocated to the Patent Rights shall be determined on a pro rata basis, based upon the number of patent families. Payments for the overall license, such as license fees, shall be allocated based upon the total number of patent families included in the license at the time the payment was received. [\*\*\*].

2.3 “Expenses” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, paid by the Institution for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.

2.4 “Research License” means a [\*\*\*].

2.5 “Practical Application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the Government of the United States of America (hereinafter referred to as “Government”), available to the public on reasonable terms.

### 3. GRANT AND RESERVATION OF RIGHTS

3.1 PHS hereby grants and the Institution accepts, subject to the terms and conditions of this Agreement, [\*\*\*].

3.2 The Government shall have [\*\*\*]. Any license granted by the Institution under the terms of this Agreement shall be subject to this right of the Government.

3.3 PHS reserves the right to require the Institution, or its licensees, to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to RIM]] health or safety needs or when necessary to meet requirements for public use specified by Federal regulations.

3.4 in addition to the reserved right of Paragraph 3.3, PHS [\*\*\*].

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3.5 PHS acknowledges that Institution is required to, and that Institution may, include in any license for the Patent Rights granted by Institution provisions which comply with the HHMI licensing provisions set forth on Appendix B.

#### 4. PATENT PROSECUTION AND PROTECTION

- 4.1 The Institution shall file, prosecute, and maintain patent application(s) relating to the Patent Rights and shall promptly provide to PHS all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the Institution, shall file with Patent Offices, a Power of Attorney, that names both the institution and PHS. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to Patent Rights. The Institution shall consult with PHS, when so requested, prior to communicating with any Patent Office with respect to the Patent Rights.
  - 4.2 The Institution shall make an election with respect to foreign filing, upon consultation with PHS, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the Institution shall promptly provide to PHS all serial numbers and filing dates. The Institution also shall provide PHS copies of foreign patent applications and Patent Office actions. The Institution shall consult with PHS, when so requested, prior to communication with any Patent Office with respect to the Patent Rights.
  - 4.3 The Institution shall promptly record Assignments of domestic Patent Rights in the United States Patent and Trademark Office and shall promptly provide PHS with the original of each recorded Assignment with respect to PHS.
  - 4.4 Notwithstanding any other provision of this Agreement, the Institution shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this Agreement, without prior written notice to PHS. Upon receiving the written notice, PHS may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.
  - 4.5 The institution shall promptly provide PHS with copies of all issued patents under this Agreement.
  - 4.6 In the event that the Institution anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, the Institution shall provide PHS with all relevant information, and these extraordinary expenditures shall be included as Expenses only upon written agreement of PHS, provided that if such extraordinary expenses are necessary to
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preserve or to avoid abandonment of the Patent Rights, PHS shall not unreasonably withhold its approval of such extraordinary expenses. The Institution and PHS shall agree on a mutually acceptable course of action prior to incurring these expenditures.

## 5. LICENSING

- 5.1 The Institution shall diligently seek licensees for the commercial development of the Patent Rights and shall administer the Patent Rights for the mutual benefit of the parties and in the public interest. The Institution shall ensure that any license granted for the Patent Rights is subject to the provisions of 37 C.F.R. Part 401 and the rights retained by the Government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.
- 5.2 The Institution shall [\*\*\*], notwithstanding any other provision of this Agreement, without the prior written consent of PHS; provided, however, that PHS hereby agrees that HHMI has a paid-up, non-exclusive, irrevocable license to use the Patent Rights for [\*\*\*], The Institution shall consult with PHS [\*\*\*], notwithstanding any other provision of this Agreement, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of PHS.
- 5.3 Before licensing of the Patent Rights or any part thereof by the Institution, the Institution shall first notify and confer with PHS regarding any research funding related to the Patent Rights so as to determine PHS' interest in participating in any funded collaborative research project.
- 5.4 The Institution shall promptly provide PHS with complete copies of all licenses and sublicenses granted for the Patent Rights.
- 5.5 Institution agrees that its licensees shall supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the licensed products or licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

## 6. ROYALTIES AND EXPENSES

- 6.1 [\*\*\*].
  - 6.2 All payments to PHS, required under this Agreement, shall be [\*\*\*] and payment options are listed in Appendix A.
  - 6.3 Institution shall submit to PUS annual statements of itemized Expenses as defined in Paragraph 2.3 and shall deduct the Expenses as provided for in Paragraph 2.2,
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except where PHS has identified discrepancies in billing by Institution, in which case, deduction of the contested item(s), as a part of Expenses as provided for in Paragraph 2.2, from Net Revenues shall be delayed pending resolution thereof.

- 6.4 in no event shall PUS be obligated to bear any costs for Expenses under this Agreement.
- 6.5 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the Patent Rights any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

#### 7. RECORDS AND REPORTS

- 7.1 The Institution shall keep complete, true, and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the Patent Rights and shall permit PHS or PHS' designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.
- 7.2 Upon request by PHS, the Institution shall submit to PHS an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the Patent Rights for the preceding calendar year.

#### 8. PATENT INFRINGEMENT

- 8.1 In the event PHS or the Institution, including its licensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The Institution and its licensees, in cooperation with PHS, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by the Institution, the Institution shall have the right, after consulting with PHS, to commence suit on its own account or to permit the Institution's licensee to commence suit on the licensee's own account. PHS may join the Institution's suit or commence its own suit.
  - 8.2 If neither the Institution nor *its* licensee (i) bring suit within one (1) year after the parties are formally notified of the existence of an infringement, or (ii) are in negotiations with the infringing party to abate the infringement within such one (1) year period and either abate the infringement or bring suit within an additional one (1) year period; then PHS may bring suit to abate the infringement at PUS' sole expense.
-

- 8.3 Neither a licensee nor the Institution shall take action to compel PHS either to initiate or to join in any suit for patent infringement. Should the Government be made a party to any suit by motion or any other action of a licensee or the institution, the licensee or the Institution shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of the motion or other action, including any and all costs incurred by PHS in opposing any joinder action.
- 8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered Net Revenues.
- 8.5 Each party agrees to cooperate with the other in litigation proceedings. PHS may be represented, at its expense, by counsel of its choice in any suit.

#### 9. GOVERNING LAWS, SETTling DISPUTES

- 9.1 This Agreement shall be construed in accordance with [\*\*\*], as interpreted and applied [\*\*\*]. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this Agreement. The Institution agrees to be subject to the [\*\*\*].
- 9.2 Any controversy or any disputed claim by either party against the other arising under or related to this Agreement shall be submitted jointly to the Institution's President or designee and to the Director of the NIH or designee for resolution. The Institution and PHS shall be free after written decisions are issued by those officials to pursue all administrative or judicial remedies which may be available.

#### 10. TERM AND TERMINATION

- 10.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 11.10 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the Patent Rights unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.
- 10.2 The Institution may terminate this Agreement upon at least sixty (60) days written notice to PHS, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.
- 10.3 In the event the institution has made no commitments to any third party for exclusive license rights relating to the Patent Rights, PHS may terminate this Agreement for any reason upon thirty (30) days written notice to the Institution.
-

During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the Patent Rights between the Institution and an optionee or licensee, MS may terminate this Agreement when:

- (a) it is determined by PHS' Office of Technology Transfer that:
  - (i) The Institution or its licensee has not taken and is not expected to take effective steps to achieve Practical Application of the Patent Rights;
  - (ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the Institution or its licensee;
  - (iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the Institution or its licensees; or
  - (iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the Patent Rights in the United States is in breach of its agreement obtained pursuant to Section 204; the Institution or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and the institution's or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.

10.4 PHS may terminate this Agreement in whole or in part if:

- (a) the Institution fails to make any payment or periodic reports required by this Agreement;
- (b) the Institution has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the Agreement or in any report required by the Agreement;
- (c) the Institution has committed a substantial breach of a covenant or duty contained in this Agreement;  
or
- (d) PHS and the Institution are involved in a dispute under this Agreement which cannot be resolved under the procedures specified in Paragraph 9.2.

If the Agreement is terminated under this Paragraph 10.4, PHS agrees, subject to the restrictions of 37 C.F.R. Part 404, that any licenses that have been granted by the Institution shall remain in effect and Institution obligations to PHS including, paying royalties shall survive termination of this Agreement.

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- 10.5 Following termination by PHS, PHS shall have no further rights or obligations under this Agreement, except that the Institution shall be obligated to administer subsequent gross proceeds from licensing the Patent Rights according to the Institution policy, and to distribute royalties to PHS for PHS Inventor(s) as though they were Inventor(s) of the Institution under that policy with respect to royalties and payment schedules.

## II. GENERAL

- 11.1 The Institution agrees that, for use *and* sale of the Patent Rights in the United States, any products embodying the Patent Rights, or produced through use of the Patent Rights, shall be manufactured substantially in the United States unless a waiver is granted by PHS.
- 11.2 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 11.3 This Agreement shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this Agreement shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.
- 11.5 This Agreement is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this Agreement may not be assigned by either party without the prior written consent of the other party.
- 11.6 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the PHS other than the Patent Rights regardless of whether such patents are dominant or subordinate to the Patent Rights.
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- 11.7 Any modification to this Agreement must be in writing and agreed to by both parties.
- 11.8 It is understood and agreed by the institution and PHS that this Agreement constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 11.9 HHMI is not a party to this Agreement and has no liability to any party, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.
- 11.10 The terms and conditions of this Agreement shall, at PHS' sole option, be considered by PHS to be withdrawn from Institution's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Institution and a fully executed original is received by PHS within sixty (60) days from the date of PHS signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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PHS INTERINSTITUTIONAL AGREEMENT-- INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For PHS:

/s/ Richard U. Rodriguez                      7/20/12  
Richard U. Rodriguez    Date  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

[E-mail: LicenseNotices\\_Reports@mailmil.gov](mailto:LicenseNotices_Reports@mailmil.gov)

For the Institution:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Institution made or referred to in this Agreement are truthful and accurate.

/s/ Abram M. Goldfinger                      7/23/12  
Signature of Authorized Official    Date

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Official and Mailing Address for Agreement notices:

Abram M. Goldfinger  
Printed Name

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Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University  
Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)  
Phone: 212-263-8178  
Fax: 212-263-8189

And:

Annette Johnson, Esq.  
Name

Vice Dean and Senior Counsel for Medical School Affairs  
Title

Mailing Address:

550 First Avenue, HCC 15  
New York, New York 10016 U.S.A.

Email Address: [annettejohnson@nyumc.org](mailto:annettejohnson@nyumc.org)  
Phone: 212-263-7921  
Fax: 212-263-3235

Official and Mailing Address for Financial notices (Institution's contact person for royalty payments)

Abram M. Goldfinger  
Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University

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Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. 03801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

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**APPENDIX A — ROYALTY PAYMENT OPTIONS**

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## **APPENDIX B — HHMI LICENSING PROVISIONS**

Any licenses granted by the Institution under this Agreement shall include the following HI•IMI licensing provisions, where University shall mean Institution:

### **1. Identification of HHMI Investigators**

If inventors are named in the license, HHMI investigators and HHMI inventor/employees should be properly identified as employees of the Howard Hughes Medical Institute doing research at the HHMI laboratory at the University.

*Example:* The invention was made by Dr. \_\_\_\_\_, an employee of the Howard Hughes Medical Institute and a faculty member at the University.

### **2. Scope of Rights**

HHMI requires that the scope of rights in future technology granted under a license not go beyond the following:

“Patent rights” shall mean and include all of the following intellectual property of the University:

The United States patents and/or patent applications listed in Appendix A [to the license]; United States patents issued from the applications listed in Appendix A and from divisionals and continuations of these applications and any reissues of such United States patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the applications listed in Appendix A; and claims of all foreign patent applications, patents, and other intellectual property which are directed to subject matter specifically described in the United States patents and/or patent applications listed in Appendix A.

### **3. HHMI Research Use License**

The license must reflect the fact that HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use the intellectual property for its research purposes (without the right to sublicense or assign) by including the following:

Licensee acknowledges that it has been informed that the [licensed technology] was developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable license to use the [licensed technology] for HHMI’s research purposes, but with no right to assign or sublicense (the “HHMI License”). This license is explicitly made subject to the HHMI License.

When exclusive licenses are being negotiated, HHMI’s research tools policies must be considered. If research tools developed in an HHMI laboratory (including software) are to be licensed on an exclusive basis, unless otherwise agreed by HHMI, HHMI requires that the

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University establish a licensing plan acceptable to HHMI showing how the research tools will be made available to the research community on reasonably acceptable terms.

#### 4. **Indemnification**

HHMI requires that it and its trustees, officers, employees and agents be indemnified and held harmless by licensees against claims based on or arising out of the license. The following is the indemnification provision that HHMI requires in licenses.

Howard Hughes Medical Institute (“HHMI”), and its trustees, officers, employees, and agents (collectively, “HHMI Indemnitees”), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by [the licensee, sublicensee, or other contracting party] from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) (collectively, “Claims”), based upon, arising out of, or otherwise relating to this [license, sublicense, or other contract or agreement], including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee.

HHMI’s indemnification must survive termination indefinitely.

HHMI’s required indemnification language does not provide a right to receive notice of claims or to settle claims. If the licensee requires the right to settle claims against HHMI and/or to receive notice of claims, then the following provisions should be added.

An indemnified party shall provide Licensee with prompt notice of any claim for which indemnification may be sought pursuant to this Agreement. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of [any indemnified party] [ally HHMI Indemnitee] to give reasonably prompt notice to Licensee of any such claim shall not affect the rights of such [HHMI Indemnitee] [indemnified party) unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Licensee.

Licensee agrees not to settle any Claim against an HHMI Indemnitee without HHMI’s written consent, where (a) such settlement would include any admission of liability on the part of any HHMI Indemnitee, (b) such settlement would impose any restriction on any HHMI indemnitee’s conduct of any of its activities, or (c) such settlement would not include an unconditional release of all HHMI Indemnitees from all liability for claims that are the subject matter of the settled Claim.

#### 5. **Insurance**

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HHMI asks for the same insurance protection as the University receives in any license. This insurance protection should survive termination.

Licensee shall have the insurance coverage set forth below. Such coverage shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name the University and HHMI as additional insureds.

6. **HHMI Third-Party Beneficiary Status**

The license should describe HHMI's status and rights as a third-party beneficiary as follows:

HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

7. **Arbitration**

HHMI does not permit the provisions in the license governing its rights to be subject to binding arbitration. Accordingly, if the licensee requires that all parties submit to binding arbitration, disputes relating to HHMI's rights must be carved out of the requirements. The following is model language to exclude HHMI's rights from a binding arbitration provision.

Notwithstanding the foregoing, no dispute affecting the rights or property of HHMI shall be subject to the arbitration provisions set forth above.

8. **Sublicenses**

HHMI requires that sublicensees be bound by the obligations in the sections of the License on indemnification, insurance and HHMI's third party beneficiary status, in accordance with the following:

Licensee shall have the right to grant sublicenses consistent with this Agreement, which sublicenses shall include, without limitation, a provision binding sublicensees to all terms hereof intended for the protection of the University and other indemnified parties, including HHMI, against liability or loss.

9. **Use of Name Provision**

The University shall include one of the two following provisions:

LICENSEE acknowledges that under HHMI policy, LICENSEE may not use the name of HHMI or of any HHMI employee (including Dr. [Investigator Name]) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference

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to the name of HHMI or any MIMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

LICENSEE may use Dr. \_\_\_\_\_'s name so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of LICENSEE or of any LICENSEE program, product or service. However, LICENSEE shall not use Dr. \_\_\_\_\_'s name or the Institute's name in any press release, or quote Dr. \_\_\_\_\_ in any company materials, or otherwise use Dr. \_\_\_\_\_'s name or the Institute's name in a manner not specifically permitted by the preceding sentence, unless in each case LICENSEE obtains in advance the written consent of the Institute, and, in the case of the use of Dr. \_\_\_\_\_'s name, Dr. \_\_\_\_\_'s consent as well.

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# THE NATIONAL INSTITUTES OF HEALTH

## INTERINSTITUTIONAL AGREEMENT

### INSTITUTION-LEAD

This Agreement is entered into between the National Institutes of Health (“NIH”) within the Department of Health and Human Services (“HHS”) through the Office of Technology Transfer, NIH, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A and New York University School of Medicine, a not for profit education corporation, hereinafter referred to as the “**Institution**”, having an address at One Park Avenue, 6<sup>th</sup> Floor, New York, New York 10016, U.S.A.

#### I. BACKGROUND

- 1.1 In the course of fundamental research programs at the **NIH** or at the Food and Drug Administration and by the **Institution**, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member of the **Institution**, [\*\*\*] (**Institution**), [\*\*\*] (NM), [\*\*\*] (NIH) and [\*\*\*] (**NIH**) (**Inventor(s)**) made or reduced to practice certain inventions which are included within the **Patent Rights**, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the **Institution and the NIH** that their respective undivided interests in the **Patent Rights** be administered in a manner to ensure the rapid commercialization of the **Patent Rights** and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 C.F.R. §401.10, the **NIH** [\*\*\*] under the conditions set forth herein.
- 1.3 The **Institution and HHMI** are parties to a Collaboration Agreement under which (i) **HHMI** employees at the **Institution**, including Daniel Littman, assign their rights in inventions to the **Institution**, (ii) the **Institution** seeks patent protection for such inventions and seeks to license them to companies to be developed into products to benefit the public, (iii) the **Institution** shares any revenues from such licensing with **HHMI**, and (iv) the **Institution** grants **HHMI** a license to such inventions for its non-commercial purposes, and inserts certain language in license agreements with companies for **HHMI**'s benefit.

#### 2. DEFINITIONS

- 2.1 “**Government**” means the government of the United States of America.
  - 2.2 “**FDA**” means the Food and Drug Administration.
  - 2.3 “**Patent Rights**” means:
    - (a) [\*\*\*];
-

- (b) [\*\*\*];  
and
- (c) [\*\*\*];  
and
- (d) [\*\*\*].

- 2.4 “Net Revenues” means all consideration received by the Institution from the licensing of the Patent Rights pursuant to this Agreement less (a) Expenses and then (b) [\*\*\*]. It is contemplated that Patent Rights may be licensed together with other patent rights solely owned by the Institution, or owned jointly by the Institution and a third party. In such instance, [\*\*\*].
- 2.5 “Expenses” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, paid by the Institution for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.
- 2.6 “Research License” means [\*\*\*].
- 2.7 “Practical Application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the Government, available to the public on reasonable terms.

### 3. GRANT AND RESERVATION OF RIGHTS

- 3.1 The NIH hereby grants and the Institution accepts, subject to the terms and conditions of this Agreement, [\*\*\*].
  - 3.2 The Government shall [\*\*\*]. Any license granted by the Institution under the terms of this Agreement shall be subject to this right of the **Government**.
  - 3.3 The **NIH** reserves the right to require the Institution, or its licensees, to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by Federal regulations.
  - 3.4 In addition to the reserved right of Paragraph 3.3, the **NIH** reserves the right to require the Institution to grant Research Licenses on reasonable terms and conditions. The purpose of these Research Licenses is to encourage basic research, whether conducted at an academic or corporate facility.
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3.5 The **NIH** acknowledges that Institution is required to, and that **Institution** may, include in any license for the **Patent Rights** granted by **Institution** provisions which comply with the HHMI licensing provisions set forth on Appendix B.

#### 4. PATENT PROSECUTION AND PROTECTION

- 4.1 The Institution shall file, prosecute, and maintain patent application(s) relating to the Patent Rights and shall promptly provide to the NIH all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the Institution, shall file with Patent Offices, a Power of Attorney, that names both the Institution and the NIH. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to Patent Rights. The Institution shall consult with the NIH, when so requested, prior to communicating with any Patent Office with respect to the Patent Rights.
  - 4.2 The Institution shall make an election with respect to foreign filing, upon consultation with the NIH, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the Institution shall promptly provide to the NIH all serial numbers and filing dates. The Institution also shall provide the NIH copies of foreign patent applications and Patent Office actions. The Institution shall consult with the NIH, when so requested, prior to communication with any Patent Office with respect to the Patent Rights.
  - 4.3 The Institution shall promptly record Assignments of domestic Patent Rights in the United States Patent and Trademark Office and shall promptly provide the NIH with the original of each recorded Assignment with respect to the NIH.
  - 4.4 Notwithstanding any other provision of this Agreement, the Institution shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this Agreement, without prior written notice to the NIH. Upon receiving the written notice, the NIH may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.
  - 4.5 The Institution shall promptly provide the NIH with copies of all issued patents under this Agreement.
  - 4.6 In the event that the Institution anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, the Institution shall provide the NIH with all relevant information, and these extraordinary expenditures shall be included as Expenses only upon
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written agreement of the NIH, provided that if such extraordinary expenses are necessary to preserve or to avoid abandonment of the Patent Rights, the NIH shall not unreasonably withhold its approval of such extraordinary expenses. The Institution and the NIH shall agree on a mutually acceptable course of action prior to incurring these expenditures.

## 5. LICENSING

- 5.1 The Institution shall diligently seek licensees for the commercial development of the Patent Rights and shall administer the Patent Rights for the mutual benefit of the parties and in the public interest. The Institution shall ensure that any license granted for the Patent Rights is subject to the provisions of 37 C.F.R. Part 401 and the rights retained by the Government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.
- 5.2 The Institution shall [\*\*\*], notwithstanding any other provision of this Agreement, without the prior written consent of the NIH, provided, however, that the NIH hereby agrees that HHMI [\*\*\*].
- 5.3 The Institution shall consult with the NIH in [\*\*\*], notwithstanding any other provision of this Agreement, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of the NIH.
- 5.4 Before licensing of the Patent Rights or any part thereof by the Institution, the Institution shall first notify and confer with the NIH regarding any research funding related to the Patent Rights so as to determine the NIH's interest in participating in any funded collaborative research project.
- 5.5 The Institution shall promptly provide the NIH with complete copies of all licenses and sublicenses granted for the Patent Rights.
- 5.6 Institution agrees that its licensees shall supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the licensed products or licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

## 6. ROYALTIES AND EXPENSES

- 6.1 [\*\*\*].
  - 6.2 All payments to the NIH, required under this Agreement, shall be in [\*\*\*] and payment options are listed in Appendix A.
  - 6.3 The Institution shall submit to the NIH annual statements of itemized Expenses as defined in Paragraph 2.5 and shall deduct the Expenses as provided for in
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Paragraph 2.4, except where NIH has identified discrepancies in billing by the Institution, in which case, deduction of the contested item(s), as a part of the Expenses as provided for in Paragraph 2.4, from Net Revenues shall be delayed pending resolution thereof.

- 6.4 In no event shall the NIH be obligated to bear any costs for Expenses under this Agreement.
- 6.5 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the Patent Rights any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

## 7. RECORDS AND REPORTS

- 7.1 The Institution shall keep complete, true, and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the Patent Rights and shall permit the NIH or the NIH's designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.
- 7.2 Upon request by the NIH, the Institution shall submit to the NIH an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the Patent Rights for the preceding calendar year.

## 8. PATENT INFRINGEMENT

- 8.1 In the event the NIH or the Institution, including its licensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The **Institution** and its licensees, in cooperation with the **NIH**, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by the **Institution**, **the Institution** shall have the right, after consulting with the **NIH**, to commence suit on its own account or permit the **Institution's** licensee to commence suit on the licensee's own account. The NIH may join the Institution's suit or commence its own suit.
  - 8.2 'If neither the **Institution** nor its licensee (i) bring suit within one (1) year after the parties are formally notified of the existence of an infringement, or (ii) are in negotiations with the infringing party to abate the infringement within such one (1) year period and either abate the infringement or bring suit within an additional one (1) year period; then **the NIH** may bring suit to abate the infringement at the **NIIP** sole expense.
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- 8.3 Neither a licensee nor the **Institution** shall take action to compel the **NIH** either to initiate or to join in any suit for patent infringement. Should the **Government** be made a party to any suit by motion or any other action of a licensee or the **Institution**, the licensee or the **Institution** shall reimburse the **Government** for any costs, expenses, or fees which the Government incurs as a result of the motion or other action, including any and all costs incurred by the **NIH** in opposing any joinder action.
- 8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered Net Revenues,
- 8.5 Each party agrees to cooperate with the other in litigation proceedings. The **NIH** may be represented, at its expense, by counsel of its choice in any suit.

#### 9. GOVERNING LAWS, SETTLING DISPUTES

- 9.1 This **Agreement** shall be construed in accordance [\*\*\*]. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. The **Institution** agrees to be subject to the [\*\*\*].
- 9.2 Any controversy or any disputed claim by either party against the other arising under or related to this **Agreement** shall be submitted jointly to the **Institution's** President or designee and to the Director of the **NIH** or designee for resolution. The **Institution** and the **NIH** shall be free after written decisions are issued by those officials to pursue all administrative or judicial remedies which may be available.

#### 10. TERM AND TERMINATION

- 10.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 11.10 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the Patent Rights unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.
- 10.2 The **Institution** may terminate this Agreement upon at least sixty (60) days written notice to the NIH, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.
- 10.3 In the event the **Institution** has made no commitments to any third party for exclusive license rights relating to the Patent Rights, the NIH may terminate this Agreement for any reason upon thirty (30) days written notice to the Institution.
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During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the **Patent Rights** between the **Institution and an optionee or licensee**, the **NIH** may terminate this **Agreement when**:

- (a) it is determined by the NIH's Office of Technology Transfer that:
  - (i) The Institution or its licensee has not taken and is not expected to take effective steps to achieve **Practical Application** of the **Patent Rights**;
  - (ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the **Institution** or its licensee;
  - (iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the **Institution** or its licensees; or
  - (iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the Patent Rights in the United States is in breach of its agreement obtained pursuant to Section 204;
- (b) the **Institution** or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and
- (c) the **Institution's** or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.

10.4 The NIH may terminate this Agreement in whole or in part if:

- (a) the **Institution** fails to make any payment or periodic reports required by this Agreement;
  - (b) the **Institution** has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the Agreement or in any report required by the **Agreement**;
  - (c) the Institution has committed a substantial breach of a covenant or duty contained in this Agreement;  
or
  - (d) the NIH and the Institution are involved in a dispute under this Agreement which cannot be resolved under the procedures specified in Paragraph 9.2 If the Agreement is terminated under this Paragraph 10.4, the NIH agrees, subject to the restrictions of 37 C.F.R. Part 404, that any licenses that have been granted by the Institution shall remain in effect and, Institution
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obligations to the NIH including, paying royalties shall survive termination of this Agreement.

- 10.5 Following termination by the NIH, the NIH shall have no further rights or obligations under this Agreement, except that the Institution shall be obligated to administer subsequent gross proceeds from licensing the Patent Rights according to the Institution policy, and to distribute royalties to the NIH for the NIH Inventor(s) as though they were Inventor(s) of the Institution under that policy with respect to royalties and payment schedules.

## 11. GENERAL

- 11.1 [\*\*\*].
- 11.2 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 11.3 This Agreement shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this Agreement shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.
- 11.5 This Agreement is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this Agreement may not be assigned by either party without the prior written consent of the other party.
- 11.6 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the NIH other than the Patent Rights regardless of whether such patents are dominant or subordinate to the **Patent Rights**.
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- 11.7 Any modification to this Agreement must be in writing and agreed to by both parties.
- 11.8 It is understood and agreed by the Institution and the NIH that this Agreement constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 11.9 HHMI is not a party to this Agreement and has no liability to any party, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.
- 11.10 The terms and conditions of this Agreement shall, at the NIH's sole option, be considered by the NIH to be withdrawn from Institution's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Institution and a fully executed original is received by the NIH within sixty (60) days from the date of the NIH's signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

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PHS INTERINSTITUTIONAL AGREEMENT-- INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For NIH:

/s/ Richard U. Rodriguez                      5/10/13  
Richard U. Rodriguez    Date  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

[E-mail: LicenseNotices\\_Reports@mailmil.gov](mailto:LicenseNotices_Reports@mailmil.gov)

For the Institution:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Institution made or referred to in this Agreement are truthful and accurate.

/s/ Abram M. Goldfinger                      5/13/13  
Signature of Authorized Official    Date

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Official and Mailing Address for Agreement notices:

Abram M. Goldfinger  
Name

---

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University  
Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

And:

Annette Johnson, Esq.  
Name

Vice Dean and Senior Counsel for Medical School Affairs  
Title

Mailing Address:

550 First Avenue, HCC 15  
New York, New York 10016 U.S.A.

Email Address: [annettejohnson@nyumc.org](mailto:annettejohnson@nyumc.org)

Phone: 212-263-7921

Fax: 212-263-3235

Official and Mailing Address for Financial notices (Institution's contact person for royalty payments)

Abram M. Goldfinger  
Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University

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Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. 03801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

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**APPENDIX A — ROYALTY PAYMENT OPTIONS**

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## **APPENDIX B — HHMI LICENSING PROVISIONS**

Any licenses granted by the Institution under this Agreement shall include the following HI•IMI licensing provisions, where University shall mean Institution:

### **1. Identification of HHMI Investigators**

If inventors are named in the license, HHMI investigators and HHMI inventor/employees should be properly identified as employees of the Howard Hughes Medical Institute doing research at the HHMI laboratory at the University.

*Example:* The invention was made by Dr. \_\_\_\_\_, an employee of the Howard Hughes Medical Institute and a faculty member at the University.

### **2. Scope of Rights**

HHMI requires that the scope of rights in future technology granted under a license not go beyond the following:

“Patent rights” shall mean and include all of the following intellectual property of the University:

The United States patents and/or patent applications listed in Appendix A [to the license]; United States patents issued from the applications listed in Appendix A and from divisionals and continuations of these applications and any reissues of such United States patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the applications listed in Appendix A; and claims of all foreign patent applications, patents, and other intellectual property which are directed to subject matter specifically described in the United States patents and/or patent applications listed in Appendix A.

### **3. HHMI Research Use License**

The license must reflect the fact that HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use the intellectual property for its research purposes (without the right to sublicense or assign) by including the following:

Licensee acknowledges that it has been informed that the [licensed technology] was developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable license to use the [licensed technology] for HHMI’s research purposes, but with no right to assign or sublicense (the “HHMI License”). This license is explicitly made subject to the HHMI License.

When exclusive licenses are being negotiated, HHMI’s research tools policies must be considered. If research tools developed in an HHMI laboratory (including software) are to be licensed on an exclusive basis, unless otherwise agreed by HHMI, HHMI requires that the

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University establish a licensing plan acceptable to HHMI showing how the research tools will be made available to the research community on reasonably acceptable terms.

#### 4. **Indemnification**

HHMI requires that it and its trustees, officers, employees and agents be indemnified and held harmless by licensees against claims based on or arising out of the license. The following is the indemnification provision that HHMI requires in licenses.

Howard Hughes Medical Institute (“HHMI”), and its trustees, officers, employees, and agents (collectively, “HHMI Indemnitees”), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by [the licensee, sublicensee, or other contracting party] from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) (collectively, “Claims”), based upon, arising out of, or otherwise relating to this [license, sublicense, or other contract or agreement], including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee.

HHMI’s indemnification must survive termination indefinitely.

HHMI’s required indemnification language does not provide a right to receive notice of claims or to settle claims. If the licensee requires the right to settle claims against HHMI and/or to receive notice of claims, then the following provisions should be added.

An indemnified party shall provide Licensee with prompt notice of any claim for which indemnification may be sought pursuant to this Agreement. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of [any indemnified party] [ally HHMI Indemnitee] to give reasonably prompt notice to Licensee of any such claim shall not affect the rights of such [HHMI Indemnitee] [indemnified party) unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Licensee.

Licensee agrees not to settle any Claim against an HHMI Indemnitee without HHMI’s written consent, where (a) such settlement would include any admission of liability on the part of any HHMI Indemnitee, (b) such settlement would impose any restriction on any HHMI indemnitee’s conduct of any of its activities, or (c) such settlement would not include an unconditional release of all HHMI Indemnitees from all liability for claims that are the subject matter of the settled Claim.

#### 5. **Insurance**

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HHMI asks for the same insurance protection as the University receives in any license. This insurance protection should survive termination.

Licensee shall have the insurance coverage set forth below. Such coverage shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name the University and HHMI as additional insureds.

6. **HHMI Third-Party Beneficiary Status**

The license should describe HHMI's status and rights as a third-party beneficiary as follows:

HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

7. **Arbitration**

HHMI does not permit the provisions in the license governing its rights to be subject to binding arbitration. Accordingly, if the licensee requires that all parties submit to binding arbitration, disputes relating to HHMI's rights must be carved out of the requirements. The following is model language to exclude HHMI's rights from a binding arbitration provision.

Notwithstanding the foregoing, no dispute affecting the rights or property of HHMI shall be subject to the arbitration provisions set forth above.

8. **Sublicenses**

HHMI requires that sublicensees be bound by the obligations in the sections of the License on indemnification, insurance and HHMI's third party beneficiary status, in accordance with the following:

Licensee shall have the right to grant sublicenses consistent with this Agreement, which sublicenses shall include, without limitation, a provision binding sublicensees to all terms hereof intended for the protection of the University and other indemnified parties, including HHMI, against liability or loss.

9. **Use of Name Provision**

The University shall include one of the two following provisions:

LICENSEE acknowledges that under HHMI policy, LICENSEE may not use the name of HHMI or of any HHMI employee (including Dr. [Investigator Name]) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference

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to the name of HHMI or any MIMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

LICENSEE may use Dr. \_\_\_\_\_'s name so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of LICENSEE or of any LICENSEE program, product or service. However, LICENSEE shall not use Dr. \_\_\_\_\_'s name or the Institute's name in any press release, or quote Dr. \_\_\_\_\_ in any company materials, or otherwise use Dr. \_\_\_\_\_'s name or the Institute's name in a manner not specifically permitted by the preceding sentence, unless in each case LICENSEE obtains in advance the written consent of the Institute, and, in the case of the use of Dr. \_\_\_\_\_'s name, Dr. \_\_\_\_\_'s consent as well.

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED  
BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

**ASSET PURCHASE AGREEMENT**

**by and between**

**Brickell Biotech, Inc.  
as Purchaser,**

**and**

**Orca Pharmaceuticals LLC**

**and**

**Orca Pharmaceuticals Limited**

**as Sellers**

**Dated as of November 23, 2015**

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## ASSET PURCHASE AGREEMENT

**THIS ASSET PURCHASE AGREEMENT** is made as of November 23, 2015 (“Effective Date”) by and between Brickell Biotech, Inc., a Delaware corporation (“Purchaser”), and Orca Pharmaceuticals LLC, a Delaware limited liability company (“Orca LLC”) and Orca Pharmaceuticals Limited, a company incorporated and registered under the laws of England and Wales (“Orca Ltd”), Orca LLC and Orca Ltd each known individually as a “Seller” and collectively as “Sellers”.

### **RECITALS:**

Subject to the terms and conditions set forth herein, Sellers desire to sell, convey, transfer, assign and deliver to Purchaser, and Purchaser desires to purchase and acquire from Sellers, all of Sellers’ and their Affiliates’ right, title and interest in and to all of the Purchased Assets (the “Acquisition”).

Simultaneous with the execution of this Agreement, Orca LLC and Purchaser are entering into [\*\*\*].

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby expressly acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

### **ARTICLE I**

#### **DEFINITIONS**

**1.1 Definitions.** Unless otherwise defined herein, all capitalized terms shall have the meaning set forth in the NYU License Agreement. As used herein, the following terms shall have the following meanings:

“Acquisition” shall have the meaning given to such term in the Recitals.

“Affiliate” shall mean with respect to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with such Person; *provided, that*, for purposes of this definition, “control” (including, with correlative meanings, the terms “controlled by” and “under common control with”), as used with respect to any Person, shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities or by contract or otherwise.

“Agreement” shall mean this Asset Purchase Agreement.

“Assigned Know-How” shall mean (a) all information, data, results and analyses of any research, preclinical, clinical, stability, toxicology or other study of any Compound conducted by or on behalf of a Seller or its Affiliate, (b) all manufacturing (including process development) data with respect to any Compound generated by or on behalf of a Seller or its Affiliate, and (c) all other all Know-How that is owned by a Seller or its Affiliate and relates to any Compound or Product

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(which, for the avoidance of doubt, does not include NYU Know-How because that is licensed to Orca LLC and not owned by either Seller), and (d) all patents and patent applications (if any) that are owned by a Seller or its Affiliate and relate to any Compound or Product.

“\*\*\*” shall mean the \*\*\* having such name and \*\*\* Purchaser and Orca LLC on the Effective Date.

“Assumed Liabilities” shall have the meaning given to such term in Section 2.2.

“Business Day” shall mean any day other than a Saturday, Sunday or a day on which banks in Delaware are obligated by applicable Law or executive Order to close or are otherwise generally closed.

“Calendar Quarter” means each period of three (3) months ending on March 31, June 30, September 30 and December 31.

“Code” shall mean the Internal Revenue Code of 1986, as it may be amended from time to time, and any successor thereto.

“Compound” shall mean: (a) any compound, the composition, manufacture or use of which is claimed generically or specifically in any of the NYU/NIH Patents, and (b) any and all pharmaceutically active derivatives of any compound described in clause (a), including any prodrug, metabolite, ester, salt, hydrate, solvate, polymorph, isomer or enantiomer thereof, and including compositions containing such compound, prodrug or metabolites, or esters, salts, hydrates, solvates, polymorphs, isomers or enantiomers of any compound described in clause (a).

“Confidential Information” shall have the meaning given to such term in Section 5.9.

“Confidentiality Agreement” shall mean the One-Way Confidentiality Agreement dated June 22, 2015 entered into by Purchaser and Orca Ltd.

“Consent” means, with respect to any Person, any consent, approval, authorization, permission or waiver of, or registration, declaration or other action or filing with, or exemption by, such Person.

“Contract” means any contract, obligation, understanding, commitment, lease, license, purchase order, bid or other agreement with outstanding rights or obligations on the part of any party thereto, together with all amendments thereto.

“Damages” means all damages, liabilities, losses, expenses, and fees, including court costs and reasonable attorneys’, accountants’ and experts’ fees and expenses.

“EMA” shall mean the European Medicines Agency or any successor agency thereto.

“Exception” shall have the meaning given to such term in Section 3.2.

“FDA” shall mean the United States Food and Drug Administration or any successor agency thereto.

“First Commercial Sale” shall mean, with respect to a Licensed Compound Product in a country or other regulatory jurisdiction, the first sale of such Product for end use or consumption in such country or jurisdiction after receipt of Marketing Approval for such Licensed Compound Product in such country or jurisdiction.

“Governmental Authorities” shall mean all agencies, authorities, bodies, boards, commissions, courts, instrumentalities, legislatures and offices of any nature whatsoever of any government or political subdivision, whether foreign, federal, state, county, district, municipality, city or otherwise.

“Initiation” of a clinical trial shall mean first dosing of the first patient in such clinical trial.

“Inventory” shall mean all inventory of the Compounds or Products in the possession or control of a Seller or its Affiliate as of immediately prior to the Effective Date.

“Know-How” means any and all information, know-how, data, results, knowledge, techniques, discoveries, inventions, specifications, designs, regulatory filings, trade secrets, technology, methods, processes, discoveries, inventions, invention disclosures, developments, specifications, protocols, formulations, formulae, software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological and chemical, biochemical, preclinical test data, clinical test data and data resulting from non-clinical studies), manufacturing processes, information, records, stability data and other study data and procedures, business or financial information or information of any type whatsoever, in any tangible or intangible form.

“Laws” shall mean any Federal, state, foreign or local statute, law, ordinance, regulation, rule, code, Order, other requirement or rule of law.

“Liability” shall mean any direct or indirect indebtedness, liability, assessment, expense, claim, loss, damage, deficiency, obligation or responsibility, known or unknown, disputed or undisputed, joint or several, vested or unvested, executory or not, fixed or unfixed, choate or inchoate, liquidated or unliquidated, secured or unsecured, determinable or undeterminable, accrued or unaccrued, absolute or not, actual or potential, contingent or otherwise (including any liability under any guarantees, letters of credit, performance credits or with respect to insurance loss accruals).

“Lien” means any lien, mortgage, pledge, encumbrance, charge, security interest, adverse claim, liability, interest, charge, preference, priority, proxy, transfer restriction (other than restrictions under federal or state securities laws), encroachment, Tax, Order, community property interest, equitable interest, option, warrant or right of first refusal.

“Marketing Approval” shall mean, with respect to any Licensed Compound Product in a country or other regulatory jurisdiction, the approval by the applicable Regulatory Authority in such country or jurisdiction of an NDA for such Licensed Compound Product in such country or jurisdiction.

“\*\*\*” shall have the meaning given to such term in Section 2.4.

“\*\*\*” shall have the meaning given to such term in Section 2.4.

“NDA” shall mean: (a) in the United States, a New Drug Application (as more fully described in 21 CFR §314.50 et seq. or its successor regulation) filed with the FDA, or any successor application thereto; (b) in the European Union, a marketing authorization application filed with the EMA pursuant to the centralized EMA filing procedure; or (c) in any other jurisdiction, an application for Marketing Approval filed with the relevant Regulatory Authority for such jurisdiction.

“NYU License Agreement” means the Second Restated License Agreement dated November \_\_\_ 2015, by and between Orca LLC and New York University, a copy of which is attached as Exhibit A, which is an amendment and restatement of the Original License Agreement effective as of June 6, 2013, first amended and restated as of January 28, 2015 (Restatement Agreement).

“NYU Sublicense” shall have the meaning given to such term in Section 3.7.

“Order” shall mean any order, judgment, preliminary or permanent injunction, temporary restraining order, award, citation, decree, consent decree or writ of any Governmental Authority.

“Organizational Documents” means (a) any certificate or articles of incorporation, bylaws, certificate or articles of formation or organization, operating agreement or partnership agreement, (b) any documents comparable to those described in clause (a) as may be applicable pursuant to any Law and (c) any amendment or modification to any of the foregoing.

“Other NYU License” has the meaning given to such term in Section 3.7.

“Party” shall mean Sellers or Purchaser, individually, as the context so requires, and the term “Parties” shall mean collectively, Sellers and Purchaser.

“Permit” means any approval, license, franchise, Consent, exemption, permit, certificate, certificate of occupancy or Order issued by any Person.

“Person” shall mean an individual, corporation, partnership, limited partnership, limited liability company, limited liability partnership, syndicate, person (including a “person” as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended, together with the rules and regulations promulgated thereunder), trust, association, entity or government or political subdivision, agency or instrumentality of a government.

“Phase 2 Trial” shall mean a human clinical trial that would satisfy the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b) (or its successor regulation), or any equivalent provision of the Laws of any relevant jurisdiction.

“Phase 3 Trial” shall mean a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or its successor regulation) or any equivalent provision of the Laws of any relevant jurisdiction.

“Proceeding” means any claim, demand, dispute, action, audit, lawsuit, litigation, investigation or arbitration (in each case, whether civil, criminal or administrative) pending by or before any Governmental Authority or arbitrator.

“Product” shall mean any product containing or comprising any Compound, whether or not as the sole active ingredient, in any dosage, form or formulation.

“Purchase Price” shall have the meaning given to such term in Section 2.3.

“Purchased Assets” shall have the meaning given to such term in Section 2.1.

“Purchaser” shall have the meaning given to such term in the preamble of this Agreement.

“Regulatory Authority” shall mean any regulatory agency, ministry, department or other governmental body having authority in any country or region to control the development, manufacture, marketing, and sale of pharmaceutical products, including the FDA and EMA.

“SEC” shall mean the U.S. Securities and Exchange Commission.

“Selected Inventory” shall mean (a) that quantity of Compounds or Products from the Inventory as set out in Exhibit B plus (b) any additional quantities of Compounds or Products from the Inventory that Purchaser requests pursuant to Section 5.5.

“Seller” shall have the meaning given to such term in the preamble of this Agreement.

“Series 2 Compounds” shall mean the series of compounds generated solely by, or on behalf of, Orca Ltd, which are covered by [\*\*\*], as filed, together with any structural derivatives of such compounds reduced to practice solely by Orca Ltd or jointly by Orca Ltd and a Third Party.

“Sublicensee” shall mean a Third Party that has received (whether directly or indirectly) a license or other right from Purchaser or its Affiliate to research, develop manufacture, use, sell or otherwise commercialize any Licensed Compound Product. For clarity, “Sublicensee” shall not include a Seller, an Affiliate of a Seller or any Third Party that has received (whether directly or indirectly) a license or other right from a Seller or its Affiliate to research, develop, manufacture, use, sell or otherwise commercialize any Licensed Compound Product.

“Tax Return” shall mean any return, report, statement, form or other documentation (including any additional or supporting material and any amendments or supplements) filed or maintained, or required to be filed or maintained, with respect to or in connection with the calculation, determination, assessment or collection of any Taxes.

“Taxes” shall mean: (i) any and all taxes, fees, levies, duties, tariffs, imposts and other charges of any kind, imposed by any taxing authority, including taxes or other charges on, measured by, or with respect to income, franchise, windfall or other profits, gross receipts, property, sales, use, capital stock, payroll, employment, social security, workers’ compensation, unemployment compensation or net worth; taxes or other charges in the nature of excise, withholding, ad valorem, stamp, transfer, value-added or gains taxes; (ii) any Liability for the payment of any amounts of the

type described in clause (i) as a result of being a member of an affiliated, combined, consolidated or unitary group for any taxable period; (iii) any Liability for the payment of amounts of the type described in clause (i) or clause (ii) as a result of being a transferee of, or a successor in interest to, any Person or as a result of an express or implied obligation to indemnify any Person; and (iv) any and all interest, penalties, additions to tax and additional amounts imposed in connection with or with respect to any amounts described in clause (i), clause (ii) or clause (iii).

“Third Party” shall mean any Person other than Sellers or Purchaser or an Affiliate of Sellers or Purchaser.

“Transaction Documents” shall mean, collectively, this Agreement and [\*\*\*].

“US” means the United States of America, including its territories and possessions.

**1.2 Interpretation.** Unless the context otherwise requires, the terms defined in Section 1.1 shall have the meanings herein specified for all purposes of this Agreement, applicable to both the singular and plural forms of any of the terms defined herein. When a reference is made in this Agreement to Sections, such reference shall be to a Section of this Agreement unless otherwise indicated. Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation.”

## ARTICLE 2

### PURCHASE & SALE OF PURCHASED ASSETS

**2.1 Purchased Assets.** Sellers hereby sell, convey, transfer, assign and deliver to Purchaser, and Purchaser hereby purchases and acquires from Sellers, free and clear of all Liens, all of Sellers’ and their Affiliates’ right, title and interest in and to all of the following (collectively, the “Purchased Assets”):

- (a) [\*\*\*]
- (b) [\*\*\*]
- (c) [\*\*\*]
- (d) [\*\*\*]

**2.2 Assumed Liabilities.** Except for the Assumed Liabilities, Purchaser shall not, by virtue of its purchase of the Purchased Assets, assume or become responsible for any Liabilities of either Seller or any other Person in connection with this Agreement. Upon and subject to the terms, conditions, representations and warranties of Sellers contained herein, Purchaser hereby assumes and agrees to pay, perform, and discharge the following Liabilities: (a) all Liabilities arising out of or relating to the ownership, operation, maintenance, sale, lease or use by or on behalf of Purchaser or its Affiliates or Sublicensees of the Assigned Know-How and Selected Inventory on or after the Effective Date, (b) all Liabilities of Orca LLC under the NYU License Agreement to the extent arising on or after the Effective Date, and (c) all Liabilities for all research, development,

manufacturing, registration, commercialization, use, handling, storage, sale, offer for sale, import, export or other disposition or exploitation of Compounds and Products by or on behalf of Purchaser or its Affiliates or Sublicensees on or after the Effective Date (collectively, the “Assumed Liabilities”).

**2.3 Purchase Price; Payment of Purchase Price.** The aggregate consideration for the sale of the Purchased Assets shall be: (a) [\*\*\*] to be paid by Purchaser to Orca LLC within thirty (30) days after the Effective Date, (b) the assumption by Purchaser of [\*\*\*] and (c) all [\*\*\*] that become [\*\*\*] pursuant to Sections 2.4 and 2.5, respectively (collectively, the “Purchase Price”).

**2.4 [\*\*\*] Payments.** Within thirty (30) days after the [\*\*\*] of each of the events set forth in the table below (each, a “[\*\*\*]”) by Purchaser or its Affiliate or Sublicensee, Purchaser shall pay to Orca LLC [\*\*\*] in the table below (each such payment, a “[\*\*\*]”).

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Each [\*\*\*] shall be payable only one time, regardless of the number of times the [\*\*\*]. Under no circumstances shall Purchaser be obligated to pay to Orca LLC more than [\*\*\*] pursuant to this Section 2.4.

**2.5 [\*\*\*] Payments.**

(a) [\*\*\*] Purchaser will pay [\*\*\*] to Orca LLC equal to [\*\*\*] by Purchaser and its Affiliates and Sublicensees (“[\*\*\*]”). [\*\*\*] shall be payable [\*\*\*].

(b) Reports. Within sixty (60) days after the end of each Calendar Quarter during [\*\*\*], Purchaser shall deliver to Sellers a written report [\*\*\*] due under Section 2.5(a), in sufficient detail to permit confirmation of the accuracy of [\*\*\*] due to Orca LLC for any Calendar Quarter shall be paid no later than the date the written report for such calendar quarter is due.

**2.6 Payments; Audits.**

(a) Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in [\*\*\*]. Whenever conversion of amounts paid or reported to Purchaser or any of its Affiliates any foreign currency to US dollars is required, such conversion shall be made into US dollars based on the closing buying rate listed at [www.oanda.com](http://www.oanda.com) for the particular currency on the last business day of the Calendar Quarter for which such royalty is due. All payments owed by Purchaser under this Agreement shall be made by wire transfer to a bank and account designated in writing by Orca LLC, unless otherwise specified in writing by Orca LLC. Purchaser shall be responsible for payment to Orca LLC of all royalties due on sale, transfer or disposal of Licensed Compound Products by Affiliates of Purchaser.

(b) Interest payments. Any amount due by Purchaser to Orca LLC which has not been paid by the date on which such payment is due, shall bear interest from such date until the date on which such payment is made, at the rate of [\*\*\*] (%) per annum in excess of the prime rate prevailing at the Citibank, N.A. in New York, during the period of arrears.

(c) Audits. Until the expiration of [\*\*\*] hereunder and for a period of three (3) years thereafter, Purchaser shall keep complete and accurate records pertaining to the sale, transfer or other disposition of Licensed Compound Products for consideration by Purchaser and its Affiliates and Sublicensees, in sufficient detail to permit Sellers to [\*\*\*] hereunder. Seller shall have the right to cause an independent, nationally recognized, certified public accountant reasonably acceptable to Purchaser to audit such records to [\*\*\*], for a period covering not more than the preceding three (3) calendar years. Purchaser may require such accountant to execute a reasonable confidentiality agreement with Purchaser prior to commencing the audit. Such audits may be conducted during normal business hours upon reasonable prior written notice to Purchaser, but no more than frequently than once per year. No accounting period of Purchaser shall be subject to audit more than one time by Sellers. Prompt adjustments (including remittances of underpayments or overpayments disclosed by such audit) shall be made by the parties to reflect the results of such audit. Sellers shall bear the full cost of such audit unless such audit discloses an underpayment by Purchaser of [\*\*\*] of the amounts due under this Agreement and such [\*\*\*], in which case Purchaser shall bear the full cost of such audit.

**2.7 Allocation of Purchase Price.** Purchaser and Sellers shall cooperate in good faith to agree as to the allocation of the Purchase Price pursuant to Section 1060 of the Code and the treasury regulations promulgated thereunder. The Parties hereto further agree that: (a) the agreed upon allocation of Purchase Price shall be used in filing all required forms under Section 1060 of the Code and all Tax Returns; and (b) they will not take any position inconsistent with such allocation upon any examination of any such Tax Return, in any refund claim or in any tax litigation.

**2.8 Transfer Taxes.** Purchaser shall be responsible for the payment of any sales, use, transfer or similar taxes arising out of or in connection with the Acquisition; provided that Orca LLC shall [\*\*\*] promptly following written request from Purchaser, including documentation of any such payments.

**2.9 Withholding.** All payments made by the Purchaser under this Agreement shall be made without withholding or deduction of, or in respect of, any Tax unless required by Law. If a Law requires Purchaser to withhold or deduct Taxes of any type from payments payable hereunder to Orca LLC, Purchaser shall (a) deduct such Tax from the payment made to Orca LLC, (b) timely pay such Taxes for and on behalf of Orca LLC to the proper Government Authority, and (c) furnish Orca LLC with documentation of such payment within thirty (30) days following such payment.

### ARTICLE 3

#### REPRESENTATIONS AND WARRANTIES OF SELLERS

Sellers represent and warrant to Purchaser that the statements contained in this Article 3 are true and correct as of the Effective Date.

**3.1 Organization and Qualification.** Orca LLC is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. Orca Ltd is a limited liability company duly organized, validly existing and in good standing under the laws of England and Wales. Each of the Sellers has the requisite power to own and operate the Purchased Assets and carry on its business as now being conducted.

**3.2 Authority Relative to this Agreement.** Sellers have all requisite power and authority to execute and deliver this Agreement and the other Transaction Documents, to perform their obligations hereunder and to consummate the Acquisition. The execution, delivery and performance of this Agreement and the other Transaction Documents by Sellers and the consummation by Sellers of the Acquisition have been duly and validly authorized by all necessary action of the Sellers, and no other action on the part of either Seller is necessary to authorize this Agreement and the other Transaction Documents or to consummate the Acquisition. This Agreement and the other Transaction Documents have been duly executed and delivered by Sellers and, assuming the due authorization, execution and delivery by the other Party hereto, each such agreement constitutes a legal, valid and binding obligation of each Seller, enforceable against each Seller in accordance with its terms, subject to the effect of any applicable bankruptcy, moratorium, insolvency, reorganization or other similar law affecting the enforceability of creditors' rights generally and to the effect of general principles of equity which may limit the availability of remedies, whether in a proceeding at Law or in equity (collectively, the "Exception").

**3.3 No Conflict.** The execution and delivery of this Agreement and the other Transaction Documents by Sellers do not, and the performance by Sellers of their obligations hereunder and the consummation of the Acquisition and the transactions contemplated by the other Transaction Documents will not: (a) violate or conflict with any Law or Order to which either Seller is subject, (b) violate or conflict with any provision of the Organizational Documents of either Seller, or (c) conflict with, result in a breach of, constitute a default under, result in the acceleration of, create in any party the right to accelerate, terminate, modify, or cancel, or require any notice, Consent or payment under, any Contract, Permit, instrument, or other arrangement included in the Purchased Assets to which a Seller is a party or by which a Seller is bound or to which any of the Purchased Assets is subject (or result in the imposition of any Lien upon any of the Purchased Assets). Neither Seller is required to give any notice to, make any filing with, or obtain any Consent or Permit of any Governmental Authority or other Person in order to consummate the transactions contemplated by this Agreement or the Transaction Documents.

**3.4 Brokers' Fees.** Neither Seller is a party to any Contract as a result of which a broker, finder or agent could hold any payment obligation against Purchaser with respect to the transactions contemplated by this Agreement.

**3.5 No Liens.** Each of the Sellers has good and marketable title to the Purchased Assets, free and clear of all payment obligations, other Liens, Orders or limitations or restrictions on their use.

**3.6 Effect of Transaction.** Sellers have the right to assign their and their Affiliates' right, title and interest in the Purchased Assets to Purchaser as set forth in this Agreement. Neither the execution, delivery or performance of the Agreement nor the consummation of the transactions

contemplated hereby will: (a) cause the grant, assignment or transfer to any Person (other than Purchaser) of any license or other right or interest under, to or in any of the Purchased Assets; or (b) conflict with, result in a breach of, constitute a default under, result in the acceleration of, create in any party the right to accelerate, terminate, modify, or cancel, or require any notice, Consent or payment under any Contract, Permit, instrument, or other arrangement to which any of the Purchased Assets is subject (or result in the imposition of any Lien upon any of the Purchased Assets, including Orca LLC's rights pursuant to [\*\*\*]).

**3.7 [\*\*\*] License Agreement.** Orca LLC is party to [\*\*\*] and has not assigned, transferred, licensed, sublicensed, granted any options to or pledged any of its rights or obligations thereunder to any Third Party. Orca LLC has not assigned, transferred, licensed, sublicensed, granted any options to or pledged any of its rights or obligations thereunder to any of its Affiliates other than [\*\*\*] to Orca Ltd (such sublicense, the "NYU Sublicense"). Orca LLC complied with all obligations set forth in Section 5.06 of the 10 NYU License Agreement with respect to the NYU Sublicense. The NYU Sublicense did not permit Orca Ltd to, nor did Orca Ltd, assign, transfer, license, sublicense, grant any options to or pledge any of its rights or obligations thereunder to any Person. The NYU Sublicense was terminated in full prior to the Effective Date, without Orca Ltd retaining any post-termination rights under the NYU License Agreement or to any NYU/NIH Patents, NYU Patents or NYU Know-How other than Orca Ltd's separate sublicense under Orca LLC's non-exclusive license to the NYU Know-How pursuant to a license agreement dated January 28, 2015 between NYU and Orca LLC that is not the NYU License Agreement (such license agreement, the "Other NYU License"). Sellers have delivered or has made available to Purchaser a correct and complete copy of (a) the NYU License Agreement, together with all amendments, exhibits, attachments, waivers or other changes thereto and (b) the NYU Sublicense, together with all amendments, exhibits, attachments, waivers or other changes thereto, including with respect to the termination thereof. Subject to the Exception, the NYU License Agreement is legal, valid, binding, enforceable, in full force and effect. The NYU License Agreement has not been breached or cancelled by either Seller, or to the knowledge of Sellers, by any other party thereto. Orca LLC has not irrevocably waived any of its rights under the NYU License Agreement. Orca LLC or Orca Ltd has performed all obligations under the NYU License Agreement that are required to be performed by Orca LLC or Orca Ltd. To the knowledge of Sellers, there is no event which, upon giving of notice or lapse of time or both, would constitute a breach or default under the NYU License Agreement or would permit the termination, modification or acceleration of the NYU License Agreement.

**3.8 Assigned Know-How.** Orca Ltd is the sole and exclusive owner of the Assigned Know-How. Orca Ltd has not granted to any Person any license of, option to obtain a license of, or other right with respect to, any Assigned Know-How. There are no pending Proceedings or Orders, and to Sellers' knowledge, no Proceedings or Orders threatened in writing in any jurisdiction or territory, between a Seller and any Third Party relating to the Assigned Know-How. To the knowledge of Sellers, the creation of the Assigned Know-How did not violate, infringe, misappropriate or unlawfully use, or constitute any contributory infringement of or inducement to infringe, misappropriate or unlawfully use, any patent, Know-How, trademark, copyright or application therefor of any Person.

**3.9 Inventory.** Exhibit B provides an accurate and complete breakdown of all Inventory as of November \_\_, 2015 of the Compounds specifically identified in Exhibit B. All of the Inventory: (a) is of such quality and quantity as to be usable by Purchaser in the ordinary course of business; and (b) is free of any defect or deficiency to the knowledge of Sellers.

**3.10 Sufficiency.** Except for the Inventory not included in the Selected Inventory as of the Effective Date, the Purchased Assets constitute all of the rights, property and assets that are owned by either Seller or any of its Affiliates as of the Effective Date and that are necessary or reasonably useful for the research, development or commercialization of any Compound or Product.

**3.11** [\*\*\*]

**3.12 No Patents.** Sellers and their Affiliates do not own any patents or patent applications that disclose or claim the composition of matter, manufacture or use of any Compound or Product.

**3.13 License or Option Agreements.** Except pursuant to the NYU License Agreement, no Seller or Affiliate of a Seller has obtained any license, option to obtain license, or right to use, any patent, Know-How, trademark, copyright or application therefor that is related to any Compound or Product or the development, manufacture, use, offer for sale or sale thereof.

**3.14 Contracts.** Except for the NYU License Agreement, [\*\*\*] (including the research, development, manufacture, transport, distribution, marketing, use, offer for sale, or sale thereof).

**3.15 Litigation.** There are no pending, and to the knowledge of Seller, no threatened, adverse actions, claims, investigations, suits or proceedings against a Seller or any of its Affiliates, at Law or in equity, or before or by any Governmental Authority, involving the Purchased Assets or any Compound or Product.

**3.16 Other Compounds.** Other than the Compounds and the Series 2 Compounds, no Seller and no Affiliate of a Seller possesses any right, title, license, option or other interest in or to any compound or other molecule that was developed or arose through the use of the NYU Know-How or that [\*\*\*]

**3.17** [\*\*\*] and its Affiliates do not have any rights (including any licenses or options to obtain a license) to any Compounds or Products or to any NYU/NIH Patents. No Seller or Affiliate of a Seller has any obligations to [\*\*\*] or its Affiliates that prohibit or place any limitations on a Seller's or its Affiliate's ability to research, develop, manufacture or commercialize any Compounds or Products or to enable or grant rights to others to do so.

#### ARTICLE 4

##### REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to Sellers, that each of the following representations and warranties is true and correct as of the Effective Date:

**4.1 Organization and Qualification.** Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite power and authority and all necessary governmental approvals to own, lease and operate its properties and to carry on its business as now being conducted.

**4.2 Authority Relative to this Agreement.** Purchaser has all necessary power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party, to perform its obligations hereunder and to consummate the Acquisition. The execution and delivery of this Agreement and the other Transaction Documents by Purchaser and the consummation by Purchaser of the Acquisition have been duly and validly authorized by all necessary action of the Purchaser and its board of directors, and no other proceedings on the part of Purchaser are necessary to authorize this Agreement or to consummate the Acquisition. This Agreement and the other Transaction Documents have been or when executed and delivered will be duly executed and delivered by Purchaser and, assuming the due authorization, execution and delivery by the other Parties hereto, each such agreement constitutes a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, subject to the Exception.

**4.3 No Conflict.** The execution and delivery of this Agreement by Purchaser do not, and the performance by Purchaser of its obligations hereunder and the consummation of the Acquisition will not: (a) conflict with or violate any provision of the Organizational Documents of Purchaser or (b) conflict with or violate any Law or Order applicable to Purchaser or by which Purchaser is bound or affected. Purchaser is not required to give any notice to, make any filing with, or obtain any Consent or Permit of any Governmental Authority or other Person in order to consummate the transactions contemplated by this Agreement.

**4.4 Brokers' Fees.** Purchaser is not party to any Contract as a result of which a broker, finder or agent could hold any payment obligation against Sellers with respect to the transactions contemplated by this Agreement.

**4.5 Litigation.** The Purchaser is not party to any Proceedings pending or, to Purchaser's knowledge, threatened in writing by a Third Party challenging, or that would have the effect of preventing, delaying, making illegal or otherwise interfering with, the transactions contemplated hereby.

## ARTICLE 5

### ADDITIONAL COVENANTS

**5.1 Further Assurances.** Sellers hereby agree, without further consideration, to execute and deliver following the Effective Date such other instruments of transfer and take such other action as Purchaser (or Purchaser's counsel on behalf of Purchaser) may reasonably request in order to [\*\*\*] in accordance with this Agreement. To the extent that Purchaser is required to make any filing with the SEC that includes financial statements under Regulation S-X with respect to [\*\*\*], Sellers shall reasonably cooperate with Purchaser in the preparation of any such SEC-required financial statements (including pro forma financials).

**5.2 Technology Transfer.** Promptly after the Effective Date, Seller shall transfer to Purchaser [\*\*\*].

**5.3 Development and Commercialization by Purchaser.**

(a) Purchaser shall provide to Sellers a copy of the current Development Plan within thirty (30) days following the Effective Date, and shall promptly (and in any event within thirty (30) days) provide to Seller all amendments to the Development Plan that are agreed between Purchaser and New York University during the term of the NYU License Agreement.

(b) Purchaser shall provide to Sellers copies of all the written reports on all activities and actions undertaken by Purchaser to develop and commercialise the Licensed Products as provided to New York University pursuant to Section 8.04 of the NYU License Agreement, at the same time that Purchaser provides such reports to New York University, pursuant to the aforesaid Section 8.04.

**5.4 Transfer of Purchased Assets.** Sellers shall transfer and deliver to Purchaser all Assigned Know-How and Selected Inventory within thirty (30) calendar days of the Effective Date, at Purchaser's expense for shipping and handling costs, to the locations, and in accordance with the instructions, specified by Purchaser. Sellers will, to the extent any such Assigned Know-How exists in a form suitable for electronic transfer, make such transfer to Purchaser electronically.

**5.5 Request of Inventory.** At any time during the first twelve (12) months following the Effective Date (the "First Year"), Purchaser shall have the right to request the transfer by Sellers of further Compounds and/or Products from the Inventory, at Purchaser's expense for shipping and handling costs, to the locations, and in accordance with the instructions, specified by Purchaser. Sellers shall provide such further Compounds and/or Products within thirty (30) days of such request.

**5.6 Grant of Rights to Orca Ltd.**

(a) Purchaser hereby grants to Orca Ltd a [\*\*\*] (as defined below), to perform [\*\*\*] during the First Year directly relating to (a) [\*\*\*] of one or more Compounds for [\*\*\*]; and/or (b) use of one or more Compounds that [\*\*\*] ((a) and (b) collectively, the "[\*\*\*]"); provided that Orca Ltd shall not perform any research on any Compound that Purchaser identifies in writing to Orca Ltd as a lead compound or a candidate therefor. In the event that Orca Ltd undertakes any such internal research, Orca Ltd shall promptly disclose to Purchaser any and all intellectual property (including patentable inventions), Know-How, data and results generated through the conduct of such research (collectively, the "Research Results"), and Sellers shall and hereby do assign to Purchaser all right, title and interest in and to the Research Results, including the sole right to apply for any patents and patent applications that disclose or claim any inventions included in the Research Results (the "Research Patents"). At Purchaser's reasonable request and expense, Sellers shall, and shall ensure that their employees and consultants, take all actions necessary or useful to demonstrate or perfect Purchaser's ownership of the Research Results and Research Patents or to facilitate the filing, prosecution, maintenance, defense or enforcement of any Research Patent. The foregoing license under the Licensed Technology is a sublicense under the License granted pursuant to the NYU License Agreement and Purchaser is required upon granting such a sublicense to impose

certain obligations on the sublicensee. Accordingly, the Parties agree to the provisions set forth in Exhibit E.

(b) At Orca Ltd's written request any time [\*\*\*], or within 30 days after [\*\*\*] Orca Ltd pursuant to sub-section 5.6(a) above, whichever is earlier ("["\*\*\*]"), the Parties will negotiate in good faith to agree upon the terms and conditions of, and upon agreement upon such terms and conditions, promptly enter into an agreement pursuant to which Purchaser will grant to Seller [\*\*\*], which terms and conditions will include the terms and conditions set forth in [\*\*\*] and additional, mutually agreed terms and conditions ("["\*\*\*]"). If the Purchaser and Orca Ltd do not enter into [\*\*\*] prior to [\*\*\*], Purchaser shall not have any obligations to Orca Ltd, and Orca Ltd. shall not have any rights, with respect to [\*\*\*] provided, however, that the foregoing shall not be interpreted as depriving Orca Ltd to any rights it may have to the NYU Know-How as a result of a sublicense from Orca LLC under the Other NYU License.

**5.7 Bulk Sales.** Each of the Parties hereby waives compliance with the notification and all other requirements of the bulk sales laws in force in the jurisdiction in which such laws are applicable to the Purchased Assets or the transactions contemplated by this Agreement.

**5.8 Press Releases and Public Announcements.** Purchaser may issue a press release announcing this Agreement promptly after the Effective Date, subject to the mutual agreement by the Parties of the content and form of such press release. Except for such press release, and except as set forth in Section 5.9, no Party shall issue any press release or make any public announcement related to the subject matter of this Agreement without the prior consent of the other Party; provided, that nothing in this Section 5.8 shall prevent any Party from: (a) making any disclosure it believes in good faith it is required to make by applicable Law or any listing or trading agreement concerning its securities (in which case the disclosing Party shall use its reasonable best efforts to advise the other Party prior to making the disclosure) or (b) enforcing its rights hereunder.

**5.9 Confidentiality.**

(a) Each Party shall hold, and shall use commercially reasonable efforts to cause its representatives (which, for the purposes of this Section 5.9 shall include such Party's: (i) Affiliates, (ii) underwriters or initial purchasers in connection with their due diligence for securities offerings of such Party, (iii) potential investors or other financing sources in connection with their due diligence for financings of such Party, or (iv) potential acquirers of such Party, in each case, so long as they are otherwise subject to similar confidentiality obligations to such Party) to hold, in strict confidence from any Person (other than any such representative), and shall not use for any purpose, the terms and conditions of this Agreement and all non-public documents and information furnished to it or its Affiliates by or on behalf of the other Party or its Affiliates under this Agreement or the Confidentiality Agreement ("Confidential Information"), except to the extent necessary to perform its obligations or to exercise its rights under this Agreement or as otherwise expressly authorized by this Agreement (which in the case of the representatives described in the parenthetical above, shall include the right to disclose or use for due diligence and transactions described therein) or otherwise agreed in writing by the Parties. For clarity, all non-public information included in the Purchased Assets shall be deemed Confidential Information of Purchaser, and Sellers shall be deemed the receiving Party of such Confidential Information.

**(b)** The foregoing confidentiality and non-use obligations shall not apply to any information that can be shown by the receiving Party to have been: (i) previously known by the receiving Party (excluding information included in the Purchased Assets); (ii) in the public domain (either prior to or after the furnishing of such documents or information hereunder) other than through the receiving Party's breach of its confidentiality obligations hereunder; or (iii) lawfully acquired by the receiving Party or any of their Affiliates after the Effective Date from another source that is not under an obligation to the other Party or another Person to keep such documents and information confidential.

**(c)** In the event that a Party (or any of its Affiliates) is requested or required by oral question, interrogatory, request for information or documents, subpoena, civil investigative demand or similar process or by applicable Law or any listing or trading agreement concerning its securities to disclose any Confidential Information of the other Party, such Person shall (i) provide the other Party with prompt notice so that such other Party may seek a protective order or other appropriate remedy or, in such other Party's sole discretion, waive compliance with the provisions of this Section 5.9 and (ii) cooperate with the other Party, at such other Party's expense, in any effort to obtain a protective order or other remedy. In the event that such protective order or other remedy is not obtained or the other Party waives compliance with the provisions of this Section 5.9, such Person shall (x) disclose only that portion of the Confidential Information that such Person is advised, by its counsel, is legally required and shall use commercially reasonable efforts to obtain reliable assurance that confidential treatment is accorded the Confidential Information so disclosed (to the extent available) and (y) use reasonable best efforts to promptly furnish to the other Party a copy (in whatever form or medium) of such Confidential Information that it intends to furnish.

**(d)** Notwithstanding anything in this Section 5.9, each Party may disclose this Agreement and its terms and conditions in securities filings with the Securities Exchange Commission (the "SEC") or equivalent foreign agency to the extent required by applicable Law after complying with the procedure set forth in this Section 5.9(d). In the event a Party is required to file a Form 8-K, such Party shall provide the other Party with a copy of such Form 8K and such other Party agrees to promptly review such disclosure within one (1) Business Day of receipt of such Form 8-K. In addition, such Party shall prepare a proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party agrees to promptly (and in any event, no less than seven (7) days after receipt of such proposed redactions) give its input in a reasonable manner in order to allow the Party seeking disclosure to file its request within the time lines specified by applicable Law. The Party seeking such disclosure shall reasonably consider any comments thereto provided by the other Party within such one (1) day or seven (7) day period, as applicable, and shall use reasonable efforts to obtain confidential treatment of this Agreement from the SEC (or equivalent foreign agency) as represented by the redacted version revised by the other Party. If both Parties determine that they are required to disclose this Agreement and its terms and conditions in securities filings as described in the first sentence of this Section 5.9(d), then the Parties shall use good faith efforts to agree upon a redacted version of this Agreement for which each Party will request confidential treatment and to coordinate with each other with respect to any revisions to such redacted version requested or required by the SEC or equivalent foreign agency.

(e) The Confidentiality Agreement is hereby terminated as of the Effective Date, without further action by any party thereto and information exchanged under the Confidentiality Agreement shall be deemed to be exchanged under this Agreement.

**5.10 Termination of the NYU License.** In the event of termination of the NYU License Purchaser shall provide Sellers with written notice within five (5) business days of termination, or within five (5) business days of receipt of a notice to terminate, whichever the earlier.

**5.11 Expenses.** Each of the Parties shall bear its own expenses incurred in connection with the preparation, execution and performance of this Agreement and the Acquisition, including all fees and expenses of its representatives.

## ARTICLE 6

### GENERAL

#### 6.1 Indemnification

**(a) Indemnification by Sellers.** Sellers shall indemnify and hold harmless Purchaser and its Affiliates and their respective Representatives (the "Purchaser Indemnified Parties") from and against any and all Damages incurred by any Purchaser Indemnified Party in connection with any claim, demand, action, proceeding, or investigation relating to or arising from:

(i) any breach by a Seller of any warranty or the inaccuracy of any representation of such Seller contained in this Agreement, the Transaction Documents or in any other agreement or instrument contemplated by this Agreement;

(ii) any breach by a Seller of any of such Sellers' covenants contained in this Agreement, the Transaction Documents or in any other agreement or instrument contemplated by this Agreement; or

(iii) the practice of the license set forth in Section 5.6(a);

(iv) any third-party claim to the extent Damages resulting therefrom are (1) as a result of the use of, or the research, development, manufacture, commercialization, use or sale of, any Compound or Product by or on behalf of a Seller or any of its Affiliates, licensees or sublicensees prior to the Effective Date and (2) not Damages for which the Seller Indemnitees are entitled to seek indemnification pursuant to Section 6.1(b).

**(b) Indemnification by Purchaser.** Purchaser shall indemnify and hold harmless Sellers and their respective Representatives (the "Seller Indemnified Parties") from and against any and all Damages incurred by any Seller Indemnified Party in connection with any claim, demand, action, proceeding, or investigation relating to or arising from:

(i) any breach by Purchaser of any warranty or the inaccuracy of any representation of Purchaser contained in this Agreement, the Transaction Documents or in any other agreement or instrument contemplated by this Agreement;

(ii) any breach by Purchaser of any of Purchaser's covenants contained in this Agreement, the Transaction Documents or in any other agreement or instrument contemplated by this Agreement;

(iii) any Assumed Liability; and

(iv) any third-party claim to the extent Damages resulting therefrom are (i) as a result of the use of, or the research, development, manufacture, commercialization, use or sale of, any Compound or Product by or on behalf of Purchaser or any of its Affiliates or Sublicensees after the Effective Date and (ii) not Damages for which the Purchaser Indemnitees are entitled to seek indemnification pursuant to Section 6.1(a).

**(c) Third Party Claims.** If any action at law or suit in equity is instituted by or against a third party with respect to which any Purchaser Indemnified Party or Seller Indemnified Party (the "Indemnified Party") believes is reasonably likely to result in Damages under this Section 6.1, such Indemnified Party shall promptly notify the other Party (the "Indemnifying Party") of such action or suit; provided that any delay or failure to so notify shall not relieve the Indemnifying Party of its obligations hereunder except to the extent Indemnifying Party is materially prejudiced by such delay or failure. Indemnifying Party shall, promptly and in no event later than five (5) days after receipt of the notice, notify such Indemnified Party whether Indemnifying Party elects to conduct and control such action or suit, but only after confirming in writing to such Indemnified Party that it accepts responsibility to indemnify such Indemnified Party for all Damages arising from such action or suit. If Indemnifying Party provides the foregoing notice, Indemnifying Party shall have the right to conduct and control, at its sole expense and with counsel of its choice (which counsel must be reasonably satisfactory to such Indemnified Party), such action or suit, and such Indemnified Party shall reasonably cooperate in connection therewith; provided that Indemnifying Party shall not settle such action or suit without the prior consent of such Indemnified Party (not to be unreasonably withheld, conditioned or delayed), unless the third-party claimant and Indemnifying Party provide to such Indemnified Party an unqualified release from all liability in respect of such action or suit and such settlement, compromise or judgment does not involve any nonmonetary penalty or admission of fault or liability on the part of such Indemnified Party or its Affiliates. Such Indemnified Party may participate in the defense of such action or suit that is defended by Indemnifying Party with counsel of its choice; provided, however, that the fees and expenses of such Indemnified Party's counsel shall be paid by such Indemnified Party unless (i) Indemnifying Party has agreed in writing to pay such fees and expenses or (ii) such Indemnified Party shall have reasonably determined based on the advice of counsel that a conflict or potential conflict exists between Indemnifying Party and such Indemnified Party that would make such separate representation advisable or there are one or more factual or legal defenses available to such Indemnified Party that are different or in addition to those that are available to Indemnifying Party.

**(d) Right of Set-Off.** Notwithstanding anything to the contrary in this Agreement, and without prejudice to any other right or remedy it has or may have, Purchaser may set off or recoup any indemnification payments owed to it by Seller pursuant to Section 6.1(b) against any Milestone Payments or Royalties to Seller pursuant to Sections 2.4 and 2.5, respectively.

**6.2 Liability.** NO PARTY OR ANY OF ITS AFFILIATES SHALL BE LIABLE WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), BREACH OF STATUTORY DUTY, RESTITUTION OR OTHERWISE) FOR ANY SPECIAL, INDIRECT OR CONSEQUENTIAL LOSSES, WHETHER OR NOT THE PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH TYPES OF DAMAGES.

### **6.3 Anti-bribery and anti-corruption**

(a) In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Purchaser and Sellers and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner which is compliant with all Laws, including the U.S. Foreign Corrupt Practices Act, the UK Bribery Act 2010, good business ethics, and its ethics and other corporate policies. Specifically, each Party agrees that it has not, and covenants that it, its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

(b) Neither Party shall contact, nor otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Laws.

(c) Each Party shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party must maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

(d) Each Party agrees to ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 6.3. In addition, each Party agrees to ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, in accordance with such Party's standard operating procedures with respect to training.

**6.4 Notices.** All notices or other communications required or permitted to be given hereunder shall be in writing and shall be delivered by hand or sent by facsimile or email or sent,

postage prepaid, by registered, certified or express mail or overnight courier service and shall be deemed given when so delivered by hand or facsimile, upon receipt of confirmation if sent by email, or if mailed, three (3) Business Days after mailing (one Business Day in the case of express mail or overnight courier service), to the parties at the following addresses, facsimiles or email addresses (or at such other address, facsimile or email address for a Party as shall be specified in a notice given in accordance with this Section 6.4):

(a) If to Purchaser:

[\*\*\*]

(b) If to Sellers:

[\*\*\*]

**6.5 Severability.** If any provision of this Agreement for any reason shall be held to be illegal, invalid or unenforceable, such illegality shall not affect any other provision of this Agreement, but this Agreement shall be construed as if such illegal, invalid or unenforceable provision had never been included herein.

**6.6 Succession and Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties named herein and their respective personal representatives, heirs, successors and permitted assigns. No Party may assign either this Agreement or any of its rights, interests or obligations hereunder without the prior written consent of the other Party; provided, that each Party may assign (a) any or all of its rights, interests or obligations hereunder to one or more of its Affiliates or (b) all of its rights, interests and obligations hereunder to its successor in interest in connection with a merger, acquisition or similar transaction or the sale of all or substantially all of its stock or assets. Any attempted assignment not in accordance with this Section 6.6 shall be null and void and of no legal effect. Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement. The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the Parties and their respected successors and permitted assigns.

**6.7 No Third-Party Beneficiaries.** This Agreement is for the sole benefit of the Parties and their successors and permitted assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder.

**6.8 Incorporation of Exhibits.** All Exhibits and Schedules attached hereto and referred to herein are hereby incorporated herein and made a part of this Agreement for all purposes as if fully set forth herein.

**6.9 Governing Law and Jurisdiction.** THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF [\*\*\*] OTHER THAN CONFLICT OF LAWS PRINCIPLES THEREOF DIRECTING THE APPLICATION OF ANY LAW OTHER THAN THAT OF DELAWARE. The courts of the State

of Delaware shall have jurisdiction with respect to any dispute between the Parties arising under or in connection with this Agreement, and the Parties submit to the jurisdiction of those courts

#### **6.10 Dispute Resolution.**

(a) Notwithstanding the provisions of Section 6.9 above, in the case of any dispute between the Parties any matters in dispute shall be first referred to the Chief Executive Officer of Purchaser and the Chief Executive Officer of Orca Ltd (collectively, the “Executives”), and the Parties shall attempt to resolve it in good faith through their Executives within thirty (30) days. Any final decision mutually agreed to by the said Executives shall be in writing and shall be conclusive and binding on the Parties. All discussions under this Section 6.10 shall be confidential and shall be treated as settlement negotiations for purposes of applicable rules of evidence.

(b) If the Executives are unable to resolve the dispute within the period specified in Section 6.10(a), then the Parties may seek to have the dispute resolved pursuant to last sentence of Section 6.9.

(c) Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

**6.11 Headings; Interpretation.** The descriptive headings contained in this Agreement are included for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.

**6.12 Counterparts; Facsimiles.** This Agreement may be executed and delivered (including by electronic or facsimile transmission) in two or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

**6.13 Entire Agreement.** This Agreement (including the Schedules and Exhibits attached hereto) and [\*\*\*] executed in connection with the consummation of the [\*\*\*], contain the entire agreement between the Parties with respect to the subject matter hereof and related transactions and supersede all prior agreements, written or oral, with respect thereto.

**6.14 Specific Enforcement.** The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached or threatened to be breached and that an award of money damages would be inadequate in such event. Accordingly, it is acknowledged that the Parties shall be entitled to equitable relief, without proof of actual damages, to enforce performance of this Agreement in accordance with its terms, including an Order for specific performance, to prevent

breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, in addition to any other remedy under this Agreement. Each Party further agrees that neither the other Party nor any other Person shall be required to obtain, furnish or post any bond or similar instrument in connection with or as a condition to obtaining any remedy referred to in this Section 6.14, and each Party hereto irrevocably waives any right it may have to require the obtaining, furnishing or posting of any such bond or similar instrument.

**6.15 Waivers and Amendments; Non-Contractual Remedies; Preservation of Remedies.** This Agreement may be amended, superseded, canceled, renewed or extended only by a written instrument signed by all of the Parties. The provisions hereof may be waived only in writing signed by all of the Parties. No delay on the part of any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of any Party of any such right, power or privilege, nor any single or partial exercise of any such right, power or privilege, preclude any further exercise thereof or the exercise of any other such right, power or privilege. Except as otherwise provided herein, the rights and remedies herein provided are cumulative and are not exclusive of any rights or remedies that any Party may otherwise have at Law or in equity.

*[Signatures appear on next page]*

IN WITNESS WHEREOF, intending to be legally bound hereby, the Parties have caused this Agreement to be signed in their respective names by their duly authorized representatives as of the date first above written.

BRICKELL BIOTECH, INC.

By: /s/ Andrew Sklawer  
Name: Andrew Sklawer  
Title: COO

ORCA PHARMACEUTICALS LLC

By: /s/ Michael Hunter  
Name: Michael Hunter  
Title: CEO

ORCA PHARMACEUTICALS LIMITED

By: /s/ Baiju R. Shah  
Name: Baiju R. Shah  
Title: Director

**EXHIBIT A**  
**NYU LICENSE AGREEMENT**

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SECOND RESTATED LICENSE AGREEMENT

This Restated License Agreement (this “Agreement”), effective as of June 6, 2013 (the “Effective Date”) and first amended as of 28 January 2015 (the “License Restatement Effective Date”), and subsequently amended as of 23 November 2015 (the “Second License Restatement Effective Date”) is by and between:

NEW YORK UNIVERSITY (hereinafter “NYU”), a corporation organized and existing under the laws of the State of New York and having a place of business at 70 Washington Square South, New York, New York, 10012.

AND

ORCA PHARMACEUTICALS LLC (hereinafter “CORPORATION”), a limited liability company organized and existing under the laws of the State of Delaware having its principal office at 3605 Warrensville Center Rd., MSC 2394, Cleveland, OH 44122.

RECITALS

WHEREAS, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member at NYU; and [\*\*\*], an employee of NYU (hereinafter “the NYU Scientists”) have made certain inventions relating to [\*\*\*], all as more particularly described in pending U.S. patent applications and counterpart foreign patent applications owned by NYU, identified in annexed Appendix I.A and forming an integral part hereof (hereinafter “the NYU Pre-Existing Inventions”);

WHEREAS, the NYU Scientists and researchers of the National Institutes of Health (hereinafter “NIH”) have made certain inventions relating to [\*\*\*], all as more particularly described in pending U.S. patent applications and counterpart foreign patent applications jointly owned by NYU and the NIH, identified in annexed Appendix I.13 and forming an integral part hereof (hereinafter “the NYU/NIH Pre-Existing Inventions”);

WHEREAS, the [\*\*\*] with NYU dated 05/13/2013, 07/23/2012 and 06/26/2012 attached hereto as Appendix IV under which [\*\*\*] (the “Inter-Institutional Agreements”);

WHEREAS, HHMI has assigned its rights in the NYU Pre-Existing Inventions and NYU/NIH Pre-Existing Inventions to NYU, subject to an HHMI License (as hereinafter defined).

WHEREAS, the parties entered into a license agreement dated June 7, 2013 for the NYU Pre-Existing Inventions, the NYU/NIH Pre-Existing Inventions and the NYU Know-How (as defined below) (the “Original License”);

WHEREAS, the parties have previously re-stated the Original License in two agreements: a Restated License Agreement dated January 28, 2015 (the “Restated Agreement”) and a separate know-how license to the NYU Know-How dated January 28, 2015; and WHEREAS, subject to the terms and conditions hereinafter set forth, NYU and CORPORATION are willing to restate the

Restated Agreement to provide that NYU grants to CORPORATION and CORPORATION accepts from NYU the license to the NYU Pre-Existing Inventions, the NYU/NIH Pre-Existing Inventions and the NYU Know-How on the terms set out below;

NOW, THEREFORE, in consideration of the mutual promises and agreements contained herein, the parties hereto hereby agree as follows:

**1. Definitions.**

1.01 "Affiliate" shall mean any company or other legal entity which controls, or is controlled by, or is under common control with, CORPORATION; control for purposes of this definition means the holding of (i) fifty percent (50%) or more of the capital and/or the voting rights and/or (H) the right to elect or appoint fifty percent (50%) or more of the directors.

1.02 "Agreement Year" shall mean the yearly period beginning on the License Restatement Effective Date and each succeeding year thereafter for the term of the Agreement.

1.03 "Date of First Commercial Sale" shall mean, [\*\*\*] the date on which a Licensed Product is first sold by CORPORATION or an Affiliate or sublicensee of CORPORATION.

1.04 "Field" shall mean all fields and uses.

1.05 "License" shall mean (i) the [\*\*\*] the NYU/NIH Patents (as hereinafter defined), and (ii) the [\*\*\*] the NYU Patents and the NYU Know-How (as hereinafter defined); in each case [\*\*\*]

1.06 "Licensed Patents" shall mean the NYU Patents and the NYU/NIH Patents.

1.07 "Licensed Products" shall mean Licensed Compound Products and Licensed Know-How Products.

1.08 "Licensed Compound Products" shall mean all products which in the absence of the License would infringe any Valid Claim.

1.09 "Licensed Know-How Products" shall mean all products that are (i) not Licensed Compound Products, and (ii) which also are not Series 2 Licensed Products (as hereinafter defined), and (Hi) which either incorporate or are discovered or developed using NYU Know-How.

1.10 "Licensed Technology" shall mean all [\*\*\*]

1.11 "Net Sales" shall mean the total amount invoiced by CORPORATION, its Affiliates, and its sublicensees in connection with sales of the Licensed Products to any person or entity that is not an Affiliate or a sublicensee of CORPORATION under the License, after deduction of all the following to the extent applicable to such sales;

- i) all trade, case and quantity credits, discounts, refunds or rebates, including Medicaid, managed care and other such rebates;

- ii) allowances or credits for returns and recalls;
- iii) sales taxes (including value-added tax), custom duties and other governmental charges levied on sales of Licensed Product; and
- iv) amounts for transportation, transportation insurance, handling and shipping.

If CORPORATION, a CORPORATION Affiliate, or any sublicensee sells any Licensed Product in [\*\*\*] containing [\*\*\*], Net Sales of such [\*\*\*] for the purpose of determining [\*\*\*] to NYU pursuant to Section 6.01(c) will be calculated by [\*\*\*] If, on a country-by-country basis, such other [\*\*\*] are not sold separately in such country, but the Licensed Product component of [\*\*\*] in such country, Net Sales for the purpose of [\*\*\*] shall be [\*\*\*]. If, on a country-by-country basis, such Licensed Product component is not sold separately in such country, Net Sales of [\*\*\*] for the purposes of [\*\*\*] for the [\*\*\*] shall be [\*\*\*] of CORPORATION and NYU, based upon [\*\*\*] and available market information. Notwithstanding anything above to the contrary, in no event shall [\*\*\*]

1.12 “NYU Know-Hove shall mean any information that was discovered, developed or acquired by, or on behalf of the NYU Scientists as of the Effective Date and, in each case, provided by NYU to CORPORATION, including but not limited to the information listed in Appendix II.

1.13 “NYU Patents” shall mean the patent applications listed in Appendix I.A and any divisions, continuations or claims of foreign counterparts thereof, or patents issuing thereon, or reissues, renewals and extensions thereof which are directed to subject matter specifically described in the patent applications listed in Appendix I.A.

1.14 “NYU/NIH Patents” shall mean the patent applications listed in Appendix I.13 and any divisions, continuations, continuations-in-part (but only to the extent that such continuations-in-part claim inventions specifically described in, and are directed to subject matter specifically described in, the patent applications listed in Appendix 1.B) or claims of foreign counterparts thereof, or claims of patents issuing thereof which are directed to subject matter specifically described in the patent applications listed in Appendix 1.B, or reissues, renewals and extensions thereof which are directed to subject matter specifically described in the patent applications listed in Appendix I.B.

1.15 “Series 2 Licensed Products” shall mean the series of compounds generated solely by Orca Pharmaceuticals Limited or on Orca Pharmaceuticals Limited’s behalf and which [\*\*\*] as filed, [\*\*\*]

1.16 “Valid Claim” shall mean on a territory by territory basis, any claim of any issued unexpired Licensed Patent or any pending patent application within Licensed Patents which has been pending for less than five (5) years from the earliest date to which it claims priority, in each case which has not been disclaimed, permitted to lapse or held invalid by a court of competent jurisdiction or patent office from which no appeal can be taken or is taken within the time limits provided for such an appeal.

## **2. Effective Date.**

This Agreement shall be effective as of the Effective Date and shall remain in full force and effect until it expires or is terminated in accordance with Section 13 hereof.

## **3. Title.**

3.01 Subject to the License granted to CORPORATION hereunder, and the HHMI License, it is hereby agreed that all right, title and interest, in and to the (i) NYU Patents and NYU Know-How, and in and to any drawings, plans, diagrams, specifications, and other documents containing any of the NYU Patents and NYU Know-How shall [\*\*\*] and (ii) NYU/NIH Patents, and in and to any drawings, plans, diagrams, specifications, and other documents containing any of the NYU/NIH Patents shall [\*\*\*]. At the request of NYU, CORPORATION shall take [\*\*\*] as may be [\*\*\*] to give full effect to said right, title and interest of NYU and NIH including, but not limited to, the execution of any documents that may be required to record such right, title and interest with the appropriate agency or government office.

3.02 For so long as each of the NYU Scientists is employed by NYU or HHMI, any and all inventions made by such NYU Scientist and relating to the Field shall be owned [\*\*\*] (as hereinafter defined).

3.03 NYU shall not terminate [\*\*\*] without CORPORATION's prior written consent. If NYU receives any notice pursuant to Section 10.3 of one or more of [\*\*\*], NYU shall provide CORPORATION with a copy of such notice [\*\*\*], shall permit CORPORATION to control the content of and approve the response [\*\*\*] with respect to such notice, in consultation with NYU, and shall permit CORPORATION to participate in any discussions or other communication [\*\*\*] regarding any potential termination of [\*\*\*] thereof.

## **4. Patents and Patent Applications.**

4.01 [\*\*\*]

4.02 At the initiative of CORPORATION or NYU, the parties shall consult with each other regarding the prosecution of all patent applications with respect to the NYU/NIH Patents. Copies of all such patent applications, patent office actions and proposed responses shall be forwarded to each of NYU and CORPORATION sufficiently prior to filing to allow for review and comment by each party, and the comments of each party shall be reasonably considered.

4.03 Subject to Section 4.02, all applications and proceedings with respect to the NYU/NIH Patents shall be filed, prosecuted and maintained by CORPORATION at the expense of CORPORATION. CORPORATION may select patent counsel, NYU may object to appointment of patent counsel where it believes such patent counsel are not qualified to file, prosecute and maintain the NYU/NIH Patents on behalf of CORPORATION. Where such objection is received, CORPORATION shall select alternative counsel reasonably acceptable to NYU, such acceptance not to be unreasonably withheld. CORPORATION shall file and prosecute the NYU/NIH Patents in good faith to obtain as broad a protection as reasonably possible, based on advice received from

its patent counsel on obtaining such broad protection. The final decision in relation to any prosecution shall vest with CORPORATION.

4.04 If at any time during the term of this Agreement CORPORATION decides that it is undesirable, as to one or more countries, to prosecute or maintain any patents or patent applications within the NYU/NIH Patents, it shall give prompt written notice thereof to NYU at least 60 days in advance of any deadline, and upon receipt of such notice CORPORATION shall be released from its obligations to bear all of the expenses to be incurred thereafter as to such countries in conjunction with such patent(s) or patent application(s) and such patent(s) or application(s) shall be deleted from the Licensed Technology and NYU shall be free to prosecute such patents or patent applications at its sole discretion and expense, and to grant rights in and to such patent(s) or patent application(s) in such countries to third parties, without further notice or obligation to CORPORATION, and the CORPORATION shall have no rights whatsoever to exploit such patent(s) or patent application(s) in such countries.

4.05 NYU shall prosecute the NYU Patents at its sole discretion and expense and may abandon any NYU Patents at NYU's sole discretion.

4.06 Subject to Section 16, Nothing herein contained shall be deemed to be a warranty by NYU, NIH, or HHMI that

- i) NYU can or will be able to obtain any patent or patents on any patent application or applications in the Licensed Patents or any portion thereof, or that any of the Licensed Patents will afford adequate or commercially worthwhile protection, or
- ii) that the manufacture, use, or sale of any element of the Licensed Technology or any Licensed Product will not infringe any patent(s) of a third party.

4.07 CORPORATION and any Affiliates and sublicensees of CORPORATION shall insure that they apply patent markings that meet all requirements of U.S. law, 35 U.S.C. § 287, with respect to all Licensed Products.

## **5. Grant of License.**

5.01 Subject to the terms and conditions hereinafter set forth, NYU hereby grants to CORPORATION and CORPORATION hereby accepts from NYU the License.

5.02 NYU reserves [\*\*\*].

5.03 The parties acknowledge that the United States government retains rights in intellectual property funded under any grant or similar contract with a Federal agency. The License is expressly subject to all applicable United States government rights, including, but not limited to, any applicable requirement that products, which result from such intellectual property and are sold in the United States, must be substantially manufactured in the United States. NYU will take all

actions reasonably requested by CORPORATION, at CORPORATION's expense, to obtain a waiver from the United States government of such substantial manufacture requirement.

5.04 The parties acknowledge that the Licensed Technology was developed, at least in part, by [\*\*\*]

5.05 The License granted to CORPORATION in Section 5.01 hereto shall commence upon the Effective Date and shall remain in force [\*\*\*], if not previously terminated under the terms of this Agreement for [\*\*\*] or until the expiration date of the last to expire of the NYU Patents and the NYU/NIH Patents that cover such Licensed Product [\*\*\*], whichever shall be later (the "License Term"). CORPORATION shall inform NYU in writing of the Date of First Commercial Sale with respect to each Licensed Product [\*\*\*] as soon as practicable after the making of each such first commercial sale. Following the expiration of the License Term, [\*\*\*], CORPORATION shall [\*\*\*].

5.06 CORPORATION shall be entitled to [\*\*\*] under the License on terms and conditions in compliance and not inconsistent with the terms and conditions of this Agreement (except that [\*\*\*] (i) to an Affiliate or (ii) to other third parties for consideration and in an arms-length transaction. The NYU Patents may only be [\*\*\*]. All [\*\*\*] shall only be granted by CORPORATION under a written agreement, a copy of which shall be provided by CORPORATION to NYU and NIH as soon as practicable after the signing thereof; provided, that, (a) the copy of the [\*\*\*] may be redacted by CORPORATION with respect to obligations that are not relevant to this Agreement and (b) the terms of each such [\*\*\*] shall be Confidential Information of CORPORATION for purposes of this Agreement. Each [\*\*\*] granted by CORPORATION hereunder shall be subject and subordinate to the terms and conditions of this Agreement and shall contain (inter-alia) the following provisions:

- (1) [\*\*\*]
- (2) [\*\*\*]
- (3) [\*\*\*]
- (4) [\*\*\*]
- (5) [\*\*\*]
- (6) [\*\*\*]

## **6. Payments for License.**

6.01 In consideration for the grant and during the term of the License with respect to each Licensed Product, CORPORATION shall pay to NYU:

- (a) [\*\*\*];  
and
- (b) Within [\*\*\*] after [\*\*\*] with respect to each Licensed Compound Product and each Licensed Know-How Product, the payments as indicated below:

[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

The foregoing [\*\*\*] with respect to the [\*\*\*], regardless of how many times [\*\*\*]. If a particular above [\*\*\*] is achieved by a sublicensee of CORPORATION, and if CORPORATION [\*\*\*], for which a payment is due to NYU under Section 6.01(d) below, then NYU shall [\*\*\*] For example, if [\*\*\*] shall fully satisfy CORPORATION's obligations to NYU pursuant to this Section 6.01(b) and Section 6.01(d).

- (c) [\*\*\*];  
and
- (d) [\*\*\*] under the terms of, or as a consideration for the grant of, a sublicense of any rights hereunder or for [\*\*\*] such a sublicense, based upon the development stage of the [\*\*\*] included in such grant at the time of the grant other than [\*\*\*]:
  - (I) [\*\*\*]
  - (II) [\*\*\*]
  - (III) [\*\*\*]

6.02 For the purpose of [\*\*\*] hereunder, the year shall be divided into four parts ending on March 31, June 30, September 30, and December 31. Not later than sixty (60) days after each December, March, June, and September in each Agreement Year during the term of the License, CORPORATION shall submit to NYU a full and detailed report [\*\*\*] NYU under the terms of this Agreement for the preceding quarter year (hereinafter "the Quarter-Year Report"), setting forth the [\*\*\*] including:

- i) [\*\*\*];
- ii) [\*\*\*];
- iii) [\*\*\*]
- iv) [\*\*\*]

If no [\*\*\*] payments are due, a statement shall be sent to NYU stating such fact. Payment of the full amount of [\*\*\*] for the preceding quarter year shall accompany each Quarter-Year Report on [\*\*\*]. CORPORATION shall keep for a period of at least [\*\*\*], full, accurate and complete books

and records consistent with sound business and accounting practices and in such form and in such detail as to enable [\*\*\*] to NYU from CORPORATION pursuant to the terms of this Agreement.

6.03 Within sixty (60) days after the end of each Agreement Year, commencing on the Date of First Commercial Sale CORPORATION shall furnish NYU with a report (hereinafter "the Annual Report"), relating to [\*\*\*] pursuant to this Agreement in respect of the Agreement Year covered by such Annual Report and containing the same details as those specified in Section 6.02 above in respect of the Quarter-Year Report.

6.04 On [\*\*\*] notice and during regular business hours and not more than once per calendar year, NYU or the authorized representative of NYU shall each have the right to designate an independent, certified public accountant reasonably acceptable to CORPORATION to inspect the books of accounts, records and other relevant documentation of CORPORATION or of any Affiliate of CORPORATION insofar as they relate to the production, marketing and sale of the Licensed Products, in order to [\*\*\*] hereunder, and the accuracy of the information provided to NYU in the aforementioned reports. The cost of such inspection shall be borne by NYU, unless it is determined in such inspection that NYU has been underpaid in any period by more than [\*\*\*] of the amount which NYU should have been paid, in which case the cost of such inspection shall be reimbursed to NYU by CORPORATION.

## **7. Method of Payment.**

7.01 [\*\*\*] hereunder shall be paid to NYU in [\*\*\*]. Any such [\*\*\*] based on the closing buying rate listed at [\*\*\*] on the last business day of the accounting period for which such royalty or other payment is due.

7.02 CORPORATION shall be responsible for payment to NYU of [\*\*\*] by each Affiliate of CORPORATION.

7.03 Any amount payable hereunder by one of the parties to the other, which has not been paid by the date on which such payment is due, shall bear interest from such date until the date on which such payment is made, at the rate of [\*\*\*] per annum in excess of the prime rate prevailing at the Citibank, N.A., in New York, during the period of arrears and such amount and the interest thereon may be set off against any amount due, whether in terms of this Agreement or otherwise, to the party in default by any non-defaulting party.

## **8. Development and Commercialization.**

8.01 CORPORATION undertakes to use [\*\*\*] to carry out the Development Plan (annexed hereto as Appendix III and which is an integral part of this Agreement, as such Development Plan may be updated from time-to-time by mutual agreement of the parties), including but not limited to, the performance of all efficacy, pharmaceutical, safety, toxicological and clinical tests, trials and studies and all other activities necessary in order to obtain the approval of the FDA for the production, use and sale of the Licensed Products, all as set forth in the Development Plan (as updated from time-to-time by mutual agreement of the parties) and within all timetables set forth therein. CORPORATION further undertakes to exercise [\*\*\*], and to include in each

sublicense agreement an obligation of such sublicensee, to [\*\*\*], to obtain the appropriate approvals of the health authorities for the production, use and sale of the Licensed Products, [\*\*\*] in which CORPORATION or its sublicensees intend to produce, use, and/or sell Licensed Products.

8.02 Provided that applicable laws, rules and regulations require that the performance of the tests, trials, studies and other activities specified in Paragraph 8.01 above shall be carried out in accordance with FDA Good Laboratory Practices and in a manner acceptable to the relevant health authorities, CORPORATION shall carry out such tests, trials, studies and other activities in accordance with FDA Good Laboratory Practices and in a manner acceptable to the relevant health authorities. Furthermore, the Licensed Products shall be produced in accordance with FDA Good Manufacturing Practice (“GMP”) procedures in a facility which has been certified by the FDA as complying with GMP, provided that applicable laws, rules and regulations so require.

8.03 CORPORATION agrees to use [\*\*\*] to begin the regular commercial production, use, and sale of the Licensed Products [\*\*\*] in accordance with the Development Plan and to continue diligently thereafter to commercialize the Licensed Products.

8.04 CORPORATION shall provide NYU with written reports on all activities and actions undertaken by CORPORATION to develop and commercialize the Licensed Products; such reports shall be made within sixty (60) days after each six (6) months during the term of this Agreement, commencing six (6) months after the Effective Date. CORPORATION shall include sufficient details in such reports for NYU to ascertain CORPORATION’s progress in developing and commercializing Licensed Products.

## **9. CONFIDENTIAL INFORMATION.**

9.01 “Confidential Information” shall mean non-public information provided by one party (a “Disclosing Party”) to the other party (“Recipient”). Except as otherwise provided in Section 9.02 and 9.03 below, each Recipient shall maintain any and all of the Confidential Information in confidence and shall not release or disclose any tangible or intangible component thereof to any third party without first receiving the prior written consent of, the Disclosing Party to said release or disclosure.

9.02 The obligations of confidentiality set forth in Sections 9.01 shall not apply to any Confidential Information that (i) is or becomes publicly available through no wrongful act of Recipient; (ii) was known by Recipient prior to disclosure by the Disclosing Party, as evidenced by tangible records; (iii) becomes known to Recipient after disclosure from a third party having an apparent bona fide right to disclose it; (iv) is independently developed or discovered by Recipient without use of the Disclosing Party’s Confidential Information, as evidenced by tangible records; or (v) is disclosed to another party by the Disclosing Party without restriction on further disclosure.

9.03 Recipient shall have the right to, and agrees that it will, use the Disclosing Party’s Confidential Information solely as provided under this Agreement, except a Recipient may disclose Confidential Information of the Disclosing Party to (x) its Affiliates, and to its and their directors, employees, consultants, and agents in each case who have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restriction on use, (y)

any bona fide actual or prospective collaborators, sublicensees, underwriters, investors, lenders or other financing sources who are obligated to keep such information confidential, to the extent reasonably necessary to enable such actual or prospective collaborators, sublicensees, underwriters, investors, lenders or other financing sources to determine their interest in collaborating with, sublicensing, underwriting or making an investment in, or otherwise providing financing to, the Recipient, and (z) the extent such disclosure is required to comply with applicable law or regulation or the order of a court of competent jurisdiction or to defend or prosecute litigation; provided, however, that the Recipient provides prior written notice of such disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure. Notwithstanding any other provision of this Agreement, each Recipient may disclose and use Confidential Information of the Disclosing Party as necessary to file or prosecute patent applications, prosecute or defend litigation or otherwise establish rights or enforce obligations under this Agreement, or to submit regulatory filings.

**10. Infringement of NYU and NYU/NIH Patents.**

10.01 In the event a party to this Agreement acquires information that a third party is infringing one or more of the NYU Patents or NYU/NIH Patents, the party acquiring such information shall promptly notify the other party to the Agreement in writing of such infringement.

10.02 In the event of an infringement of an NYU/NIH Patent, CORPORATION shall have the right but not the obligation to bring suit against the infringer. Should CORPORATION elect to bring suit against an infringer and NYU is joined as a party plaintiff in any such suit, NYU shall have the right to approve the counsel selected by CORPORATION to represent CORPORATION and NYU. The expenses of such suit or suits that CORPORATION elects to bring, including the reasonable expenses of NYU incurred in conjunction with the prosecution of such suit or the settlement thereof, shall be paid for entirely by CORPORATION and CORPORATION shall reimburse NYU, NIH, and HHMI for their reasonable costs and expenses incurred in connection with such litigation, including attorneys' fees. CORPORATION shall not compromise or settle such litigation without the prior written consent of NYU which shall not be unreasonably withheld.

10.03 In the event CORPORATION exercises the right to sue herein conferred, it shall have the right to first reimburse itself out of any sums recovered in such suit or in settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys' fees, necessarily involved in the prosecution of any such suit, and if after such reimbursement, any funds shall remain from said recovery, CORPORATION shall promptly pay to NYU an amount as follows: (i) in the case of damages representing lost profits of CORPORATION, lost sales shall be calculated based on such lost profits and CORPORATION's profit margin, and [\*\*\*], (ii) in the case of damages representing [\*\*\*], then such damages shall be deemed to be consideration for the grant of a sublicense, and [\*\*\*] and [\*\*\*]; and, in each case, CORPORATION shall be entitled to receive and retain the balance of the remainder of such recovery.

10.04 If CORPORATION does not bring suit against said infringer pursuant to Section 10.02 herein, or has not commenced negotiations with said infringer for discontinuance of said infringement, within ninety (90) days after receipt of such notice, NYU shall have the right, but shall not be obligated, to bring suit for such infringement. Should NYU elect to bring suit against

an infringer and CORPORATION is joined as a party plaintiff in any such suit, CORPORATION shall have the right to approve the counsel selected by NYU to represent NYU and CORPORATION, and NYU shall reimburse CORPORATION for its reasonable costs and expenses incurred in connection with such litigation, including attorneys' fees. If CORPORATION has commenced negotiations with an alleged infringer of the NYU/NIH Patent for discontinuance of such infringement within such 90-day period, CORPORATION shall have an additional ninety (90) days from the termination of such initial 90-day period to conclude its negotiations before NYU may bring suit for such infringement. In the event NYU brings suit for infringement of any NYU/NIH Patent, NYU shall not compromise or settle any such suit by licensing the alleged infringer without the prior consent of CORPORATION, which shall not be unreasonably withheld. In the event NYU brings suit for infringement of any NYU/NIH Patent, NYU shall have the right to first reimburse itself out of any sums recovered in such suit or settlement thereof for all costs and expenses of every kind and character, including reasonable attorneys' fees necessarily involved in the prosecution of such suit, and if after such reimbursement, any funds shall remain from said recovery, [\*\*\*] and NYU shall be entitled to receive and retain the balance of the remainder of such recovery.

10.05 Each party shall always have the right to be represented by counsel of its own selection in any suit for infringement of the NYU/NIH Patents instituted by the other party to this Agreement under the terms hereof. The expense of such counsel shall be borne by the party initiating such infringement suit.

10.06 CORPORATION agrees to cooperate fully with NYU at the request of NYU, including, by giving testimony and producing documents lawfully requested in the prosecution of any suit by NYU for infringement of the NYU/NIH Patents; provided, NYU shall pay all reasonable expenses (including attorneys' fees) incurred by CORPORATION in connection with such cooperation. NYU shall cooperate and shall endeavor to cause the NYU Scientists to cooperate with CORPORATION at the request of CORPORATION, including by giving testimony and producing documents lawfully requested, in the prosecution of any suit by CORPORATION for infringement of the NYU/NIH Patents; provided, that CORPORATION shall pay all reasonable expenses (including attorneys' fees) incurred by NYU in connection with such cooperation.

10.07 NYU shall have the sole right, but not the obligation to take any action with regard to infringement of the NYU Patents, and to retain any recovery therefrom.

#### **11. Liability and Indemnification.**

11.01 CORPORATION shall indemnify, defend and hold harmless NYU and NIH and their trustees, officers, medical and professional staff, employees, students and agents and their respective successors, heirs and assigns (the "Indemnitees"), against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with any claims, suits, actions, demands or judgments (i) arising out of the design, production, manufacture, sale, use in commerce or in human clinical trials, lease, or promotion by CORPORATION or by a licensee, Affiliate or agent of CORPORATION of any Licensed Product, process or service relating to, or developed pursuant to, this Agreement or (ii) arising out of any other activities to be carried out pursuant to this Agreement.

11.02 With respect to an Indemnitee, CORPORATION's indemnification under subsection 11.01(i) shall apply to any liability, damage, loss or expense whether or not it is attributable to the negligent activities of such Indemnitee. CORPORATION's indemnification obligation under subsection 11.0101) shall not apply to any liability, damage, loss or expense to the extent that it is attributable to the negligent activities of any such Indemnitee.

11.03 An Indemnitee or HHMI Indemnitee (as hereinafter defined) shall provide CORPORATION with notice of any Claim or HHMI Claim (as hereinafter defined) for which indemnification may be sought pursuant to this Agreement. Such notice shall be given reasonably promptly following actual receipt of written notice thereof. In the case of any **HHMI** Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of any Indemnitee or HHMI Indemnitee to give reasonably prompt notice to CORPORATION of any such Claim or HHMI Claim shall not affect the rights of such Indemnitee or HHMI Indemnitee, as applicable, unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects CORPORATION. CORPORATION shall, at its own expense, provide attorneys reasonably acceptable to the Indemnitee to defend against any actions brought or filed against any Indemnitee hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought. NYU or NIH, as relevant, shall cooperate as reasonably requested (at the expense of CORPORATION) in the investigation and defense of any Claim. NYU, HHMI, or NH-I, as relevant, shall permit CORPORATION to assume direction and control of the defense of the Claim or HHMI Claim (including the right to settle the Claim solely for monetary consideration); provided, however, that CORPORATION shall not settle any Claim or HHMI Claim without the prior written consent of NYU, HHMI or NIH, as relevant, where such settlement (a) would include any admission of liability on the part of the relevant Indemnitee or HHMI Indemnitee, (b) would impose any restriction on the relevant Indemnitee's or HHMI Indemnitee's conduct of any of its activities or (c) would not include an unconditional release of the relevant Indemnitee or HHMI Indemnitee from all liability for claims that are the subject matter of the settled Claim or HHMI Claim. CORPORATION agrees to keep each affected Indemnitee informed of the progress in the defense and disposition of such Claim.

11.04 HHMI, and its trustees, officers, employees, and agents (collectively, "HHMI Indemnitees"), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by CORPORATION from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "HHMI Claims"), based upon, arising out of, or otherwise relating to this Agreement or any other sublicense, including without limitation any cause of action relating to product liability. The previous sentence will not apply to any HHMI Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee. Notwithstanding any other provision of this Agreement, CORPORATION's obligation to defend, indemnify and hold harmless the HHMI Indemnitees under this paragraph will not be subject to any limitation or exclusion of liability or damages or otherwise limited in any way.

## **12. Insurance.**

12.01 At such time as any Licensed Product, process or service relating to, or developed pursuant to, this Agreement is being commercially distributed or sold or tested in clinical trials by CORPORATION or by a licensee, Affiliate or agent of CORPORATION, CORPORATION shall at its sole cost and expense, procure and maintain policies of comprehensive general liability insurance in amounts not less than (i) [\*\*\*] during the period that such [\*\*\*], and (ii) [\*\*\*] during the period that such [\*\*\*] as additional insureds. Such comprehensive general liability insurance shall provide (i) product liability coverage and (H) broad form contractual liability coverage for CORPORATION's indemnification under Section 11 of this Agreement. If CORPORATION elects to self-insure all or part of the limits described above (including deductibles or retentions [\*\*\*]) such self-insurance program shall include assets or reserves which have been actuarially determined for the liabilities associated with this Agreement and must be acceptable to NYU.

The minimum amounts of insurance coverage required under this Section 12 shall not be construed to create a limit of CORPORATION's liability with respect to its indemnification under Section 11 of this Agreement.

12.02 CORPORATION shall provide NYU with written evidence of such insurance upon request of NYU. If insurance is cancelled, not renewed or a material change is made to such insurance; if CORPORATION does not obtain replacement insurance providing comparable coverage within such sixty (60) day period, NYU shall have the right to terminate this Agreement effective at the end of such sixty (60) day period without notice or any additional waiting periods.

12.03 CORPORATION shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold or tested in clinical trials by CORPORATION or by a sublicensee, Affiliate or agent of CORPORATION and (H) a reasonable period after the period referred to in (i) above.

### **13. Expiry and Termination**

13.01 Unless earlier terminated pursuant to this Section 13 this Agreement shall expire upon the expiration of the period of the License in all countries as set forth in Section 5.05 above.

13.02 At any time prior to expiration of this Agreement, either party may terminate this Agreement forthwith for cause, as "cause" is described below, by giving written notice to the other party. Cause for termination by one party of this Agreement shall be deemed to exist if the other party materially breaches or materially defaults in the performance or observance of any of the provisions of this Agreement and such breach or default is not cured within sixty (60) days or, in the case of failure to pay any amounts due hereunder, thirty (30) days (unless otherwise specified herein) after the giving of notice by the other party specifying such breach or default, or if either NYU or CORPORATION discontinues its business or becomes insolvent or bankrupt.

13.03 Upon termination of this Agreement for any reason and prior to expiration as set forth in Section 13.01 hereof, all rights in and to the Licensed Technology shall revert to NYU, and CORPORATION shall not be entitled to make any further use whatsoever of the Licensed Technology; provided, that, for a period of up to ninety (90) days from the effective date of

termination, CORPORATION will have the right to sell any existing inventory of Licensed Products, subject to its payment of the royalty applicable thereto and the provision of royalty reports pursuant to Sections 6 and 7.

13.04 In the event that this Agreement is terminated, any granted sublicenses shall remain in full force and effect and each sublicensee shall become a direct license of NYU; provided, that, (i) the sublicensee is not then in breach of its sublicense agreement, (ii) the scope of such sublicensee's rights with respect to the Licensed Technology shall remain unchanged and the sublicensee agrees to be bound to NYU as a licensee under the non-financial terms and conditions of this Agreement that apply to such scope, and (iii) the sublicensee agrees to pay to NYU all annual license fees due pursuant to Section 6.01(a) and all amounts that CORPORATION would have been obligated to pay to NYU under this Agreement as a result of the activities of such sublicensee.

13.05 Termination of this Agreement shall not relieve either party of any obligation to the other party incurred prior to such termination.

13.06 Sections 3.01, 3.02, 4.01, 9, 11, 12, 13, 17, 18 and 19.01 hereof shall survive and remain in full force and effect after any termination, cancellation or expiration of this Agreement.

Following termination for any reason prior to expiration as set forth in Section 13.01 hereof, should CORPORATION continue to sell Licensed Know-How Products or develop Licensed Know-How Products after such termination despite Section 13.03 above, in each case where NYU Know-How was used to discover or develop such Licensed Know-How Product prior to termination but no NYU Know-How is needed to develop or sell such Licensed Know-How Product after termination, then termination shall not relieve the CORPORATION from payment of milestones and royalties in accordance with Sections 6.01(b) and 6.01(c) of this Agreement and Sections 6.02-6.04 and 7.01-7.03 shall survive and remain in full force and effect after such termination of this Agreement solely with respect to the development and sales of such Licensed Know-How Products and solely for the period of time that such payments would have been owed if the Agreement had not terminated early. Following termination, royalty reports under clause 6.02 shall only be due where CORPORATION does in fact sell such Licensed Know-How Products.

13.07 CORPORATION may at any time terminate this Agreement by providing 30 days prior written notice to NYU.

13.08 NYU may terminate this Agreement by providing 30 days prior written notice to CORPORATION if CORPORATION or its Affiliate institutes a legal proceeding that challenges the validity of the Licensed Patents.

#### **14. Representations and Warranties by CORPORATION.**

CORPORATION hereby represents and warrants to NYU as follow:

- (1) CORPORATION is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. CORPORATION has been granted all requisite power and authority to carry on its business and to

own and operate its properties and assets. The execution, delivery and performance of this Agreement have been duly authorized by the Board of Directors of CORPORATION.

- (2) There is no pending or, to CORPORATION's knowledge, threatened litigation involving CORPORATION which would have an adverse effect on this Agreement or on CORPORATION's ability to perform its obligations hereunder; and
- (3) There is no indenture, contract, or agreement to which CORPORATION is a party or by which CORPORATION is bound which prohibits or would prohibit the execution and delivery by CORPORATION of this Agreement or the performance or observance by CORPORATION of any term or condition of this Agreement.

**15. Representations and Warranties by NYU.**

NYU hereby represents and warrants to CORPORATION as follows:

- (1) NYU is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. NYU has been granted all requisite power and authority to carry on its business and to own and operate its properties and assets. The execution, delivery and performance of this Agreement have been duly authorized by the Board of Trustees of NYU.
- (2) There is no pending or, to NYU's knowledge, threatened litigation involving NYU which would have any effect on this Agreement or on NYU's ability to perform its obligations hereunder; and
- (3) There is no indenture, contract, or agreement to which NYU is a party or by which NYU is bound which prohibits or would prohibit the execution and delivery by NYU of this Agreement or the performance or observance by NYU of any term or condition of this Agreement.
- (4) it is the owner by assignment and/or the co-owner with NIH of all Licensed Patents listed on Appendix I.A and LB and the inventions described and claimed therein, and it has the right to grant the licenses to CORPORATION under this Agreement;
- (5) NYU has not received any notice from any third party that any third party patent, patent application or other intellectual property rights would be infringed (i) by practicing any method covered by the Licensed Patents or by making, using or selling any composition covered by the Licensed Patents, or (ii) by making, using, offering for sale, selling or importing Licensed Products; and

- (6) NYU is not aware of any infringement or misappropriation by any third party of the Licensed Patents.

**16. Limitation of Liability.**

IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES OR ANY OF THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, MEDICAL AND PROFESSIONAL STAFF, EMPLOYEES AND AGENTS BE LIABLE TO CORPORATION OR ANY OF ITS AFFILIATES, SUBLICENSEES OR DISTRIBUTORS FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE LICENSE RIGHTS GRANTED HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION ECONOMIC DAMAGES OR INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

**17. No Assignment.**

17.01 Neither CORPORATION nor NYU shall have the right to assign, delegate or transfer at any time to any party, in whole or in part, any or all of the rights, duties and interest herein granted without first obtaining the written consent of the other to such assignment, [\*\*\*].

17.02 NYU hereby consents to [\*\*\*]. Effective upon such assignment, all references to CORPORATION in this Agreement shall be deemed, with respect to time periods after such assignment, to be references to Brickell (or in the event one or more subsequent assignments pursuant to Section 17.01, the then current direct or indirect assignee of Brickell). Also effective upon the assignment from ORCA to Brickell described above, the contact information for CORPORATION for the purposes of Section 19.05 shall be [\*\*\*]. Brickell and its direct and indirect assignees are intended third party beneficiaries of this Section 17.02.

**18. Use of Name.**

18.01 Without the prior written consent of the other party, neither CORPORATION nor NYU shall use the name of the other party or any adaptation thereof or of any staff member, employee or student of the other party:

- i) in any product labeling, advertising, promotional or sales literature;
- ii) in connection with any public or private offering or in conjunction with any application for regulatory approval, unless disclosure is otherwise required by law, in which case either party may make factual statements concerning the Agreement or file copies of the Agreement after providing the other party with an opportunity to comment and reasonable time within which to do so on such statement in draft.

Except as provided herein, neither NYU nor CORPORATION will issue public announcements about this Agreement without prior written approval of the other party.

18.02 CORPORATION acknowledges that under HHMI policy, CORPORATION may not use the name of HHMI or of any HHMI employee ([\*\*]) in a manner that could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference to the name of HHMI or any HHMI employee in press releases or similar materials intended for public release is approved by HHMI in advance.

**19. Miscellaneous.**

19.01 HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

19.02 In carrying out this Agreement the parties shall comply with all local, state and federal laws and regulations including but not limited to, the provisions of Title 35 United States Code §200 et seq. and 15 CFR §730-774.

19.03 If any provision of this Agreement is determined to be invalid or void, the remaining provisions shall remain in effect.

19.04 This Agreement shall be governed by and construed in accordance with the [\*\*], without regard to principles relating to conflicts of law. The courts of the [\*\*] shall have exclusive jurisdiction over the parties with respect to any dispute or controversy between them arising under or in connection with this Agreement and, by execution and delivery of this Agreement, the parties to this Agreement submit to the jurisdiction of those courts, including, but not limited to, the in personam and subject matter jurisdiction of those courts, waive any objection to such jurisdiction on the grounds of venue or forum non conveniens, the absence of in personam or subject matter jurisdiction and any similar grounds, consent to service of process by mail in accordance with paragraph 19.05 or any other manner permitted by law and irrevocably agree to be bound by any such judgment rendered thereby in connection with this Agreement. These consents to jurisdiction shall not be deemed to confer rights on any person other than the parties to this Agreement.

19.05 All payments or notices required or permitted to be given under this Agreement shall be given in writing and shall be effective when either personally delivered or deposited, postage prepaid, in the United States registered or certified mail, or sent via a recognized national overnight delivery service (such as Federal Express or DHL), addressed as follows:

To NYU: [\*\*]

To CORPORATION:

[\*\*]

or such other address or addresses as either party may hereafter specify by written notice to the other. Such notices and communications shall be deemed effective on the date of delivery or fourteen (14) days after having been sent by registered or certified mail, whichever is earlier.

19.06 This Agreement (and the annexed Appendices) constitute the entire Agreement between the parties and no variation, modification or waiver of any of the terms or conditions hereof shall be deemed valid unless made in writing and signed by both parties hereto. This Agreement supersedes any and all prior agreements or understandings, whether oral or written, between CORPORATION and NYU.

19.07 No waiver by either party of any non-performance or violation by the other party of any of the covenants, obligations or agreements of such other party hereunder shall be deemed to be a waiver of any subsequent violation or non-performance of the same or any other covenant, agreement or obligation, nor shall forbearance by any party be deemed to be a waiver by such party of its rights or remedies with respect to such violation or non-performance.

19.08 The descriptive headings contained in this Agreement are included for convenience and reference only and shall not be held to expand, modify or aid in the interpretation, construction or meaning of this Agreement.

19.09 It is not the intent of the parties to create a partnership or joint venture or to assume partnership responsibility or liability. The obligations of the parties shall be limited to those set out herein and such obligations shall be several and not joint.

**[Remainder of page intentionally left blank.]**

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective as of the Second License Restatement Effective Date.

**Appendix I.A**

**[\*\*] Patents and Applications**

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**Appendix I.B**

**[\*\*\*] Patent and Patent Applications**

[\*\*\*]

**Appendix II**

**NYU Know-How**

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**Appendix III**  
**Development Plan**

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**Initial plan for selection of lead compound:**

1. \*\*\*

**Appendix IV**

**Inter-Institutional Agreements with NIH**

**PUBLIC HEALTH SERVICE**  
**PHS INTERINSTITUTIONAL AGREEMENT**  
**INSTITUTION-LEAD**

This Agreement is entered into between the National Institutes of Health (“NIH”) or the Food and Drug Administration (“FDA”), hereinafter singly or collectively referred to as “PHS”, agencies of the United States Public Health Service within the Department of Health and Human Services (“HHS”) through the Office of Technology Transfer, NIH, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and New York University School of Medicine a not for profit education corporation, hereinafter referred to as the “Institution”, having an address at One Park Avenue, 6<sup>th</sup> Floor, New York, New York 10016, U.S.A.

**BACKGROUND**

- 1.1 In the course of fundamental research programs at the PHS and by the Institution, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member of the Institution, [\*\*\*] (Institution), [\*\*\*] (PHS), [\*\*\*] (PHS) (Inventor(s)) made or reduced to practice certain inventions which are included within the Patent Rights, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the Institution and the PHS that their respective undivided interests in the Patent Rights be administered in a manner to ensure the rapid commercialization of the Patent Rights and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 C.F.R. §401.10, PHS is granting an exclusive license to PHS’ rights in the Patent Rights to the Institution under the conditions set forth herein.
- 1.3 The Institution and HHMI are parties to a Collaboration Agreement under which (i) HHMI employees at the Institution, including [\*\*\*], assign their rights in inventions to the Institution, (ii) the Institution seeks patent protection for such inventions and seeks to license them to companies to be developed into products to benefit the public, (iii) the Institution shares any revenues from such licensing with HHMI, and (iv) the Institution grants HHMI a license to such inventions for its non-commercial purposes, and inserts certain language in license agreements with companies for HHMI’s benefit.

**2. DEFINITIONS**

- 2.1 “Patent Rights” means:
  - (a) Patent applications (including provisional patent applications and PCT patent applications) or patents as follows:  
[\*\*\*];

(b) [\*\*\*];

(i) [\*\*\*];

(ii) [\*\*\*];

(iii) [\*\*\*];

(iv) [\*\*\*];  
and

(v) [\*\*\*]

(c) [\*\*\*];  
and

(d) Patent Rights shall  
[\*\*\*].

2.2 “Net Revenues” means all consideration received by the Institution [\*\*\*], less (a) Expenses and then (b) [\*\*\*]. It is contemplated that Patent Rights may be licensed together with other patent rights solely owned by the institution, or owned jointly by the Institution and a third party. In such instance, the portion of consideration from such licensing allocated to the Patent Rights shall be determined on a pro rata basis, based upon the number of patent families. Payments for the overall license, such as license fees, shall be allocated based upon the total number of patent families included in the license at the time the payment was received. Product-specific payments, such as royalties and milestone payments, shall be allocated based upon the total number of patent families covering the product generating the payments, at the time the payment was received.

2.3 “Expenses” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, paid by the Institution for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.

2.4 “Research License” means a nontransferable, nonexclusive license to make and to use any tangible embodiment of the Patent Rights and to practice any process(es) included within the Patent Rights for purposes of internal research and not for purposes of commercial manufacture or distribution or in lieu of purchase.

2.5 “Practical Application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the Government of the United States of America (hereinafter referred to as “Government”), available to the public on reasonable terms.

### 3. GRANT AND RESERVATION OF RIGHTS

- 3.1 PHS hereby grants and the Institution accepts, subject to the terms and conditions of this Agreement, an [\*\*\*].
- 3.2 The Government shall [\*\*\*]. Any license granted by the Institution under the terms of this Agreement shall be subject to [\*\*\*].
- 3.3 PHS reserves the right to require the Institution, or its licensees, to [\*\*\*].
- 3.4 In addition to the reserved right of Paragraph 3.3, PHS reserves the right to [\*\*\*]. The purpose of these [\*\*\*] is to encourage basic research, whether conducted at an academic or corporate facility.
- 3.5 PHS acknowledges that Institution is required to, and that Institution may, include in any license for the Patent Rights granted by institution provisions which comply with the HHMI licensing provisions set forth on Appendix B.

### 4. PATENT PROSECUTION AND PROTECTION

- 4.1 The Institution shall file, prosecute, and maintain patent application(s) relating to the Patent Rights and shall promptly provide to PHS all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the Institution, shall file with Patent Offices, a Power of Attorney, that names both the Institution and PHS. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to Patent Rights. The Institution shall consult with PHS, when so requested, prior to communicating with any Patent Office with respect to the Patent **Rights**.
- 4.2 The Institution shall make an election with respect to foreign filing, upon consultation with PHS, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the Institution shall promptly provide to PHS all serial numbers and filing dates. The Institution also shall provide PITS copies of foreign patent applications and Patent Office actions. The Institution shall consult with PHS, when so requested, prior to communication with any Patent Office with respect to the Patent Rights.
- 4.3 The Institution shall promptly record Assignments of domestic Patent Rights in the United States Patent and Trademark Office and shall promptly provide PHS with the original of each recorded Assignment with respect to PHS.
- 4.4 Notwithstanding any other provision of this Agreement, the Institution shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the

maintenance of any patent contemplated by this Agreement, without prior written notice to PHS. Upon receiving the written notice, PHS may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.

- 4.5 The Institution shall promptly provide PHS with copies of all issued patents under this Agreement.
- 4.6 In the event that the Institution anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, the Institution shall provide PHS with all relevant information, and these extraordinary expenditures shall be included as Expenses only upon written agreement of PHS, provided that if such extraordinary expenses are necessary to preserve or to avoid abandonment of the Patent Rights, PHS shall not unreasonably withhold its approval of such extraordinary expenses. The Institution and PHS shall agree on a mutually acceptable course of action prior to incurring these expenditures.

## 5. LICENSING

- 5.1 The Institution shall diligently seek licensees for the commercial development of the Patent Rights and shall administer the Patent Rights for the mutual benefit of the parties and in the public interest. The Institution shall ensure that any license granted for the Patent Rights is subject to the provisions of 22 C.F.R. Part 401 mid the rights retained by the Government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.
- 5.2 The Institution [\*\*\*], notwithstanding any other provision of this Agreement, without the prior written consent of PHS; provided, however, that PHS hereby agrees that HHMI [\*\*\*]. The Institution shall consult with PHS in the negotiation of [\*\*\*], notwithstanding any other provision of this Agreement, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of PHS.
- 5.3 Before licensing of the Patent Rights or any part thereof by the Institution, the Institution shall first notify and confer with PHS regarding any research funding related to the Patent Rights so as to determine PHS' interest in participating in any funded collaborative research project.
- 5.4 The Institution shall promptly provide PHS with complete copies of all licenses and sublicenses granted for the Patent Rights.
- 5.5 Institution agrees that its licensees shall supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology

Transfer, **NIH** with inert samples of the licensed products or licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

## 6. ROYALTIES AND EXPENSES

- 6.1 [\*\*\*].
- 6.2 All payments to PHS, required under this Agreement, shall be in [\*\*\*] and payment options are listed in Appendix A.
- (a) Institution shall submit to MS annual statements of itemized Expenses as defined in Paragraph 2.3 and shall deduct the Expenses as provided for in Paragraph 2.2, except where PITS has identified discrepancies in billing by Institution, in which case, deduction of the contested item(s), as a part of Expenses as provided for in Paragraph 2.2, from Net Revenues shall be delayed pending resolution thereof.
- 6.3 In no event shall PHS be obligated to bear any costs for Expenses under this Agreement.
- 6.4 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the Patent Rights any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

## 7. RECORDS AND REPORTS

- 7.1 The institution shall keep complete, true, and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the Patent Rights and shall permit PHS or PHS' designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.
- 7.2 Upon request by PHS, the Institution shall submit to PHS an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the Patent Rights for the preceding calendar year.

## 8. PATENT INFRINGEMENT

- 8.1 In the event PHS or the Institution, including its licensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The Institution and its licensees, in cooperation with PHS, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the

infringer has been formally notified of the infringement by the Institution, the Institution shall have the right, after consulting with PHS, to commence suit on its own account or to permit the Institution's licensee to commence suit on the licensee's own account. PITS may join the Institution's suit or commence its own suit.

- 8.2 If neither the Institution nor its licensee (i) bring suit within one (1) year after the parties are formally notified of the existence of an infringement, or (ii) are in negotiations with the infringing party to abate the infringement within such one (1) year period and either abate the infringement or bring suit within an additional one (1) year period; then PHS may bring suit to abate the infringement at PHS' sole expense.
- 8.3 Neither a licensee nor the Institution shall take action to compel PHS either to initiate or to join in any suit for patent infringement. Should the Government be made a party to any suit by motion or any other action of a licensee or the Institution, the licensee or the Institution shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of the motion or other action, including any and all costs incurred by PHS in opposing any joinder action.
- 8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered Net Revenues.
- 8.5 Each party agrees to cooperate with the other in litigation proceedings. PHS may be represented, at its expense, by counsel of its choice in any suit.

#### 9. GOVERNING LAWS. SETTLING DISPUTES

- 9.1 This Agreement shall be construed in accordance with [\*\*\*]. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this Agreement. The Institution agrees to be subject to the jurisdiction of [\*\*\*].
- 9.2 Any controversy or any disputed claim by either party against the other arising under or related to this Agreement shall be submitted jointly to the Institution's President or designee and to the Director of the NIH or designee for resolution. The Institution and PHS shall be free after written decisions are issued by those officials to pursue all administrative or judicial remedies which may be available.

#### 10. TERM AND TERMINATION

- 10.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 11.10 are not fulfilled, and shall extend to the expiration of the last to

expire of the patents included within the Patent Rights unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.

- 10.2 The Institution may terminate this Agreement upon at least sixty (60) days written notice to PHS, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.
- 10.3 In the event the Institution has made no commitments to any third party for exclusive license rights relating to the Patent Rights, PHS may terminate this Agreement for any reason upon thirty (30) days written notice to the Institution. During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the Patent Rights between the Institution and an option= or licensee, PHS may terminate this Agreement when:
- (a) it is determined by PHS' Office of Technology Transfer that:
    - (i) The Institution or its licensee has not taken and is not expected to take effective steps to achieve Practical Application of the Patent Rights;
    - (ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the Institution or its licensee;
    - (iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the Institution or its licensees; or
    - (iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the Patent Rights in the United States is in breach of its agreement obtained pursuant to Section 204;
  - (b) the Institution or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and
  - (c) the Institution's or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.
- 10.4 PHS may terminate this Agreement in whole or in part if:
- (a) the Institution fails to make any payment or periodic reports required by this Agreement;

- (b) the Institution has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the Agreement or in any report required by the Agreement;
- (c) the Institution has committed a substantial breach of a covenant or duty contained in *this* Agreement;  
or
- (d) PHS and the Institution are involved in a dispute under this Agreement which cannot be resolved under the procedures specified in Paragraph 9.2.

If the Agreement is terminated under this Paragraph 10.4, PHS agrees, subject to the restrictions of 37 C.F.R. Part 404, that any licenses that have been granted by the Institution shall remain in effect and Institution obligations to PHS including, paying royalties shall survive termination of this Agreement.

- 10.5 Following termination by PHS, PHS shall have no further rights or obligations under this Agreement, except that the Institution shall be obligated to administer subsequent gross proceeds from licensing the Patent Rights according to the Institution policy, and to distribute royalties to PHS for PHS Inventor(s) as though they were Inventor(s) of the Institution under that policy with respect to royalties and payment schedules.

## 11. GENERAL

- 11.1 [\*\*\*].
- 11.2 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 11.3 This Agreement shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this Agreement shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

- 11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.
- 11.5 This Agreement is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this Agreement may not be assigned by either party without the prior written consent of the other party.
- 11.6 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the PBS other than the Patent Rights regardless of whether such patents are dominant or subordinate to the Patent Rights.
- 11.7 Any modification to this Agreement must be in writing and agreed to by both parties.
- 11.8 It is understood and agreed by the Institution and PBS that this Agreement constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 11.9 HHMI is not a party to this Agreement and has no liability to any party, but HHMI is an intended third- party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.
- 11.10 The terms and conditions of this Agreement shall, at PHS' sole option, be considered by PHS to be withdrawn from Institution's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Institution and a fully executed original is received by PHS within sixty (60) days from the date of PHS signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

PHS INTERINSTITUTIONAL AGREEMENT-- INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For PHS:

By: /s/ Richard U. Rodriguez      6/9/12 \_\_\_\_\_  
Richard U. Rodriguez              Date  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

[E-mail: LicenseNotices\\_Reports@mailmil.gov](mailto:LicenseNotices_Reports@mailmil.gov)

For the Institution:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Institution made or referred to in this Agreement are truthful and accurate.

By: /s/ Abram M. Goldfinger      6/26/2012 \_\_\_\_\_  
Signature of Authorized Official      Date

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Official and Mailing Address for Agreement notices:

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University  
Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

And:

Annette Johnson, Esq.

Name

Vice Dean and Senior Counsel for Medical School Affairs

Title

Mailing Address:

550 First Avenue, HCC 15  
New York, New York 10016 U.S.A.

Email Address: [annettejohnson@nyumc.org](mailto:annettejohnson@nyumc.org)

Phone: 212-263-7921

Fax: 212-263-3235

Official and Mailing Address for Financial notices (Institution's contact person for royalty payments)

Abram M. Goldfinger

Name

Executive Director Industrial Liaison/Technology Transfer

Title

Mailing Address:

New York University

Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. 03801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

**APPENDIX A — ROYALTY PAYMENT OPTIONS**

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## APPENDIX B — HHMI LICENSING PROVISIONS

Any licenses granted by the Institution under this Agreement shall include the following HI•IMI licensing provisions, where University shall mean Institution:

### 1. **Identification of HHMI Investigators**

If inventors are named in the license, HHMI investigators and HHMI inventor/employees should be properly identified as employees of the Howard Hughes Medical Institute doing research at the HHMI laboratory at the University.

*Example:* The invention was made by Dr. \_\_\_\_\_, an employee of the Howard Hughes Medical Institute and a faculty member at the University.

### 2. **Scope of Rights**

HI-IMI requires that the scope of rights in future technology granted under a license not go beyond the following:

“Patent rights” shall mean and include all of the following intellectual property of the University:

The United States patents and/or patent applications listed in Appendix A [to the license]; United States patents issued from the applications listed in Appendix A and from divisionals and continuations of these applications and any reissues of such United States patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the applications listed in Appendix A; and claims of all foreign patent applications, patents, and other intellectual property which are directed to subject matter specifically described in the United States patents and/or patent applications listed in Appendix A.

### 3. **HHMI Research Use License**

The license must reflect the fact that HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use the intellectual property for its research purposes (without the right to sublicense or assign) by including the following:

Licensee acknowledges that it has been informed that the [licensed technology] was developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable license to use the [licensed technology] for HHMI’s research purposes, but with no right to assign or sublicense (the “HHMI License”). This license is explicitly made subject to the HHMI License.

When exclusive licenses are being negotiated, HHMI’s research tools policies must be considered. If research tools developed in an HHMI laboratory (including software) are to be licensed on an exclusive basis, unless otherwise agreed by HHMI, HHMI requires that the

University establish a licensing plan acceptable to HHMI showing how the research tools will be made available to the research community on reasonably acceptable terms.

#### 4. **Indemnification**

HHMI requires that it and its trustees, officers, employees and agents be indemnified and held harmless by licensees against claims based on or arising out of the license. The following is the indemnification provision that MIMI requires in licenses.

Howard Hughes Medical Institute (“HHMI”), and its trustees, officers, employees, and agents (collectively, “HHMI Indemnitees”), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by [the licensee, sublicensee, or other contracting party] from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) (collectively, “Claims”), based upon, arising out of, or otherwise relating to this [license, sublicense, or other contract or agreement], including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee.

HHMI’s indemnification must survive termination indefinitely.

HHMI’s required indemnification language does not provide a right to receive notice of claims or to settle claims. If the licensee requires the right to settle claims against HHMI and/or to receive notice of claims, then the following provisions should be added.

An indemnified party shall provide Licensee with prompt notice of any claim for which indemnification may be sought pursuant to this Agreement. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of [any indemnified party] [ally HHMI Indemnitee] to give reasonably prompt notice to Licensee of any such claim shall not affect the rights of such [HHMI Indemnitee] [indemnified party) unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Licensee.

Licensee agrees not to settle any Claim against an HHMI Indemnitee without HHMI’s written consent, where (a) such settlement would include any admission of liability on the part of any HHMI Indemnitee, (b) such settlement would impose any restriction on any HHMI indemnitee’s conduct of any of its activities, or (c) such settlement would not include an unconditional release of all HHMI Indemnitees from all liability for claims that are the subject matter of the settled Claim.

#### 5. **Insurance**

HHMI asks for the same insurance protection as the University receives in any license. This insurance protection should survive termination.

Licensee shall have the insurance coverage set forth below. Such coverage shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name the University and HHMI as additional insureds.

6. **HHMI Third-Party Beneficiary Status**

The license should describe HHMI's status and rights as a third-party beneficiary as follows:

HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

7. **Arbitration**

HHMI does not permit the provisions in the license governing its rights to be subject to binding arbitration. Accordingly, if the licensee requires that all parties submit to binding arbitration, disputes relating to HHMI's rights must be carved out of the requirements. The following is model language to exclude HHMI's rights from a binding arbitration provision.

Notwithstanding the foregoing, no dispute affecting the rights or property of HHMI shall be subject to the arbitration provisions set forth above.

8. **Sublicenses**

HHMI requires that sublicensees be bound by the obligations in the sections of the License on indemnification, insurance and HHMI's third party beneficiary status, in accordance with the following:

Licensee shall have the right to grant sublicenses consistent with this Agreement, which sublicenses shall include, without limitation, a provision binding sublicensees to all terms hereof intended for the protection of the University and other indemnified parties, including HHMI, against liability or loss.

9. **Use of Name Provision**

The University shall include one of the two following provisions:

LICENSEE acknowledges that under HHMI policy, LICENSEE may not use the name of HHMI or of any HHMI employee (including Dr. [Investigator Name]) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference

to the name of HHMI or any MIMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

LICENSEE may use Dr. \_\_\_\_\_'s name so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of LICENSEE or of any LICENSEE program, product or service. However, LICENSEE shall not use Dr. \_\_\_\_\_'s name or the Institute's name in any press release, or quote Dr. \_\_\_\_\_ in any company materials, or otherwise use Dr. \_\_\_\_\_'s name or the Institute's name in a manner not specifically permitted by the preceding sentence, unless in each case LICENSEE obtains in advance the written consent of the Institute, and, in the case of the use of Dr. \_\_\_\_\_'s name, Dr. \_\_\_\_\_'s consent as well.

**PUBLIC HEALTH SERVICE**  
**PITS INTERINSTITUTIONAL AGREEMENT**  
**INSTITUTION-LEAD**

This Agreement is entered into between the National Institutes of Health (“NIH”) or the Food and Drug Administration (“FDA”), hereinafter singly or collectively referred to as “PHS”, agencies of the United States Public Health Service within the Department of Health and Human Services (“HHS”) through the Office of Technology Transfer, NIH, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A. and New York University School of Medicine a not for profit education corporation, hereinafter referred to as the “Institution”, having an address at One Park Avenue, 6<sup>th</sup> Floor, New York, New York 10016, U.S.A.

**BACKGROUND**

- 1.1 In the course of fundamental research programs at the PHS and by the Institution, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member of the Institution, [\*\*\*] (Institution), [\*\*\*] (PHS), [\*\*\*] (PHS) and [\*\*\*] (PHS) (Inventor(s)) made or reduced to practice certain inventions which are included within the Patent Rights, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the Institution and the PHS that their respective undivided interests in the Patent Rights be administered in a manner to ensure the rapid commercialization of the Patent Rights and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 C.F.R. §401.10, PHS is granting an exclusive license to PHS’ rights in the Patent Rights to the Institution under the conditions set forth herein.
- 1.3 The Institution and HHMI are parties to a Collaboration Agreement under which (i) HHMI employees at the Institution, including Daniel Littman, assign their rights in inventions to the institution, (ii) the institution seeks patent protection for such inventions and seeks to license them to companies to be developed into products to benefit the public, (iii) the Institution shares any revenues from such licensing with HHMI, and (iv) the Institution grants HHMI a license to such inventions for its non-commercial purposes, and inserts certain language in license agreements with companies for HHMI’s benefit.

**2. DEFINITIONS**

- 2.1 “Patent Rights” means:
  - (a) [\*\*\*];
  - (b) [\*\*\*]:
    - (i) [\*\*\*];

- (ii) [\*\*\*];
- (iii) [\*\*\*];
- (iv) [\*\*\*];  
and
- (v) [\*\*\*]
- (c) [\*\*\*];  
and
- (d) [\*\*\*].

- 2.2 “Net Revenues” means all consideration received by the institution from the licensing of the Patent Rights pursuant to this Agreement, less (a) Expenses and then [\*\*\*] It is contemplated that Patent Rights may be licensed together with other patent rights solely owned by the institution, or owned jointly by the Institution and a third party. In such instance, the portion of consideration from such licensing allocated to the Patent Rights shall be determined on a pro rata basis, based upon the number of patent families. Payments for the overall license, such as license fees, shall be allocated based upon the total number of patent families included in the license at the time the payment was received. [\*\*\*]
- 2.3 “Expenses” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, paid by the Institution for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.
- 2.4 “Research License” means a [\*\*\*]
- 2.5 “Practical Application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits arc, to the extent permitted by law or by regulations of the Government of the United States of America (hereinafter referred to as “Government”), available to the public on reasonable terms.

### 3. GRANT AND RESERVATION OF RIGHTS

- 3.1 PHS hereby grants and the Institution accepts, subject to the terms and conditions of this Agreement, [\*\*\*].
- 3.2 The Government shall have the [\*\*\*]. Any license granted by the Institution under the terms of this Agreement shall be subject to this right of the Government.

- 3.3 PHS reserves the right to require the Institution, or its licensees, to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to RIM]] health or safety needs or when necessary to meet requirements for public use specified by Federal regulations.
- 3.4 in addition to the reserved right of Paragraph 3.3, PHS  
[\*\*\*]
- 3.5 PHS acknowledges that Institution is required to, and that Institution may, include in any license for the Patent Rights granted by Institution provisions which comply with the HHMI licensing provisions set forth on Appendix B.

#### 4. PATENT PROSECUTION AND PROTECTION

- 4.1 The Institution shall file, prosecute, and maintain patent application(s) relating to the Patent Rights and shall promptly provide to PHS all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the Institution, shall file with Patent Offices, a Power of Attorney, that names both the institution and PHS. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to Patent Rights. The Institution shall consult with PHS, when so requested, prior to communicating with any Patent Office with respect to the Patent Rights.
- 4.2 The Institution shall make an election with respect to foreign filing, upon consultation with PHS, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the Institution shall promptly provide to PHS all serial numbers and filing dates. The Institution also shall provide PHS copies of foreign patent applications and Patent Office actions. The Institution shall consult with PHS, when so requested, prior to communication with any Patent Office with respect to the Patent Rights.
- 4.3 The Institution shall promptly record Assignments of domestic Patent Rights in the United States Patent and Trademark Office and shall promptly provide PHS with the original of each recorded Assignment with respect to PHS.
- 4.4 Notwithstanding any other provision of this Agreement, the Institution shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this Agreement, without prior written notice to PHS. Upon receiving the written notice, PHS may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.
- 4.5 The institution shall promptly provide PHS with copies of all issued patents under this Agreement.

- 4.6 In the event that the Institution anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, the Institution shall provide PHS with all relevant information, and these extraordinary expenditures shall be included as Expenses only upon written agreement of PHS, provided that if such extraordinary expenses are necessary to preserve or to avoid abandonment of the Patent Rights, PHS shall not unreasonably withhold its approval of such extraordinary expenses. The Institution and PHS shall agree on a mutually acceptable course of action prior to incurring these expenditures.

## 5. LICENSING

- 5.1 The Institution shall diligently seek licensees for the commercial development of the Patent Rights and shall administer the Patent Rights for the mutual benefit of the parties and in the public interest. The Institution shall ensure that any license granted for the Patent Rights is subject to the provisions of 37 C.F.R. Part 401 and the rights retained by the Government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.
- 5.2 The Institution shall [\*\*\*] notwithstanding any other provision of this Agreement, without the prior written consent of PHS; provided, however, that PHS hereby agrees that [\*\*\*] The Institution shall consult with PHS [\*\*\*], notwithstanding any other provision of this Agreement, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of PHS.
- 5.3 Before licensing of the Patent Rights or any part thereof by the Institution, the Institution shall first notify and confer with PHS regarding any research funding related to the Patent Rights so as to determine PHS' interest in participating in any funded collaborative research project.
- 5.4 The Institution shall promptly provide PHS with complete copies of all licenses and sublicenses granted for the Patent Rights.
- 5.5 Institution agrees that its licensees shall supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the licensed products or licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

## 6. ROYALTIES AND EXPENSES

- 6.1 [\*\*\*]

- 6.2 All payments to PHS, required under this Agreement, shall be in U.S. dollars and payment options are listed in Appendix A.
- 6.3 Institution shall submit to PUS annual statements of itemized Expenses as defined in Paragraph 2.3 and shall deduct the Expenses as provided for in Paragraph 2.2, except where PHS has identified discrepancies in billing by Institution, in which case, deduction of the contested item(s), as a part of Expenses as provided for in Paragraph 2.2, from Net Revenues shall be delayed pending resolution thereof.
- 6.4 in no event shall PUS be obligated to bear any costs for Expenses under this Agreement.
- 6.5 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the Patent Rights any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

7. RECORDS AND REPORTS

- 7.1 The Institution shall keep complete, true, and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the Patent Rights and shall permit PHS or PHS' designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.
- 7.2 Upon request by PHS, the Institution shall submit to PHS an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the Patent Rights for the preceding calendar year.

8. PATENT INFRINGEMENT

- 8.1 In the event PHS or the Institution, including its licensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The Institution and its licensees, in cooperation with PHS, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by the Institution, the Institution shall have the right, after consulting with PHS, to commence suit on its own account or to permit the Institution's licensee to commence suit on the licensee's own account. PHS may join the Institution's suit or commence its own suit.
- 8.2 If neither the Institution nor its licensee (i) bring suit within one (1) year after the parties are formally notified of the existence of an infringement, or (ii) are in

negotiations with the infringing party to abate the infringement within such one (1) year period and either abate the infringement or bring suit within an additional one (1) year period; then PHS may bring suit to abate the infringement at PUS' sole expense.

- 8.3 Neither a licensee nor the Institution shall take action to compel PHS either to initiate or to join in any suit for patent infringement. Should the Government be made a party to any suit by motion or any other action of a licensee or the institution, the licensee or the Institution shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of the motion or other action, including any and all costs incurred by PHS in opposing any joinder action.
- 8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered Net Revenues.
- 8.5 Each party agrees to cooperate with the other in litigation proceedings. PHS may be represented, at its expense, by counsel of its choice in any suit.

#### 9. GOVERNING LAWS, SETTLING DISPUTES

- 9.1 This Agreement shall be construed in accordance with [\*\*\*], as interpreted and applied [\*\*\*]. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this Agreement. The Institution agrees to be subject to the [\*\*\*].
- 9.2 Any controversy or any disputed claim by either party against the other arising under or related to this Agreement shall be submitted jointly to the Institution's President or designee and to the Director of the NIH or designee for resolution. The Institution and PHS shall be free after written decisions are issued by those officials to pursue all administrative or judicial remedies which may be available.

#### 10. TERM AND TERMINATION

- 10.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 11.10 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the Patent Rights unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.
- 10.2 The Institution may terminate this Agreement upon at least sixty (60) days written notice to PHS, but in any event not less than sixty (60) days prior to the date on

which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.

10.3 In the event the institution has made no commitments to any third party for exclusive license rights relating to the Patent Rights, PHS may terminate this Agreement for any reason upon thirty (30) days written notice to the Institution. During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the Patent Rights between the Institution and an optionee or licensee, MS may terminate this Agreement when:

- (a) it is determined by PHS' Office of Technology Transfer that:
  - (i) The Institution or its licensee has not taken and is not expected to take effective steps to achieve Practical Application of the Patent Rights;
  - (ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the Institution or its licensee;
  - (iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the Institution or its licensees; or
  - (iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the Patent Rights in the United States is in breach of its agreement obtained pursuant to Section 204; the Institution or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and the institution's or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.

10.4 PHS may terminate this Agreement in whole or in part if:

- (a) the Institution fails to make any payment or periodic reports required by this Agreement;
  - (b) the Institution has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the Agreement or in any report required by the Agreement;
  - (C) the Institution has committed a substantial breach of a covenant or duty contained in this Agreement;
- or

- (d) PHS and the Institution are involved in a dispute under this Agreement which cannot be resolved under the procedures specified in Paragraph 9.2.

If the Agreement is terminated under this Paragraph 10.4, PHS agrees, subject to the restrictions of 37 C.F.R. Part 404, that any licenses that have been granted by the Institution shall remain in effect and Institution obligations to PHS including, paying royalties shall survive termination of this Agreement.

- 10.5 Following termination by PHS, PHS shall have no further rights or obligations under this Agreement, except that the Institution shall be obligated to administer subsequent gross proceeds from licensing the Patent Rights according to the Institution policy, and to distribute royalties to PHS for PHS Inventor(s) as though they were Inventor(s) of the Institution under that policy with respect to royalties and payment schedules.

## II. GENERAL

- 11.1 The Institution agrees that, for use *and* sale of the Patent Rights in the United States, any products embodying the Patent Rights, or produced through use of the Patent Rights, shall be manufactured substantially in the United States unless a waiver is granted by PHS.
- 11.2 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 11.3 This Agreement shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this Agreement shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.

- 11.5 This Agreement is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this Agreement may not be assigned by either party without the prior written consent of the other party.
- 11.6 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the PHS other than the Patent Rights regardless of whether such patents are dominant or subordinate to the Patent Rights.
- 11.7 Any modification to this Agreement must be in writing and agreed to by both parties.
- 11.8 It is understood and agreed by the institution and PHS that this Agreement constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 11.9 HHMI is not a party to this Agreement and has no liability to any party, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.
- 11.10 The terms and conditions of this Agreement shall, at PHS' sole option, be considered by PHS to be withdrawn from Institution's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Institution and a fully executed original is received by PHS within sixty (60) days from the date of PHS signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

PHS INTERINSTITUTIONAL AGREEMENT-- INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For PHS:

/s/ Richard U. Rodriguez      7/20/12  
Richard U. Rodriguez    Date  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

[E-mail: LicenseNotices\\_Reports@mailmil.gov](mailto:LicenseNotices_Reports@mailmil.gov)

For the Institution:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Institution made or referred to in this Agreement are truthful and accurate.

/s/ Abram M. Goldfinger      7/23/12  
Signature of Authorized Official    Date

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Official and Mailing Address for Agreement notices:

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University  
Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

And:

Annette Johnson, Esq.  
Name

Vice Dean and Senior Counsel for Medical School Affairs  
Title

Mailing Address:

550 First Avenue, HCC 15  
New York, New York 10016 U.S.A.

Email Address: [annettejohnson@nyumc.org](mailto:annettejohnson@nyumc.org)

Phone: 212-263-7921

Fax: 212-263-3235

Official and Mailing Address for Financial notices (Institution's contact person for royalty payments)

Abram M. Goldfinger  
Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University

Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. 03801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

**APPENDIX A — ROYALTY PAYMENT OPTIONS**

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## APPENDIX B — HHMI LICENSING PROVISIONS

Any licenses granted by the Institution under this Agreement shall include the following HI•IMI licensing provisions, where University shall mean Institution:

### 1. **Identification of HHMI Investigators**

If inventors are named in the license, HHMI investigators and HHMI inventor/employees should be properly identified as employees of the Howard Hughes Medical Institute doing research at the HHMI laboratory at the University.

*Example:* The invention was made by Dr. \_\_\_\_\_, an employee of the Howard Hughes Medical Institute and a faculty member at the University.

### 2. **Scope of Rights**

HHMI requires that the scope of rights in future technology granted under a license not go beyond the following:

“Patent rights” shall mean and include all of the following intellectual property of the University:

The United States patents and/or patent applications listed in Appendix A [to the license]; United States patents issued from the applications listed in Appendix A and from divisionals and continuations of these applications and any reissues of such United States patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the applications listed in Appendix A; and claims of all foreign patent applications, patents, and other intellectual property which are directed to subject matter specifically described in the United States patents and/or patent applications listed in Appendix A.

### 3. **HHMI Research Use License**

The license must reflect the fact that HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use the intellectual property for its research purposes (without the right to sublicense or assign) by including the following:

Licensee acknowledges that it has been informed that the [licensed technology] was developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable license to use the [licensed technology] for HHMI’s research purposes, but with no right to assign or sublicense (the “HHMI License”). This license is explicitly made subject to the HHMI License.

When exclusive licenses are being negotiated, HHMI’s research tools policies must be considered. If research tools developed in an HHMI laboratory (including software) are to be licensed on an exclusive basis, unless otherwise agreed by HHMI, HHMI requires that the

University establish a licensing plan acceptable to HHMI showing how the research tools will be made available to the research community on reasonably acceptable terms.

#### 4. **Indemnification**

HHMI requires that it and its trustees, officers, employees and agents be indemnified and held harmless by licensees against claims based on or arising out of the license. The following is the indemnification provision that HHMI requires in licenses.

Howard Hughes Medical Institute (“HHMI”), and its trustees, officers, employees, and agents (collectively, “HHMI Indemnitees”), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by [the licensee, sublicensee, or other contracting party] from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) (collectively, “Claims”), based upon, arising out of, or otherwise relating to this [license, sublicense, or other contract or agreement], including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee.

HHMI’s indemnification must survive termination indefinitely.

HHMI’s required indemnification language does not provide a right to receive notice of claims or to settle claims. If the licensee requires the right to settle claims against HHMI and/or to receive notice of claims, then the following provisions should be added.

An indemnified party shall provide Licensee with prompt notice of any claim for which indemnification may be sought pursuant to this Agreement. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of [any indemnified party] [ally HHMI Indemnitee] to give reasonably prompt notice to Licensee of any such claim shall not affect the rights of such [HHMI Indemnitee] [indemnified party) unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Licensee.

Licensee agrees not to settle any Claim against an HHMI Indemnitee without HHMI’s written consent, where (a) such settlement would include any admission of liability on the part of any HHMI Indemnitee, (b) such settlement would impose any restriction on any HHMI indemnitee’s conduct of any of its activities, or (c) such settlement would not include an unconditional release of all HHMI Indemnitees from all liability for claims that are the subject matter of the settled Claim.

#### 5. **Insurance**

HHMI asks for the same insurance protection as the University receives in any license. This insurance protection should survive termination.

Licensee shall have the insurance coverage set forth below. Such coverage shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name the University and HHMI as additional insureds.

6. **HHMI Third-Party Beneficiary Status**

The license should describe HHMI's status and rights as a third-party beneficiary as follows:

HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

7. **Arbitration**

HHMI does not permit the provisions in the license governing its rights to be subject to binding arbitration. Accordingly, if the licensee requires that all parties submit to binding arbitration, disputes relating to HHMI's rights must be carved out of the requirements. The following is model language to exclude HHMI's rights from a binding arbitration provision.

Notwithstanding the foregoing, no dispute affecting the rights or property of HHMI shall be subject to the arbitration provisions set forth above.

8. **Sublicenses**

HHMI requires that sublicensees be bound by the obligations in the sections of the License on indemnification, insurance and HHMI's third party beneficiary status, in accordance with the following:

Licensee shall have the right to grant sublicenses consistent with this Agreement, which sublicenses shall include, without limitation, a provision binding sublicensees to all terms hereof intended for the protection of the University and other indemnified parties, including HHMI, against liability or loss.

9. **Use of Name Provision**

The University shall include one of the two following provisions:

LICENSEE acknowledges that under HHMI policy, LICENSEE may not use the name of HHMI or of any HHMI employee (including Dr. [Investigator Name]) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference

to the name of HHMI or any MIMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

LICENSEE may use Dr. \_\_\_\_\_'s name so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of LICENSEE or of any LICENSEE program, product or service. However, LICENSEE shall not use Dr. \_\_\_\_\_'s name or the Institute's name in any press release, or quote Dr. \_\_\_\_\_ in any company materials, or otherwise use Dr. \_\_\_\_\_'s name or the Institute's name in a manner not specifically permitted by the preceding sentence, unless in each case LICENSEE obtains in advance the written consent of the Institute, and, in the case of the use of Dr. \_\_\_\_\_'s name, Dr. \_\_\_\_\_'s consent as well.

**THE NATIONAL INSTITUTES OF HEALTH**  
**INTERINSTITUTIONAL AGREEMENT**  
**INSTITUTION-LEAD**

This Agreement is entered into between the National Institutes of Health (“NIH”) within the Department of Health and Human Services (“HHS”) through the Office of Technology Transfer, NIH, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A and New York University School of Medicine, a not for profit education corporation, hereinafter referred to as the “**Institution**”, having an address at One Park Avenue, 6<sup>th</sup> Floor, New York, New York 10016, U.S.A.

**I. BACKGROUND**

- 1.1 In the course of fundamental research programs at the **NIH** or at the Food and Drug Administration and by the **Institution**, [\*\*\*], an employee of the Howard Hughes Medical Institute (“HHMI”) and a faculty member of the **Institution**, [\*\*\*] (**Institution**), [\*\*\*] (NM), [\*\*\*] (NIH) and [\*\*\*] (**NIH**) (**Inventor(s)**) made or reduced to practice certain inventions which are included within the **Patent Rights**, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the **Institution and the NIH** that their respective undivided interests in the **Patent Rights** be administered in a manner to ensure the rapid commercialization of the **Patent Rights** and to make their benefits widely available to the public. Therefore, in accordance with 35 U.S.C. §202(e) and 37 C.F.R. §401.10, the **NIH** [\*\*\*] under the conditions set forth herein.
- 1.3 The **Institution and HHMI** are parties to a Collaboration Agreement under which (i) **HHMI** employees at the **Institution**, including Daniel Littman, assign their rights in inventions to the **Institution**, (ii) the **Institution** seeks patent protection for such inventions and seeks to license them to companies to be developed into products to benefit the public, (iii) the **Institution** shares any revenues from such licensing with **HHMI**, and (iv) the **Institution** grants **HHMI** a license to such inventions for its non-commercial purposes, and inserts certain language in license agreements with companies for **HHMI**’s benefit.

**2. DEFINITIONS**

- 2.1 “**Government**” means the government of the United States of America.
- 2.2 “**FDA**” means the Food and Drug Administration.
- 2.3 “**Patent Rights**” means:
  - (a) [\*\*\*]

- (i) [\*\*\*],  
and
- (ii) [\*\*\*];
- (b) [\*\*\*]:
  - (i) [\*\*\*];
  - (ii) [\*\*\*];
  - (iii) [\*\*\*];
  - (iv) [\*\*\*];  
and
  - (v) [\*\*\*]
- (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.3(a) and to the extent that at least **one Inventor from the Institution** and at least **one Inventor from the NIH are Inventors: all counterpart foreign and U.S. patent applications and patents to 2.3(a) and 2.3(b); and**
- (d) **Patent Rights shall not** include 2.3(b) or 2.3(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.3(a).

2.4 “Net Revenues” means all consideration received by the Institution from the licensing of the Patent Rights pursuant to this Agreement less (a) Expenses and then (b) [\*\*\*]. It is contemplated that Patent Rights may be licensed together with other patent rights solely owned by the Institution, or owned jointly by the Institution and a third party. In such instance, the [\*\*\*]

2.5 “Expenses” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, paid by the Institution for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 4.6, and the maintenance of the resulting patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.

2.6 “Research License” means [\*\*\*].

2.7 “Practical Application” means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or by regulations of the Government, available to the public on reasonable terms.

### 3. GRANT AND RESERVATION OF RIGHTS

- 3.1 The NIH hereby grants and the Institution accepts, subject to the terms and conditions of this Agreement, [\*\*\*].
- 3.2 The Government shall [\*\*\*]. Any license granted by the Institution under the terms of this Agreement shall be subject to this right of the **Government**.
- 3.3 The **NIH** reserves the right to require the Institution, or its licensees, to grant sublicenses to responsible applicants, on terms that are reasonable under the circumstances when necessary to fulfill health or safety needs or when necessary to meet requirements for public use specified by Federal regulations.
- 3.4 In addition to the reserved right of Paragraph 3.3, the **NIH** reserves the right to require the Institution to grant Research Licenses on reasonable terms and conditions. The purpose of these Research Licenses is to encourage basic research, whether conducted at an academic or corporate facility.
- 3.5 The **NIH** acknowledges that Institution is required to, and that **Institution** may, include in any license for the **Patent Rights** granted by **Institution** provisions which comply with the HHMI licensing provisions set forth on Appendix B.

### 4. PATENT PROSECUTION AND PROTECTION

- 4.1 The Institution shall file, prosecute, and maintain patent application(s) relating to the Patent Rights and shall promptly provide to the NIH all serial numbers and filing dates, together with copies of all these applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the Institution, shall file with Patent Offices, a Power of Attorney, that names both the Institution and the NIH. This Power of Attorney shall be filed with every Patent Office involved in prosecuting all patent applications pertaining to Patent Rights. The Institution shall consult with the NIH, when so requested, prior to communicating with any Patent Office with respect to the Patent Rights.
- 4.2 The Institution shall make an election with respect to foreign filing, upon consultation with the NIH, including which countries foreign filing shall be done prior to the election, within eight (8) months of any United States filing. If any foreign patent applications are filed, the Institution shall promptly provide to the NIH all serial numbers and filing dates. The Institution also shall provide the NIH copies of foreign patent applications and Patent Office actions. The Institution shall consult with the NIH, when so requested, prior to communication with any Patent Office with respect to the Patent Rights.
- 4.3 The Institution shall promptly record Assignments of domestic Patent Rights in the United States Patent and Trademark Office and shall promptly provide the NIH with the original of each recorded Assignment with respect to the NIH.

- 4.4 Notwithstanding any other provision of this Agreement, the Institution shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this Agreement, without prior written notice to the NIH. Upon receiving the written notice, the NIH may, at its sole option, take over the prosecution of any patent application, or the maintenance of any patent.
- 4.5 The Institution shall promptly provide the NIH with copies of all issued patents under this Agreement.
- 4.6 In the event that the Institution anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this Agreement, including, without limitation, interferences, reexaminations, reissues and oppositions, the Institution shall provide the NIH with all relevant information, and these extraordinary expenditures shall be included as Expenses only upon written agreement of the NIH, provided that if such extraordinary expenses are necessary to preserve or to avoid abandonment of the Patent Rights, the NIH shall not unreasonably withhold its approval of such extraordinary expenses. The Institution and the NIH shall agree on a mutually acceptable course of action prior to incurring these expenditures.

## 5. LICENSING

- 5.1 The Institution shall diligently seek licensees for the commercial development of the Patent Rights and shall administer the Patent Rights for the mutual benefit of the parties and in the public interest. The Institution shall ensure that any license granted for the Patent Rights is subject to the provisions of 37 C.F.R. Part 401 and the rights retained by the Government under this Agreement, including the requirement for substantial manufacture in the United States as stated in Paragraph 11.1.
- 5.2 The Institution shall not [\*\*\*], notwithstanding any other provision of this Agreement, without the prior written consent of the NIH, provided, however, that the NIH hereby agrees that HHMI [\*\*\*].
- 5.3 The Institution shall consult with the NIH in the [\*\*\*], notwithstanding any other provision of this Agreement, and shall not grant these licenses without the prior review, opportunity for comment, and written approval of the NIH.
- 5.4 Before licensing of the Patent Rights or any part thereof by the Institution, the Institution shall first notify and confer with the NIH regarding any research funding related to the Patent Rights so as to determine the NIH's interest in participating in any funded collaborative research project.

- 5.5 The Institution shall promptly provide the NIH with complete copies of all licenses and sublicenses granted for the Patent Rights.
- 5.6 Institution agrees that its licensees shall supply, to the Mailing Address for Agreement notices indicated on the Signature Page, the Office of Technology Transfer, NIH with inert samples of the licensed products or licensed processes, as covered by the Patent Rights, or their packaging for educational and display purposes only.

#### 6. ROYALTIES AND EXPENSES

- 6.1 [\*\*\*]
- 6.2 All payments to the NIH, required under this Agreement, shall be in [\*\*\*] and payment options are listed in Appendix A.
- 6.3 The Institution shall submit to the NIH annual statements of itemized Expenses as defined in Paragraph 2.5 and shall deduct the Expenses as provided for in Paragraph 2.4, except where NIH has identified discrepancies in billing by the Institution, in which case, deduction of the contested item(s), as a part of the Expenses as provided for in Paragraph 2.4, from Net Revenues shall be delayed pending resolution thereof.
- 6.4 In no event shall the NIH be obligated to bear any costs for Expenses under this Agreement.
- 6.5 Each party shall be solely responsible for calculating and distributing to its respective Inventor(s) of the Patent Rights any share of Net Revenues in accordance with its respective patent policy, royalty policy, or Federal law during the term of this Agreement.

#### 7. RECORDS AND REPORTS

- 7.1 The Institution shall keep complete, true, and accurate accounts of all Expenses and of all Net Revenues received by it from each licensee of the Patent Rights and shall permit the NIH or the NIH's designated agent to examine its books and records in order to verify the payments due or owed under this Agreement.
- 7.2 Upon request by the NIH, the Institution shall submit to the NIH an annual report, not later than April 1 of each year, setting forth the status of all patent prosecution, commercial development, and licensing activity relating to the Patent Rights for the preceding calendar year.

#### 8. PATENT INFRINGEMENT

- 8.1 In the event the NIH or the Institution, including its licensees, shall learn of the substantial infringement of any patent subject to this Agreement, the party who

learns of the infringement shall promptly notify the other party in writing and shall provide the other party with all available evidence of the infringement. The **Institution** and its licensees, in cooperation with the **NIH**, shall use their best efforts to eliminate the infringement without litigation. If the efforts of the parties are not successful in eliminating the infringement within ninety (90) days after the infringer has been formally notified of the infringement by the **Institution**, the **Institution** shall have the right, after consulting with the **NIH**, to commence suit on its own account or permit the **Institution's** licensee to commence suit on the licensee's own account. The **NIH** may join the **Institution's** suit or commence its own suit.

- 8.2 'If neither the **Institution** nor its licensee (i) bring suit within one (1) year after the parties are formally notified of the existence of an infringement, or (ii) are in negotiations with the infringing party to abate the infringement within such one (1) year period and either abate the infringement or bring suit within an additional one (1) year period; then **the NIH** may bring suit to abate the infringement at the **NIIP** sole expense.
- 8.3 Neither a licensee nor the **Institution** shall take action to compel the **NIH** either to initiate or to join in any suit for patent infringement. Should the **Government** be made a party to any suit by motion or any other action of a licensee or the **Institution**, the licensee or the **Institution** shall reimburse the **Government** for any costs, expenses, or fees which the **Government** incurs as a result of the motion or other action, including any and all costs incurred by the **NIH** in opposing any joinder action.
- 8.4 Legal action or suits to eliminate infringement or recover damages pursuant to Paragraph 8.1 shall be at the full expense of the party by whom suit is brought. All damages recovered thereby shall first be used to reimburse each party for its expenses relating to the legal action, and the remainder of the damages shall be considered Net Revenues,
- 8.5 Each party agrees to cooperate with the other in litigation proceedings. The **NIH** may be represented, at its expense, by counsel of its choice in any suit.

#### 9. GOVERNING LAWS, SETTLING DISPUTES

- 9.1 This **Agreement** shall be construed in accordance with [\*\*\*]. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. The **Institution** agrees to be subject to the [\*\*\*].
- 9.2 Any controversy or any disputed claim by either party against the other arising under or related to this **Agreement** shall be submitted jointly to the **Institution's** President or designee and to the Director of the **NIH** or designee for resolution. The **Institution** and the **NIH** shall be free after written decisions are issued by

those officials to pursue all administrative or judicial remedies which may be available.

## 10. TERM AND TERMINATION

- 10.1 This Agreement is effective when signed by all parties, unless the provisions of Paragraph 11.10 are not fulfilled, and shall extend to the expiration of the last to expire of the patents included within the Patent Rights unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this Agreement.
- 10.2 The **Institution** may terminate this Agreement upon at least sixty (60) days written notice to the NIH, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be taken to preserve patent rights for the benefit of the parties hereto.
- 10.3 In the event the **Institution** has made no commitments to any third party for exclusive license rights relating to the Patent Rights, the NIH may terminate this Agreement for any reason upon thirty (30) days written notice to the Institution. During the term of any option agreement or license agreement to any third party for exclusive license rights relating to the **Patent Rights** between the **Institution and an optionee or licensee**, the **NIH** may terminate this **Agreement when:**
- (a) it is determined by the NIH's Office of Technology Transfer that:
    - (i) The Institution or its licensee has not taken and is not expected to take effective steps to achieve **Practical Application** of the **Patent Rights**;
    - (ii) Termination is necessary to alleviate health or safety needs which are not reasonably satisfied by the **Institution** or its licensee;
    - (iii) Termination is necessary to meet requirements for public use specified by Federal law or regulations and these requirements are not reasonably satisfied by the **Institution** or its licensees; or
    - (iv) Termination is necessary because the requirements of 35 U.S.C. §204 have not been satisfied or waived or because a licensee of the exclusive right to use or sell the Patent Rights in the United States is in breach of its agreement obtained pursuant to Section 204;
  - (b) the **Institution** or affected third party has been notified of this determination and has been given at least thirty (30) days to provide a response to this determination, and

- (c) the **Institution's** or affected third party's response to the determination of 10.3(a)(i)-(iv) is determined to be unsatisfactory by the Office of Technology Transfer.

10.4 The NIH may terminate this Agreement in whole or in part if:

- (a) the **Institution** fails to make any payment or periodic reports required by this Agreement;
- (b) the **Institution** has willfully made a false statement of, or willfully omitted, a material fact in the negotiation of the Agreement or in any report required by the **Agreement**;
- (c) the Institution has committed a substantial breach of a covenant or duty contained in this Agreement;  
or
- (d) the NIH and the Institution are involved in a dispute under this Agreement which cannot be resolved under the procedures specified in Paragraph 9.2 If the Agreement is terminated under this Paragraph 10.4, the NIH agrees, subject to the restrictions of 37 C.F.R. Part 404, that any licenses that have been granted by the Institution shall remain in effect and, Institution obligations to the NIH including, paying royalties shall survive termination of this Agreement.

10.5 Following termination by the NIH, the NIH shall have no further rights or obligations under this Agreement, except that the Institution shall be obligated to administer subsequent gross proceeds from licensing the Patent Rights according to the Institution policy, and to distribute royalties to the NIH for the NIH Inventor(s) as though they were Inventor(s) of the Institution under that policy with respect to royalties and payment schedules.

## 11. GENERAL

11.1 [\*\*\*].

11.2 All Agreement notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to the other address as may be designated in writing by such other party. Agreement notices shall be considered timely if the notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

- 11.3 This Agreement shall not be construed to confer on any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to this Agreement shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 11.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.
- 11.5 This Agreement is binding upon and shall inure to the benefit of the parties hereto and their successors or assigns, but this Agreement may not be assigned by either party without the prior written consent of the other party.
- 11.6 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the NIH other than the Patent Rights regardless of whether such patents are dominant or subordinate to the **Patent Rights**.
- 11.7 Any modification to this Agreement must be in writing and agreed to by both parties.
- 11.8 It is understood and agreed by the Institution and the NIH that this Agreement constitutes the entire agreement between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 11.9 HHMI is not a party to this Agreement and has no liability to any party, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.
- 11.10 The terms and conditions of this Agreement shall, at the NIH's sole option, be considered by the NIH to be withdrawn from Institution's consideration and the terms and conditions of this Agreement, and the Agreement itself to be null and void, unless this Agreement is executed by the Institution and a fully executed original is received by the NIH within sixty (60) days from the date of the NIH's signature found at the Signature Page.

**SIGNATURES BEGIN ON NEXT PAGE**

PHS INTERINSTITUTIONAL AGREEMENT-- INSTITUTION

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this Agreement in duplicate originals by their respective duly authorized officers, who have affixed their signatures hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For NIH:

Richard U. Rodriguez      5/13/13  
Richard U. Rodriguez    Date  
Director, Division of Technology Development and Transfer  
Office of Technology Transfer  
National Institutes of Health

Mailing Address or E-mail Address for Agreement notices and reports:

Chief, Monitoring & Enforcement Branch  
Office of Technology Transfer  
National Institutes of Health  
6011 Executive Boulevard, Suite 325  
Rockville, Maryland 20852-3804 U.S.A.

[E-mail: LicenseNotices\\_Reports@mailmil.gov](mailto:LicenseNotices_Reports@mailmil.gov)

For the Institution:

Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the Institution made or referred to in this Agreement are truthful and accurate.

Abram M. Goldfinger      5/13/13  
Signature of Authorized Official    Date

Abram M. Goldfinger  
Printed Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Official and Mailing Address for Agreement notices:

Abram M. Goldfinger  
Name

Executive Director Industrial Liaison/Technology Transfer  
Title

Mailing Address:

New York University  
Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

And:

Annette Johnson, Esq.

Name

Vice Dean and Senior Counsel for Medical School Affairs

Title

Mailing Address:

550 First Avenue, HCC 15  
New York, New York 10016 U.S.A.

Email Address: [annettejohnson@nyumc.org](mailto:annettejohnson@nyumc.org)

Phone: 212-263-7921

Fax: 212-263-3235

Official and Mailing Address for Financial notices (Institution's contact person for royalty payments)

Abram M. Goldfinger

Name

Executive Director Industrial Liaison/Technology Transfer

Title

Mailing Address:

New York University

Office of Industrial Liaison  
One Park Avenue, 6th Floor,  
New York, New York 10016 U.S.A.

Email Address: [abram.goldfinger@nyume.org](mailto:abram.goldfinger@nyume.org)

Phone: 212-263-8178

Fax: 212-263-8189

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. 03801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

**APPENDIX A — ROYALTY PAYMENT OPTIONS**

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## APPENDIX B — HHMI LICENSING PROVISIONS

Any licenses granted by the Institution under this Agreement shall include the following HI•IMI licensing provisions, where University shall mean Institution:

### 1. **Identification of HHMI Investigators**

If inventors are named in the license, HHMI investigators and HHMI inventor/employees should be properly identified as employees of the Howard Hughes Medical Institute doing research at the HHMI laboratory at the University.

*Example:* The invention was made by Dr. \_\_\_\_\_, an employee of the Howard Hughes Medical Institute and a faculty member at the University.

### 2. **Scope of Rights**

HHMI requires that the scope of rights in future technology granted under a license not go beyond the following:

“Patent rights” shall mean and include all of the following intellectual property of the University:

The United States patents and/or patent applications listed in Appendix A [to the license]; United States patents issued from the applications listed in Appendix A and from divisionals and continuations of these applications and any reissues of such United States patents; claims of continuation-in-part applications and patents directed to subject matter specifically described in the applications listed in Appendix A; and claims of all foreign patent applications, patents, and other intellectual property which are directed to subject matter specifically described in the United States patents and/or patent applications listed in Appendix A.

### 3. **HHMI Research Use License**

The license must reflect the fact that HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to use the intellectual property for its research purposes (without the right to sublicense or assign) by including the following:

Licensee acknowledges that it has been informed that the [licensed technology] was developed, at least in part, by employees of HHMI and that HHMI has a paid-up, non-exclusive, irrevocable license to use the [licensed technology] for HHMI’s research purposes, but with no right to assign or sublicense (the “HHMI License”). This license is explicitly made subject to the HHMI License.

When exclusive licenses are being negotiated, HHMI’s research tools policies must be considered. If research tools developed in an HHMI laboratory (including software) are to be licensed on an exclusive basis, unless otherwise agreed by HHMI, HHMI requires that the

University establish a licensing plan acceptable to HHMI showing how the research tools will be made available to the research community on reasonably acceptable terms.

#### 4. **Indemnification**

HHMI requires that it and its trustees, officers, employees and agents be indemnified and held harmless by licensees against claims based on or arising out of the license. The following is the indemnification provision that HHMI requires in licenses.

Howard Hughes Medical Institute (“HHMI”), and its trustees, officers, employees, and agents (collectively, “HHMI Indemnitees”), will be indemnified, defended by counsel acceptable to HHMI, and held harmless by [the licensee, sublicensee, or other contracting party] from and against any claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys’ fees and other costs and expenses of defense) (collectively, “Claims”), based upon, arising out of, or otherwise relating to this [license, sublicense, or other contract or agreement], including without limitation any cause of action relating to product liability. The previous sentence will not apply to any Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or willful misconduct of an HHMI Indemnitee.

HHMI’s indemnification must survive termination indefinitely.

HHMI’s required indemnification language does not provide a right to receive notice of claims or to settle claims. If the licensee requires the right to settle claims against HHMI and/or to receive notice of claims, then the following provisions should be added.

An indemnified party shall provide Licensee with prompt notice of any claim for which indemnification may be sought pursuant to this Agreement. In the case of any HHMI Indemnitee, notice shall be given reasonably promptly following actual receipt of written notice thereof by an officer or attorney of HHMI. Notwithstanding the foregoing, the delay or failure of [any indemnified party] [ally HHMI Indemnitee] to give reasonably prompt notice to Licensee of any such claim shall not affect the rights of such [HHMI Indemnitee] [indemnified party) unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Licensee.

Licensee agrees not to settle any Claim against an HHMI Indemnitee without HHMI’s written consent, where (a) such settlement would include any admission of liability on the part of any HHMI Indemnitee, (b) such settlement would impose any restriction on any HHMI indemnitee’s conduct of any of its activities, or (c) such settlement would not include an unconditional release of all HHMI Indemnitees from all liability for claims that are the subject matter of the settled Claim.

#### 5. **Insurance**

HHMI asks for the same insurance protection as the University receives in any license. This insurance protection should survive termination.

Licensee shall have the insurance coverage set forth below. Such coverage shall be purchased from a carrier or carriers having an A. M. Best rating of at least A- (A minus) and shall name the University and HHMI as additional insureds.

6. **HHMI Third-Party Beneficiary Status**

The license should describe HHMI's status and rights as a third-party beneficiary as follows:

HHMI is not a party to this Agreement and has no liability to any licensee, sublicensee, or user of anything covered by this Agreement, but HHMI is an intended third-party beneficiary of this Agreement and certain of its provisions are for the benefit of HHMI and are enforceable by HHMI in its own name.

7. **Arbitration**

HHMI does not permit the provisions in the license governing its rights to be subject to binding arbitration. Accordingly, if the licensee requires that all parties submit to binding arbitration, disputes relating to HHMI's rights must be carved out of the requirements. The following is model language to exclude HHMI's rights from a binding arbitration provision.

Notwithstanding the foregoing, no dispute affecting the rights or property of HHMI shall be subject to the arbitration provisions set forth above.

8. **Sublicenses**

HHMI requires that sublicensees be bound by the obligations in the sections of the License on indemnification, insurance and HHMI's third party beneficiary status, in accordance with the following:

Licensee shall have the right to grant sublicenses consistent with this Agreement, which sublicenses shall include, without limitation, a provision binding sublicensees to all terms hereof intended for the protection of the University and other indemnified parties, including HHMI, against liability or loss.

9. **Use of Name Provision**

The University shall include one of the two following provisions:

LICENSEE acknowledges that under HHMI policy, LICENSEE may not use the name of HHMI or of any HHMI employee (including Dr. [Investigator Name]) in a manner that reasonably could constitute an endorsement of a commercial product or service; but that use for other purposes, even if commercially motivated, is permitted provided that (1) the use is limited to accurately reporting factual events or occurrences, and (2) any reference

to the name of HHMI or any MIMI employees in press releases or similar materials intended for public release is approved by HHMI in advance.

LICENSEE may use Dr. \_\_\_\_\_'s name so long as any such usage (i) is limited to reporting factual events or occurrences only, and (ii) is made in a manner that could not reasonably constitute an endorsement of LICENSEE or of any LICENSEE program, product or service. However, LICENSEE shall not use Dr. \_\_\_\_\_'s name or the Institute's name in any press release, or quote Dr. \_\_\_\_\_ in any company materials, or otherwise use Dr. \_\_\_\_\_'s name or the Institute's name in a manner not specifically permitted by the preceding sentence, unless in each case LICENSEE obtains in advance the written consent of the Institute, and, in the case of the use of Dr. \_\_\_\_\_'s name, Dr. \_\_\_\_\_'s consent as well.

**EXHIBIT B**  
**SELECTED INVENTORY**

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Exhibit B-1

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**EXHIBIT C**

**RESPIRATORY INDICATIONS**

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Exhibit C-1

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## **EXHIBIT D**

### **TERMS OF SUBLICENSE AGREEMENT**

[\*\*\*]

All terms required, pursuant to Section 5.06 of the NYU License Agreement, to be included in a sublicense under the License.

Orca Ltd's diligence obligations [\*\*\*] to be determined.

Orca Ltd to pay to Purchaser all amounts due to NYU pursuant to the NYU License Agreement on account of the grant to Orca Ltd of the sublicense, the grant by Orca Ltd of sub-sublicenses or the exercise of such sublicenses or sub-sublicense by Orca Ltd or its sublicensee(s).

In addition to the amounts to be paid by Orca Ltd to Purchaser to satisfy payment obligations of Purchaser to NYU, Orca Ltd shall pay to Purchaser:

[\*\*\*]

Exhibit D-1

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## EXHIBIT E

### SUBLICENSEE OBLIGATIONS UNDER THE NYU LICENSE AGREEMENT

1. The NYU License Agreement provides in Section 5.06 that “each sublicense granted by CORPORATION hereunder shall be subject to and subordinate to the terms and conditions of this Agreement”. Accordingly:
  - a. Orca Ltd shall not knowingly do anything which will place Purchaser in breach of the NYU License Agreement; and
  - b. Orca Ltd shall provide Purchaser with all reasonable assistance requested by Purchaser (which shall be at Purchaser’s cost unless otherwise agreed or otherwise provided in this Agreement) in meeting Purchaser’s obligations under the NYU License Agreement; and
  - c. Orca Ltd shall indemnify, defend and hold harmless Purchaser and its employees, officers and agents against any liability, damage, loss or expense (including reasonable attorney’s fees and expenses of litigation) incurred by or imposed upon Purchaser (including under the NYU License Agreement) in connection with any claim, suit, action, demand or judgment (i) arising out of the design, production, manufacture or use by Orca Ltd of any Licensed Product pursuant to the license granted to Orca Ltd in Section 5.6 of this Agreement; or (ii) arising out of any other activities to be carried out pursuant to such license.
2. In relation to confidential information:
  - a. the terms of the NYU License Agreement, and any confidential information of NYU provided to Purchaser under the NYU License Agreement, shall as between the parties be the Confidential Information of Purchaser, and shall be treated by Orca Ltd accordingly in accordance with Section 5.9 of this Agreement; and the terms of this Agreement may be disclosed to NYU (and Sellers consent to such disclosure) in accordance with the NYU License Agreement (and shall be treated as Purchaser’s confidential information under the terms of the NYU License Agreement).
3. The NYU License Agreement provides in Section 5.06(5) that “the sublicense agreement shall include the text of Sections 11 and 12 of this Agreement” and in Section 5.06(4) that “the sublicense shall include, without limitation, a provision binding sublicensees to all terms hereof intended for the protection of NYU and other indemnified parties, including NIH and HHMI, against liability or loss”. The intention of these sections of the NYU License Agreement is to ensure that Orca Ltd provides the Indemnified Parties with an indemnity equivalent to that set out in Section 11 of the NYU License Agreement and to ensure that Orca Ltd is required to take out adequate insurance in this regard. Accordingly, the parties agree as follows:

- a. subject to clause 3(c), Orca Ltd shall indemnify, defend and hold harmless each of the Indemnitees against any liability, damage, loss or expense (including reasonable attorney's fees and expenses of litigation) incurred by or imposed upon that Indemnitee in connection with any claims, suits, actions, demands, or judgments (collectively "Claims"):
  - i. arising out of the design, production, manufacture, sale, use in commerce or in human clinical trials, lease or promotion by Orca Ltd or its agents of any Licensed Product, process or service related to, or developed pursuant to, the license granted in Section 5.6; or
  - ii. arising out of any other activities of Orca Ltd pursuant to this Agreement, provided that Orca Ltd shall have no obligation to indemnify, defend or hold harmless any NYU Indemnified Party against any liability, damage, loss or expense to the extent it is attributable to the negligent activities of any such NYU Indemnified Party;
- b. subject to clause 3(c), Orca Ltd shall indemnify, defend (by counsel acceptable to HHMI) and hold harmless the HHMI Indemnitees from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation, in each case of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defence) (collectively, "HHMI Claims") based upon, arising out of, or otherwise relating to this Agreement or any other sublicense, including without limitation any cause of action relating to product liability, excepting any HHMI Claim that is determined with finality by a court of competent jurisdiction to result solely from the gross negligence or wilful misconduct of an HHMI Indemnitee;
- c. Orca Ltd shall be relieved of its obligations to indemnify, defend and hold harmless any Indemnified Party in relation to any Claim or HHMI Claim (as the case may be) to the extent that the relevant Indemnified Party has delayed in giving or failed to give prompt notice to Orca Ltd of the relevant Claim or HHMI Claim in accordance with the provisions of Section 11 of the NYU License Agreement, and such failure or delay is prejudicial to or otherwise adversely affects Orca Ltd;
- d. Orca Ltd (or if required by the NYU License Agreement, Purchaser) shall direct and control the defence of any Claim or HHMI Claim governed by clause 3(a) or 3(b) (as applicable) and shall provide attorneys acceptable to the Indemnified Party (such acceptance not unreasonably to be withheld) to defend any such Claim or HHMI Claim. Orca Ltd shall keep the Licensor and relevant Indemnified Parties informed of progress in the defence and disposition of the relevant Claim or HHMI Claim. Purchaser shall use reasonable endeavours to procure that the Indemnified Parties shall cooperate as reasonably requested by Orca Ltd (at Orca Ltd's expense) in the defence of any Claim or HHMI Claim and in accordance with the NYU License Agreement. Orca Ltd shall not settle any

Claim or HHMI Claim without the prior written consent of the relevant Indemnified Party if such settlement would:

- i. include any admission of liability on the part of the relevant Indemnified Party;
  - ii. impose any restriction on the relevant Indemnified Party's activities;  
or
  - iii. not include an unconditional release of the relevant Indemnified Party from all liability for claims that are the subject matter of the relevant Claim or HHMI Claim.
- e. Orca Ltd shall during the term of the license granted in Section 5.6 (and as applicable after the expiration or termination of such license) maintain insurance policies, or self-insure, in each case in accordance with the provisions of Section 12 of the NYU License Agreement as if:
- i. references in that section to "CORPORATION" were references to Orca Ltd;  
and
  - ii. references in that section to "Section 11 of this Agreement" were references to clauses 3(a) through 3(f) (inclusive) of this Exhibit E. The taking of insurance in accordance with this clause 3(f) shall not limit Orca Ltd's liability with respect to its obligations under this Agreement.
4. The Indemnified Parties are third party beneficiaries of this Exhibit E and may enforce the terms of this Exhibit E directly as against Orca Ltd.
5. Orca Ltd and Purchaser acknowledge that the United States government retains rights in intellectual property funded under any grant or similar contract with a Federal agency, and that:
- a. the rights granted to Purchaser under the NYU License Agreement;  
and
  - b. the rights granted to Orca Ltd under Section 5.6 are subject to all applicable United States government rights and requirements, including, but not limited to, any applicable requirement that products which result from such intellectual property and are sold in the United States, must be substantially manufactured in the United States.

## AMENDMENT TO THE ASSET PURCHASE AGREEMENT

**THIS AMENDMENT TO THE ASSET PURCHASE AGREEMENT** is effective as of August 26, 2016 (this "Amendment") and amends the Asset Purchase Agreement (the "Asset Purchase Agreement") dated November 23, 2015 by and between Brickell Biotech, Inc., a Delaware corporation ("Purchaser"), and Orca Pharmaceuticals LLC, a Delaware limited liability company ("Orca LLC") and Orca Pharmaceuticals Limited, a company incorporated and registered under the laws of England and Wales ("Orca Ltd"), Orca LLC and Orca Ltd each known individually as a "Seller" and collectively as "Sellers". Terms used herein without definition shall have the meaning given them in the Asset Purchase Agreement.

## RECITALS:

A. Purchaser and Sellers have agreed to allow Sellers a certain Grant of Rights to Orca, Ltd as outlined in Section 5.6 of the Asset Purchase Agreement.

B. Purchaser and Sellers now desire to amend the Asset Purchase Agreement to allow for an additional six months to be added to the Option Period as defined in Section 5.6(b) of that agreement.

**NOW THEREFORE**, each of the undersigned, intending to be legally bound hereby, agrees as follows:

1. Option Period Extension. In Section 5.6(b) of the Asset Purchase Agreement, the words "the end of the First Year" shall be removed and replaced by the words "eighteen (18) months from the Effective Date" so that Section 5.6(b) reads as follows in its entirety (*amendment italicized*):

(b) At Orca Ltd's written request any time prior to *eighteen (18) months from the Effective Date*, or within 30 days after completion of research conducted by Orca Ltd pursuant to sub-section 5.6(a) above, whichever is earlier ("Option Period"), the Parties will negotiate in good faith to agree upon the terms and conditions of, and upon agreement upon such terms and conditions, promptly enter into an agreement pursuant to which Purchaser will grant to Seller an exclusive, sub-licensable, sub-license under the Licensed Technology and Research Results, to research, develop, manufacture, use, sell or otherwise commercialize Compounds and Products in the Orca Field, which terms and conditions will include the terms and conditions set forth in Exhibit D and additional, mutually agreed terms and conditions ("Sublicense Agreement"). If the Purchaser and Orca Ltd do not enter into the Sublicense Agreement prior to the end of the Option Period, Purchaser shall not have any obligations to Orca Ltd, and Orca Ltd. shall not have any rights, with respect to the Licensed Technology, Compounds or Products in the Orca Field or the Research Results; provided, however, that the foregoing shall not be interpreted as depriving

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Orca Ltd to any rights it may have to the NYU Know-How as a result of a sublicense from Orca LLC under the Other NYU License.

2. Entire Amendment. This Amendment sets forth the entire understanding among the parties with respect to the subject matter hereof. Except to the extent the Agreement is specifically amended hereby, the provisions of the Agreement, remain unmodified and in full force and effect and nothing in this Amendment shall be deemed a waiver of any provision of the Agreement (or any right arising thereunder) by the parties.
3. Governing Law. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF DELAWARE OTHER THAN CONFLICT OF LAWS PRINCIPLES THEREOF DIRECTING THE APPLICATION OF ANY LAW OTHER THAN THAT OF DELAWARE. The courts of the State of Delaware shall have jurisdiction with respect to any dispute between the Parties arising under or in connection with this Amendment, and the Parties submit to the jurisdiction of those courts.
4. Counterparts. This Agreement may be executed and delivered (including by electronic or facsimile transmission) in two or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

*Signature page to follow.*

IN WITNESS WHEREOF, intending to be legally bound hereby, the Parties have caused this Amendment to be signed in their respective names by their duly authorized representatives as of the date first above written.

BRICKELL BIOTECH, INC.

By: /s/ Andrew Sklawer

Name: Andrew Sklawer

Title: COO

ORCA PHARMACEUTICALS LLC

By: /s/ Baiju R. Shah

Name: Baiju R. Shah

Title: Manager

ORCA PHARMACEUTICALS LIMITED

By: /s/ Michael G. Hunter

Name: Michael G. Hunter

Title: Authorized Signatory

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED  
BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

EXECUTION VERSION

**ASSET PURCHASE AGREEMENT**

**by and between**

**Brickell Biotech, Inc.  
as Purchaser**

**And**

**Panmira Pharmaceuticals, LLC  
as Seller**

**Dated as of January 30, 2015**

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## TABLE OF CONTENTS

		<b>Page</b>
ARTICLE 1	DEFINITIONS	1
1.1	Definitions	1
1.2	Interpretation	9
ARTICLE 2	PURCHASE & SALE OF PURCHASED ASSETS	9
2.1	Purchased Assets	9
2.2	Assumed Liabilities	10
2.3	Purchase Price; Payment of Purchase Price	10
2.4	Milestone Payments	10
2.5	Royalties	12
2.6	Licensing Revenue Payments	13
2.7	Payments; Audits	14
2.8	Allocation of Purchase Price	15
2.9	Closing	15
2.10	Transfer Taxes	15
2.11	Withholding	15
ARTICLE 3	REPRESENTATIONS AND WARRANTIES OF SELLER	16
3.1	Organization and Qualification	16
3.2	Authority Relative to this Agreement	16
3.3	No Conflict	16
ARTICLE 4	REPRESENTATIONS AND WARRANTIES OF PURCHASER	16
4.1	Organization and Qualification	16
4.2	Authority Relative to this Agreement	16
4.3	No Conflict	17
4.4	No Implied Representations	17
ARTICLE 5	CLOSING DELIVERABLES	17
5.1	Closing Deliverables of Purchaser	17
5.2	Closing Deliverables of Seller	17
ARTICLE 6	ADDITIONAL COVENANTS	18
6.1	Further Assurances	18
6.2	Patent Assignment	18

6.3	Public	
	Announcements	18
6.4	Confidentiality	18
6.5	Expenses	19
6.6	Transfer of Purchased	
	Assets	19
ARTICLE 7	GENERAL	19
7.1	Survival	19
7.2	Notices	20

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
7.3 Severability	21
7.4 Assignment; Binding Effect	21
7.5 No Third-Party Beneficiaries	21
7.6 Incorporation of Exhibits	21
7.7 Governing Law	21
7.8 Headings; Interpretation	21
7.9 Counterparts; Facsimiles	21
7.10 Entire Agreement	22
7.11 Specific Enforcement	22
7.12 Waivers and Amendments; Non-Contractual Remedies; Preservation of Remedies	22

## **EXHIBITS**

Exhibit A — Form of Assignment and Assumption Agreement

Exhibit B — Form 8594

Exhibit C — Form of Patent Assignment

Exhibit D — Assigned Patents

Exhibit E-1 — [\*\*\*] Compound Structure

Exhibit E-2 — [\*\*\*] Compound Structure

Exhibit F — Inventory

Exhibit G — [\*\*\*] Reference Letter

Exhibit H — [\*\*\*] Reference Letter

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## ASSET PURCHASE AGREEMENT

**THIS ASSET PURCHASE AGREEMENT** is made as of January 30, 2015 by and between Brickell Biotech, Inc., a Delaware corporation ("Purchaser"), and Panmira Pharmaceuticals, LLC, a Delaware limited liability company ("Seller").

### **RECITALS:**

Subject to the terms and conditions set forth herein, Seller desires to sell, convey, transfer, assign and deliver to Purchaser, and Purchaser desires to purchase and acquire from Seller, all of Seller's right, title and interest in and to all of the Purchased Assets (the "Acquisition").

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby expressly acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

### **ARTICLE I**

#### **DEFINITIONS**

**1.1 Definitions.** As used herein, the following terms shall have the following meanings:

"Accounting Standards" shall mean, as applicable: (a) U.S. generally accepted accounting principles or (b) international financial reporting standards.

"Acquisition" shall have the meaning given to such term in the Recitals.

"Affiliate" shall mean with respect to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with such Person; *provided, that*, for purposes of this definition, "control" (including, with correlative meanings, the terms "controlled by" and "under common control with"), as used with respect to any Person, shall mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities or by contract or otherwise.

"Agreement" shall mean this Asset Purchase Agreement.

"Assigned Data" shall mean (a) all data and results of any research, preclinical, clinical, stability, toxicology or other study of any Compound conducted by or on behalf of Seller, and (b) all Chemistry, Manufacturing and Controls (CMC) or other manufacturing (including process development) data generated by or on behalf of Seller.

"Assigned Patents" shall mean:

(a) the patent and patent applications owned by Seller immediately prior to the Closing that claim the composition of matter or formulation of, or any method of making or using, or that otherwise claim, Compound, including the patents and patent applications listed on Exhibit D;

(b) any and all divisionals, continuations and continuations-in-part of the patents and patent applications referenced in the preceding subsection (a);

(c) the foreign patent applications associated with the patent applications referenced in the preceding subsections (a) and (b);

(d) the patents issued or issuing from the patent applications referenced in the preceding subsections (a) through (c); and

(e) reissues, reexaminations, restorations (including supplemental protection certificates) and extensions of any patent or patent application referenced in the preceding subsections (a) through (d).

“Assigned Technology” shall mean the Assigned Patents and Assigned Data.

“Assignment and Assumption Agreement” shall have the meaning given to such term in Section 5.1.

“Assumed Liabilities” shall have the meaning given to such term in Section 2.2.

“Business Day” shall mean any day other than a Saturday, Sunday or a day on which banks in California or Florida are obligated by applicable Law or executive Order to close or are otherwise generally closed.

“Closing” shall have the meaning given to such term in Section 2.99.

“Closing Cash Payment” shall have the meaning given to such term in Section 2.3.

“Closing Date” shall have the meaning given to such term in Section 2.99.

“Code” shall mean the Internal Revenue Code of 1986, as it may be amended from time to time, and any successor thereto.

“Compound” shall mean: [\*\*\*]; (c) any other compound, the manufacture, use or sale of which is claimed generically or specifically in any of the patents and patent applications listed on Exhibit D, and (d) any and all pharmaceutically active derivatives of any compound described in clause (a), clause (b) or clause (c) above, including, any prodrug, metabolite, ester, salt, hydrate, solvate, polymorph, isomer or enantiomer thereof, including compositions containing such compound, prodrug or metabolites, or esters, salts, hydrates, solvates, polymorphs, isomers or enantiomers of any compound described in clause (a), clause (b) or clause (c) above, whether existing on the Closing Date or generated or synthesized by or on behalf of Purchaser or any of its Affiliates or licensees after the Closing.

“Combination Product” shall mean a Product that is sold in a finished dosage form containing a Compound in combination with one or more Other Actives.

“Confidential Information” shall have the meaning given to such term in Section 6.4.

“Confidentiality Agreement” shall have the meaning given to such term in Section 6.4.

[\*\*\*].

“[\*\*\*]” shall have the meaning given to such term in Section 2.4(a)(i).

“[\*\*\*]” shall have the meaning given to such term in Section 2.4(a)(i).

“EMA” shall mean the European Medicines Agency or any successor agency thereto.

“EU” shall mean the European Union.

“EU Country” shall mean any EU member state.

“EU Marketing Approval” shall mean (a) in the European Union, approval by the EMA of an NDA filed pursuant to the centralized EMA filing procedure, or (b) if no NDA is filed with the EMA pursuant to the centralized EMA filing procedure, approval by the relevant Regulatory Authority of any EU Country of an NDA filed with such Regulatory Authority pursuant to the applicable filing procedures in such EU Country.

“Exception” shall have the meaning given to such term in Section 3.2.

“Excluded Assets” shall have the meaning given to such term in Section 2.1.

“FDA” shall mean the United States Food and Drug Administration or any successor agency thereto.

“First Commercial Sale” shall mean, with respect to a Product in a country or other regulatory jurisdiction, the first sale of such Product for end use or consumption in such country or jurisdiction after receipt of Marketing Approval for such Product in such country or jurisdiction.

“Form 8594” shall have the meaning given to such term in Section 2.88.

“Generic Version” shall mean, with respect to a Product, on a country-by-country basis, a pharmaceutical product that: (a) is sold in a given country by a Third Party, other than Purchaser, any of its Affiliates, any Licensee, or any other Person in a chain of distribution originating from Purchaser, any of its Affiliates or any Licensee; (b) contains the same Compound (and, if such Product is a fixed-dose combination that also contains any other active pharmaceutical ingredient that is not a Compound, the same other active ingredient(s)) as such Product in the same dosage form as such Product; and (c) has been approved for marketing by the relevant Regulatory Authority in such country (or by the EMA, if applicable, in the case of an EU Country) in reliance on the Marketing Approval for such Product in such country (or by the EMA, if applicable, in the case of an EU Country), including any such pharmaceutical product that has been approved for marketing (i) in the United States, pursuant to Section 505(b)(2) or Section 505(j) of the Act (21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j), respectively), (ii) in the EU or an EU Country, as a “generic medicinal product” pursuant to Article 10 of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004

that relies for its content on any such provision), or (iii) in any other country or jurisdiction, pursuant to any equivalent of the foregoing laws, regulations or directives, wherein the approval of such pharmaceutical product is based on reference to the Marketing Approval for such Product in such country or jurisdiction and a demonstration of bio-equivalence to such Product and which may be substituted for the Product without any action by the physician or health care practitioner.

“Governmental Authorities” shall mean all agencies, authorities, bodies, boards, commissions, courts, instrumentalities, legislatures and offices of any nature whatsoever of any government or political subdivision, whether foreign, federal, state, county, district, municipality, city or otherwise.

“IND” shall mean an Investigational New Drug Application filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations (or its successor regulation), or the equivalent application or filing filed with any equivalent agency or governmental authority outside the United States of America (including any supra-national agency such as the EMA).

“IND Reference Letters” shall have the meaning given to such term in Section 6.6.

“Indication” shall mean a specific disease, disorder or other medical condition: (a) which a Product is intended to treat, prevent or diagnose, as evidenced by the protocol for a clinical trial of such Product or by the proposed Product labeling in an NDA filed with a Regulatory Authority for such Product; or (b) which is contained in a Product’s labeling approved by a Regulatory Authority as part of the Marketing Approval for such Product.

“Initiation” of a clinical trial shall mean first dosing of the first patient in such clinical trial.

“Inventory” shall mean all inventory of the Compound or Products, and raw materials used or consumed by Seller or its agents in the production of finished goods in the possession or control of Seller as of immediately prior to the Closing which is set forth on Exhibit F.

“IRS” shall mean the United States Internal Revenue Service.

[\*\*\*].

[\*\*\*].

“Laws” shall mean any Federal, state, foreign or local statute, law, ordinance, regulation, rule, code, Order, other requirement or rule of law.

“Liability” shall mean any direct or indirect indebtedness, liability, assessment, expense, claim, loss, damage, deficiency, obligation or responsibility, known or unknown, disputed or undisputed, joint or several, vested or unvested, executory or not, fixed or unfixed, choate or inchoate, liquidated or unliquidated, secured or unsecured, determinable or undeterminable, accrued or unaccrued, absolute or not, actual or potential, contingent or otherwise (including any liability under any guarantees, letters of credit, performance credits or with respect to insurance loss accruals).

“LIBOR” shall have the meaning given to such term in Section 2.7(a).

“Licensee” shall mean any Third Party that is a licensee or sublicensee of any Product Rights.

“Licensing Revenue” shall mean all amounts received by Purchaser or any of its Affiliates from any Licensee with respect to the license or sublicense or option of Product Rights or an option to the license or sublicense of Product Rights, in each case to such Licensee, but excluding [\*\*\*]. For clarity, Licensing Revenue shall exclude amounts received by Purchaser or any of its Affiliates from any Licensee [\*\*\*], but to the extent any such amounts received by Purchaser or its Affiliates for [\*\*\*] shall be considered License Revenues.

“License Revenue Payments” shall mean the amounts payable to Seller with respect to Licensing Revenue under Section 2.6(a).

“Marketing Approval” shall mean, with respect to any Product in a country or other regulatory jurisdiction, the approval by the applicable Regulatory Authority in such country or jurisdiction of an NDA for such Product for a particular Indication in such country or jurisdiction.

[\*\*\*].

[\*\*\*].

[\*\*\*].

“NDA” shall mean: (a) in the United States, a New Drug Application (as more fully described in 21 CFR §314.50 et seq. or its successor regulation) filed with the FDA, or any successor application thereto; or (b) in any other country or group of countries, the equivalent application or submission for approval to market a pharmaceutical product filed with the governing Regulatory Authority in such country or group of countries, including in the EU, a marketing authorization application filed with the EMA pursuant to the centralized EMA filing procedure, or, if the centralized EMA filing procedure is not used, filed with the relevant Regulatory Authority of any EU Country using the applicable filing procedures in such EU Country.

“Net Sales” shall mean the gross amount invoiced for sales of Product by Purchaser, its Affiliates or Licensees (in each case, a “Selling Party”) to Third Parties (other than Selling Parties), less the following deductions from such gross amounts [\*\*\*]:

(a) [\*\*\*];

(b) [\*\*\*];

(c) [\*\*\*];

(d) [\*\*\*]; and

(e) [\*\*\*];

all as determined in accordance with the Accounting Standards used by the applicable Selling Party in its audited financial statements, consistently applied throughout the organization of the Selling

Party. All deductions for any of items (a) through (e) above shall be applied in a manner consistent with deductions applied to other pharmaceutical products of the Selling Party and will not be applied disproportionately to sales of Products.

Products [\*\*\*]. Sales of Products between Selling Parties [\*\*\*] shall be excluded from the [\*\*\*], but the subsequent [\*\*\*]. In the event of any sale or other disposition of a Product for any consideration [\*\*\*], then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold [\*\*\*] during the applicable reporting period in the country in which such sale or other disposition occurred.

For Products which are [\*\*\*], the Net Sales for such [\*\*\*]. If neither of the foregoing applies, then the Parties shall determine the Net Sales of [\*\*\*] in good faith based on the respective values of the components of [\*\*\*]. In the event the Parties are not able to reach agreement, Net Sales for such Combination Product shall be determined by an expert jointly appointed by the Parties, with such determination to be based on the respective [\*\*\*]. The decision of the expert shall be final and binding on the Parties and the fees of the expert shall be equally shared between the Parties.

“[\*\*\*]” shall mean the treatment, prevention or diagnosis of any Indication that is [\*\*\*].

“[\*\*\*]” shall have the meaning given to such term in Section 2.4(a)(ii).

“[\*\*\*]” shall have the meaning given to such term in Section 2.4(a)(ii).

“Order” shall mean any order, judgment, preliminary or permanent injunction, temporary restraining order, award, citation, decree, consent decree or writ of any Governmental Authority.

“Other Active” shall mean any active pharmaceutical ingredient that is not a Compound.

“Party” shall mean Seller or Purchaser, individually, as the context so requires, and the term “Parties” shall mean collectively, Seller and Purchaser.

“Patent Files” shall mean all files (including complete file histories) related to any Assigned Patent that are either in the possession of Seller or held or maintained on Seller’s behalf by Seller’s outside patent counsel, [\*\*\*], immediately prior to the Closing, including all contents of such files.

“Person” shall mean an individual, corporation, partnership, limited partnership, limited liability company, limited liability partnership, syndicate, person (including a “person” as defined in Section 13(d)(3) of the Securities Exchange Act of 1934, as amended, together with the rules and regulations promulgated thereunder), trust, association, entity or government or political subdivision, agency or instrumentality of a government.

“Phase 3 Trial” shall mean a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c) (or its successor regulation).

“Product” shall mean any pharmaceutical product containing or comprising any Compound, whether or not as the sole active ingredient, in any dosage, form or formulation.

“Product Rights” shall mean (a) a license or sublicense of rights to develop or commercialize a Compound or Product, or (b) an option or other right to obtain a license or sublicense covered by (a).

“Purchase Price” shall have the meaning given to such term in Section 2.3.

“Purchased Assets” shall have the meaning given to such term in Section 2.1.

“Purchaser” shall have the meaning given to such term in the preamble of this Agreement.

“Regulatory Authority” shall mean any regulatory agency, ministry, department or other governmental body having authority in any country or region to control the development, manufacture, marketing, and sale of pharmaceutical products, including the FDA, EMA and MHLW.

“Regulatory Exclusivity” shall mean marketing or data exclusivity conferred by the applicable Regulatory Authority in a country or jurisdiction on the holder of a Marketing Approval for a pharmaceutical product in such country or jurisdiction, including, by way of example and not of limitation, regulatory data exclusivity, orphan drug exclusivity, new chemical entity exclusivity and pediatric exclusivity.

“SEC” shall mean the U.S. Securities and Exchange Commission.

“Seller” shall have the meaning given to such term in the preamble of this Agreement.

“Seller INDs” shall mean [\*\*\*].

“Surviving Person” shall have the meaning given to such term in Section 2.7(b).

“Tax Return” shall mean any return, report, statement, form or other documentation (including any additional or supporting material and any amendments or supplements) filed or maintained, or required to be filed or maintained, with respect to or in connection with the calculation, determination, assessment or collection of any Taxes.

“Taxes” shall mean: (i) any and all taxes, fees, levies, duties, tariffs, imposts and other charges of any kind, imposed by any taxing authority, including taxes or other charges on, measured by, or with respect to income, franchise, windfall or other profits, gross receipts, property, sales, use, capital stock, payroll, employment, social security, workers’ compensation, unemployment compensation or net worth; taxes or other charges in the nature of excise, withholding, ad valorem, stamp, transfer, value-added or gains taxes; (ii) any Liability for the payment of any amounts of the type described in clause (i) as a result of being a member of an affiliated, combined, consolidated or unitary group for any taxable period; (iii) any Liability for the payment of amounts of the type described in clause (i) or clause (ii) as a result of being a transferee of, or a successor in interest to, any Person or as a result of an express or implied obligation to indemnify any Person; and (iv) any and all interest, penalties, additions to tax and additional amounts imposed in connection with or with respect to any amounts described in clause (i), clause (ii) or clause (iii).

“Third Party” shall mean any Person other than Seller or Purchaser or an Affiliate of Seller or Purchaser.

“Transaction Documents” shall mean, collectively, this Agreement, the Assignment and Assumption Agreement, the Patent Assignment and the IND Reference Letters.

“US” means the United States of America, including its territories and possessions.

“Update Report” shall have the meaning set forth in Section 2.4(c).

“Valid Claim” shall mean (a) any claim in any unexpired and issued patent that has not been disclaimed, revoked or held invalid or unenforceable by a decision of a court or other governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) any claim of a pending patent application that has not been abandoned, cancelled, finally rejected or expired without the possibility of appeal or re-filing.

**1.2 Interpretation.** Unless the context otherwise requires, the terms defined in Section 1.1 shall have the meanings herein specified for all purposes of this Agreement, applicable to both the singular and plural forms of any of the terms defined herein. When a reference is made in this Agreement to Sections, such reference shall be to a Section of this Agreement unless otherwise indicated. Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation.”

## ARTICLE 2

### PURCHASE & SALE OF PURCHASED ASSETS

**2.1 Purchased Assets.** Subject to the terms and conditions of this Agreement, at the Closing, Seller shall to, sell, convey, transfer, assign and deliver to Purchaser, and Purchaser shall purchase and acquire from Seller all of Seller’s right, title and interest in and to all of the following (collectively, the “Purchased Assets”):

- (a) The  
Compounds;
- (b) All Assigned Technology, and all rights to sue for or assert claims against and remedies against past, present or future infringements of any or all of the Assigned Technology and rights of priority and protection of interests therein and to retain any and all amounts therefrom except to the extent relating to any Excluded Assets;
- (c) All Inventory;  
and
- (d) All Patent Files with respect to the Assigned Patents;

in each case, excluding the Excluded Assets. The Purchased Assets shall be sold to Purchaser on an “as-is” and “where-is” basis as of the Closing Date. Purchaser agrees that the Purchased Assets

shall be delivered without any Seller warranties of whatever kind except for the representations provided in Article 3 of this Agreement, and that all Assumed Liabilities are assigned to and assumed by Purchaser. Notwithstanding anything to the contrary contained in Section 2.1 or elsewhere in this Agreement, all assets not specifically listed in Section 2.1 (collectively, the “Excluded Assets”) shall not be part of the sale and purchase contemplated hereunder, are excluded from the Purchased Assets, and shall remain the property of Seller after the Closing.

**2.2 Assumed Liabilities.** Except for the Assumed Liabilities, Purchaser shall not, by virtue of its purchase of the Purchased Assets, assume or become responsible for any Liabilities of Seller or any other Person in connection with this Agreement. Upon and subject to the terms, conditions, representations and warranties of Seller contained herein, Purchaser hereby assumes and agrees to pay, perform, and discharge in a timely manner when due any and all Liabilities (i) arising out of or relating to the prosecution and maintenance of the Assigned Patents arising on or after the Closing Date, (ii) for all research, development, manufacturing, registration, commercialization, use, handling, storage, sale, offer for sale, import or other disposition or exploitation of Compounds and Products on or after the Closing Date, (iii) for the ownership, operation, maintenance, sale, lease, disposition, exploitation or use of the Purchased Assets on or after the Closing Date, and (iv) for Taxes of Seller payable by Purchaser pursuant to Section 2.100 (collectively, the “Assumed Liabilities”).

**2.3 Purchase Price; Payment of Purchase Price.** The aggregate consideration for the [\*\*\*] shall be (i) [\*\*\*], to be paid by Purchaser to Seller at the Closing by wire transfer of immediately available funds (the “[\*\*\*]”), (ii) the assumption by Purchaser of the Assumed Liabilities and (iii) all [\*\*\*] that become due pursuant to Sections 2.44, 2.55 and 2.66, respectively (collectively, the “Purchase Price”).

**2.4 Milestone Payments.**

(a) [\*\*\*].

(i) [\*\*\*].

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

\* [\*\*\*]

(ii) [\*\*\*].

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

(iii) [\*\*\*].

(b) [\*\*\*].

(c) **Diligence.** Purchaser shall [\*\*\*] to develop and obtain Marketing Approval of the Product [\*\*\*] for [\*\*\*]. For purposes of this Section 2.4(c), the term “[\*\*\*]” means, with [\*\*\*]. Until First Commercial Sale of a Product in [\*\*\*], Purchaser shall send to Seller a status report regarding the development, manufacture and commercialization of Compounds and Products, including the status of efforts to [\*\*\*], in January and June of each year (each such report, an “Update Report”), with the first such Update Report due in June 30, 2015. Within thirty (30) days after receipt of an Update Report, if the Seller requests a meeting with representatives of Purchaser to discuss such report, Purchaser shall make available for such a meeting those of its employees and representatives as are responsible for the applicable activities set forth in the Update Report, provided that Purchaser shall not be obligated to participate in such a meeting more than once per calendar year.

**2.5 Royalties.**

(a) [\*\*\*]:

(i) [\*\*\*]; and

(ii) [\*\*\*].

(b) [\*\*\*].

(c) [\*\*\*].

(d) [\*\*\*].

**2.6 Licensing Revenue Payments.**

(a) [\*\*\*].

[***]	[***]
[***]	[***]
[***]	[***]

(b) Copy of [\*\*\*]. Within thirty (30) days after the License Date for any Licensee, Purchaser shall deliver to Seller [\*\*\*] from such copy(ies) any confidential and proprietary information that is not necessary for Seller [\*\*\*] under this Section 2.66.

(c) Reports and Payments. Within thirty (30) days after the receipt by Purchaser or its Affiliate of [\*\*\*], Purchaser shall: (i) provide Seller with written notice thereof; which notice shall include [\*\*\*].

## **2.7 Payments; Audits.**

(a) Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable [\*\*\*]. Whenever conversion of amounts paid or reported to Purchaser or any of its Affiliates any foreign currency to US dollars is required, such conversion shall be made: (i) in the case of [\*\*\*], at the rate of exchange used throughout the accounting system of Purchaser and its Affiliates for such calendar quarter; and (ii) in the case of [\*\*\*], at the rate of exchange used throughout the accounting system of Purchaser and its Affiliates for Purchaser's or its Affiliate's most-recently completed calendar quarter. All payments owed under this Agreement shall be made by wire transfer to a bank and account designated in writing by Seller, unless otherwise specified in writing by Seller.

(b) Responsibility for Payments. Purchaser shall not consolidate with or merge into any other Person, assign, convey, transfer, license or lease its properties and assets substantially as an entirety to any Person or assign, convey, transfer, license or lease substantially all the Purchased Assets or substantially all of the business or assets of Purchaser related to any Compound or Product, to any Person, unless (i) the Person formed by such consolidation or into which Purchaser is merged or the Person that acquires by conveyance or transfer, or that licenses or leases, the properties and assets of Purchaser (the "Surviving Person") has expressly assumed the obligation to [\*\*\*] and the obligation to perform every other duty and covenant of Purchaser under this Agreement; and (ii) in the event Purchaser assigns, conveys, transfers, licenses or leases its properties and assets in accordance with the terms and conditions of this Section 2.7(b), Purchaser and the Surviving Person shall be jointly and severally liable for [\*\*\*] and the performance of every duty and covenant of Purchaser under this Agreement.

(c) Audits. Until the expiration of [\*\*\*] hereunder and for a period of three (3) years thereafter, Purchaser shall keep complete and accurate records pertaining to the sale or other disposition of Products for consideration by Purchaser, its Affiliates and their respective Licensees, and the receipt by Purchaser and its Affiliates of Licensing Revenue, in each case, in sufficient detail to permit Seller to confirm the accuracy of the [\*\*\*]. Seller shall have the right to cause an independent, certified public accountant reasonably acceptable to Purchaser to audit such records to confirm [\*\*\*], for a period covering not more than the preceding three (3) calendar years. Purchaser may require such accountant to execute a reasonable confidentiality agreement with Purchaser prior to commencing the audit. Such audits may be conducted during normal business hours upon reasonable prior written notice to Purchaser, but no more than frequently than once per year. No accounting period of Purchaser shall be subject to audit more than one time by Seller, unless after an accounting period has been audited by Seller, Purchaser restates its financial results for such accounting period, in which event Seller may conduct a second audit of such accounting

period in accordance with this Section 2.7(c). Prompt adjustments (including remittances of underpayments or overpayments disclosed by such audit) shall be made by the parties to reflect the results of such audit. Seller shall bear the full cost of such audit unless such audit discloses an underpayment by Purchaser of 5% or more of the amounts due under this Agreement provided that such underpayment is at least \$500,000, in which case Purchaser shall bear the full cost of such audit.

(d) **Late Payments.** In the event that [\*\*\*] due under this Agreement is not made when due, the payment shall accrue interest from the date due at the rate of the one-month London Interbank Offered Rate (“LIBOR”) as quoted in the Wall Street Journal (or if it no longer exists, similarly authoritative source) plus [\*\*\*]; *provided, however*, that in no event shall such rate exceed the maximum legal annual interest rate. The payment of such interest shall not limit Seller from exercising any other rights it may have as a consequence of the lateness of any payment.

**2.8 Allocation of Purchase Price.** Purchaser and Seller shall cooperate in good faith to agree as to the allocation of the Purchase Price pursuant to Section 1060 of the Code and the treasury regulations promulgated thereunder. Purchaser and Seller agree to reflect such allocation on IRS Form 8594: Asset Acquisition Statement under Section 1060, including any required amendments or supplements thereto (“Form 8594”), in the form attached hereto as Exhibit B. Form 8594 shall be prepared jointly by Purchaser and Seller and shall be signed by the Parties within 45 days following the Closing Date. The Parties hereto further agree that: (a) the agreed upon allocation of Purchase Price shall be used in filing all required forms under Section 1060 of the Code and all Tax Returns; and (b) they will not take any position inconsistent with such allocation upon any examination of any such Tax Return, in any refund claim or in any tax litigation.

**2.9 Closing.** The consummation of the purchase and sale of the Purchased Assets and the Assumption of the Assumed Liabilities in accordance with this Agreement (the “Closing”) shall take place at the offices of Cooley LLP, 4401 Eastgate Mall, San Diego, CA 92121, concurrently with the execution and delivery of this Agreement by all of the Parties hereto, or at such other time and place as may be mutually agreed by the parties. The date of the Closing shall be referred to as the “Closing Date.” All events which shall occur at the Closing shall be deemed to occur simultaneously.

**2.10 Transfer Taxes.** Purchaser shall be responsible for the payment of any sales, use, transfer or similar taxes arising out of or in connection with the Acquisition; provided that Seller shall reimburse Purchaser for 50% of the amount of such payments promptly following written request from Purchaser, including documentation of any such payments.

**2.11 Withholding.** If a Law requires Purchaser to withhold Taxes of any type [\*\*\*], Purchaser shall (i) deduct such Tax from the payment made to Seller, (ii) timely pay such Taxes for and on behalf of Seller to the proper Government Authority, and (iii) furnish Seller with documentation of such payment within thirty (30) days following such payment.

### ARTICLE 3

#### REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Purchaser that the statements contained in this Article 3 are true and correct as of the Closing Date.

**3.1 Organization and Qualification.** Seller is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. Seller has the requisite power to own, operate or lease the Purchased Assets and carry on its business as now being conducted.

**3.2 Authority Relative to this Agreement.** Seller has all requisite power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party, to perform its obligations hereunder and to consummate the Acquisition. The execution, delivery and performance of this Agreement and the other Transaction Documents by Seller and the consummation by Seller of the Acquisition have been duly and validly authorized by all necessary action of the Seller, and no other action on the part of the Seller is necessary to authorize this Agreement and the other Transaction Documents or to consummate the Acquisition. This Agreement and the other Transaction Documents have been duly executed and delivered by Seller and, assuming the due authorization, execution and delivery by the other Parties hereto, each such agreement constitutes a legal, valid and binding obligation of Seller, enforceable against Seller in accordance with its terms, subject to the effect of any applicable bankruptcy, moratorium, insolvency, reorganization or other similar law affecting the enforceability of creditors' rights generally and to the effect of general principles of equity which may limit the availability of remedies, whether in a proceeding at Law or in equity (collectively, the "Exception").

**3.3 No Conflict.** The execution and delivery of this Agreement and the other Transaction Documents by Seller do not, and the performance by Seller of its obligations hereunder and the consummation of the Acquisition and the transactions contemplated by the other Transaction Documents will not: (i) conflict with or violate any provision of the organizational documents of Seller or (ii) conflict with or violate any Law or Order applicable to Seller or by which any of the Purchased Assets or Seller is bound or affected.

#### ARTICLE 4

##### REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to Seller, that each of the following representations and warranties is true and correct as of the Closing Date:

**4.1 Organization and Qualification.** Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite power and authority and all necessary governmental approvals to own, lease and operate its properties and to carry on its business as now being conducted.

**4.2 Authority Relative to this Agreement.** Purchaser has all necessary power and authority to execute and deliver this Agreement and the other Transaction Documents to which it is a party, to perform its obligations hereunder and to consummate the Acquisition. The execution and delivery of this Agreement and the other Transaction Documents by Purchaser and the

consummation by Purchaser of the Acquisition have been duly and validly authorized by all necessary action of the Purchaser and its board of directors, and no other proceedings on the part of Purchaser are necessary to authorize this Agreement or to consummate the Acquisition. This Agreement and the other Transaction Documents have been or when executed and delivered will be duly executed and delivered by Purchaser and, assuming the due authorization, execution and delivery by the other Parties hereto, each such agreement constitutes a legal, valid and binding obligation of Purchaser, enforceable against Purchaser in accordance with its terms, subject to the Exception.

**4.3 No Conflict.** The execution and delivery of this Agreement by Purchaser do not, and the performance by Purchaser of its obligations hereunder and the consummation of the Acquisition will not: (i) conflict with or violate any provision of Purchaser's certificate of incorporation or bylaws, each as amended to date, or any resolutions adopted by the board of directors of Purchaser or (ii) conflict with or violate any Law or Order applicable to Purchaser or by which Purchaser is bound or affected.

**4.4 No Implied Representations.** Purchaser agrees that neither Seller nor any other Person acting on behalf of Seller has made or is making any representations or warranties, express or implied, except those representations set forth in Article 3 of this Agreement. WITHOUT LIMITING THE GENERALITY OR THE EFFECT OF THE FOREGOING, PURCHASER ACKNOWLEDGES THAT EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, PURCHASER IS ACQUIRING THE ASSETS "AS IS" AND "WHERE IS" AS OF THE CLOSING DATE, WITHOUT ANY EXPRESS OR IMPLIED REPRESENTATIONS OR WARRANTIES AS TO THE FITNESS, MERCHANTABILITY, NON-INFRINGEMENT OR CONDITION OF THE ASSETS OR AS TO ANY OTHER MATTER.

## ARTICLE 5

### CLOSING DELIVERABLES

**5.1 Closing Deliverables of Purchaser.** At the Closing, Purchaser shall deliver to Seller the following:

- (a) A duly executed Assignment and Assumption Agreement, in the form attached hereto as Exhibit A; and
- (b) Payment of the Closing Cash Payment.

**5.2 Closing Deliverables of Seller.** At the Closing, Seller shall deliver to Purchaser the following:

- (a) A duly executed Assignment and Assumption Agreement, in the form attached hereto as Exhibit A;
- (b) A duly executed Patent Assignment in the form attached hereto as Exhibit C; and

(c) A duly executed letter to the FDA authorizing Purchaser to reference and rely upon all information and data contained in the Seller INDs and authorizing the FDA to cross reference the Seller INDs on behalf of Purchaser for any IND, NDA or other regulatory submission filed by Purchaser for the Compound or any Product in the form attached hereto as Exhibit G (the "IND Reference Letters").

## ARTICLE 6

### ADDITIONAL COVENANTS

**6.1 Further Assurances.** Seller hereby agrees, without further consideration, for a period of sixty (60) days following the Closing Date, to execute and deliver following the Closing such other instruments of transfer and take such other action as Purchaser or its counsel may reasonably request in order to put Purchaser in possession of the Purchased Assets in accordance with this Agreement. In addition to the foregoing, for a period of sixty (60) days following the Closing Date, Seller shall execute and deliver, and shall cause its Affiliates to execute and deliver as applicable, to Purchaser such documentation as shall be reasonably requested and approved by Purchaser, including assignments in substantially the forms as approved by Purchaser, in order to transfer to Purchaser, and put Purchaser in possession of any Assigned Patents in any jurisdiction.

**6.2 Patent Assignment.** Promptly following the Closing, Purchaser shall file such patent assignments with the U.S. Patent and Trademark Office and with foreign patent offices as are necessary to record the assignment of the Assigned Patents to Purchaser, at Purchaser's expense.

**6.3 Public Announcements.** Notwithstanding anything to the contrary contained herein, except as may be required to comply with the requirements of any applicable Law and the rules and regulations of any stock exchange upon which the securities of one of the parties is listed, from and after the date hereof, no press release or similar public announcement or communication shall be made or caused to be made by either Party and/or any of such Party's Affiliates relating to this Agreement or the transactions contemplated hereby unless specifically approved in advance by the other Party; provided, however, that: (a) the Parties may jointly issue one or more press release(s) announcing the consummation of the transactions contemplated by this Agreement; (b) either Party may issue such press releases, public announcements or communications or make such SEC filings as it determines are reasonably necessary to comply with applicable Law (including disclosure requirements of the SEC) or with the requirements of any stock exchange on which securities issued by a Party or its Affiliates are traded provided that it gives at least seven (7) days advance written notice (or such lesser period if not practicable) to the other Party of such planned disclosure and considers in good faith any comments of the other Party; and (c) Seller may communicate with its members regarding this Agreement and the transactions contemplated hereby as may be required by applicable Law or Seller's organizational documents or with respect to any payments hereunder, including [\*\*\*].

**6.4 Confidentiality.** The provisions of that certain Confidentiality Agreement dated October 16, 2014, by and between Purchaser and Seller (the "Confidentiality Agreement") are hereby incorporated herein and shall remain binding and in full force and effect; *provided, however,* that all obligations of the Purchaser under the Confidentiality Agreement with respect to the

Purchased Assets shall terminate simultaneously with the Closing. Except as otherwise provided herein or in the other Transaction Documents, Seller shall treat after the date hereof as strictly confidential all nonpublic, confidential or proprietary information concerning the Purchased Assets (“Confidential Information”); *provided, however*, that the foregoing obligations shall not apply to (a) any information which was or comes into the public domain through no breach of this Agreement by Seller, (b) any information in the possession of any Third Party that acquires Seller in connection with any type of merger, acquisition or change of control transaction, other than as a result of disclosure by Seller, (c) any information that is independently developed or discovered by any such Third Party acquiror without reference to information concerning the Purchased Assets that was in Seller’s possession on the Closing Date, (d) is rightfully communicated to any such Third Party acquiror by another Third Party, free and clear of any obligation of confidence, or (e) is or was communicated by the Purchaser to an unaffiliated Third Party free of any obligation of confidence. In addition, Seller shall not be prohibited from disclosing any portion of the Confidential Information that Seller is required to disclose by judicial or administrative process or, in the opinion of legal counsel, by other requirements of Law.

**6.5 Expenses.** Each of the Parties shall bear its own expenses incurred in connection with the preparation, execution and performance of this Agreement and the Acquisition, including all fees and expenses of its representatives.

**6.6 Transfer of Purchased Assets.** With respect to (i) Assigned Data in Seller’s possession and control, (ii) Patent Files and (iii) Inventory, Seller shall transfer and deliver all of the aforementioned items, promptly, but in any event within thirty (30) calendar days of the Closing Date, as may be requested by Purchaser, and at Purchaser’s expense for shipping and handling costs, to the locations, and in accordance with the instructions, specified by Purchaser. In the event that any of the abovementioned items reside in digital or electronic format on any equipment that is not included in the Purchased Assets, then the hard drive or other medium shall be imaged and provided to Purchaser in a reasonably accessible format. Seller will, to the extent any such Assigned Data or Patent Files exists in a form suitable for electronic transfer, make such transfer electronically.

## ARTICLE 7

### GENERAL

#### 7.1 Survival.

(a) The representations and warranties of Seller and Purchaser contained in this Agreement shall not survive the Closing.

(b) All covenants and agreements made by Seller or Purchaser in or pursuant to this Agreement or any other Transaction Document shall survive the Closing and remain in full force and effect to give effect to their respective terms, unless otherwise expressly provided for by their terms.

**7.2 Notices.** All notices or other communications required or permitted to be given hereunder shall be in writing and shall be delivered by hand or sent by facsimile or sent, postage

prepaid, by registered, certified or express mail or overnight courier service and shall be deemed given when so delivered by hand or facsimile, or if mailed, three (3) Business Days after mailing (one Business Day in the case of express mail or overnight courier service), to the parties at the following addresses or facsimiles (or at such other address or facsimile for a Party as shall be specified in a notice given in accordance with this Section 7.2):

(a) If to Purchaser:

[\*\*\*]

(b) If to Seller:

[\*\*\*]

**7.3 Severability.** If any provision of this Agreement for any reason shall be held to be illegal, invalid or unenforceable, such illegality shall not affect any other provision of this Agreement, but this Agreement shall be construed as if such illegal, invalid or unenforceable provision had never been included herein.

**7.4 Assignment; Binding Effect.** Neither this Agreement nor any of the rights, interests or obligations hereunder shall be transferred, conveyed or assigned, in whole or in part, by operation of Law or otherwise, by either Party without the prior written consent of the other Party, except that: (a) Purchaser may assign, in its sole discretion, (i) any or all of its rights, interests and obligations under this Agreement to any of its subsidiaries or Affiliates, but no such assignment shall relieve Purchaser of any of its obligations hereunder, or (ii) provided that the terms and conditions of Section 2.7(b), if applicable, are satisfied, this Agreement in whole to a Third Party in connection with the transfer or sale of all or substantially all of Purchaser's business related to the Purchased Assets to such third party, whether by merger, sale of stock, sale of assets or otherwise; and (b) Seller may assign, in its sole discretion, this Agreement in whole to a Third Party in connection with the transfer or sale of all or substantially all of Seller's business to such third party, whether by merger, sale of stock, sale of assets or otherwise. Any assignment not in accordance with the foregoing shall be void. Subject to the preceding sentences, this Agreement will be binding upon, inure to the benefit of and be enforceable by, the parties and their respective permitted successors and assigns.

**7.5 No Third-Party Beneficiaries.** This Agreement is for the sole benefit of the Parties and their successors and permitted assigns and nothing herein expressed or implied shall give or be construed to give to any Person, other than the Parties and such successors and assigns, any legal or equitable rights hereunder.

**7.6 Incorporation of Exhibits.** All Exhibits and Schedules attached hereto and referred to herein are hereby incorporated herein and made a part of this Agreement for all purposes as if fully set forth herein.

**7.7 Governing Law.** THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF [\*\*\*] OTHER

THAN CONFLICT OF LAWS PRINCIPLES THEREOF DIRECTING THE APPLICATION OF ANY LAW [\*\*\*].

**7.8 Headings; Interpretation.** The descriptive headings contained in this Agreement are included for convenience of reference only and shall not affect in any way the meaning or interpretation of this Agreement. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement.

**7.9 Counterparts; Facsimiles.** This Agreement may be executed and delivered (including by electronic or facsimile transmission) in two or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

**7.10 Entire Agreement.** This Agreement (including the Schedules and Exhibits attached hereto), the Transaction Documents executed in connection with the consummation of the Acquisition, and the Confidentiality Agreement (as amended by this Agreement), contain the entire agreement between the Parties with respect to the subject matter hereof and related transactions and supersede all prior agreements, written or oral, with respect thereto.

**7.11 Specific Enforcement.** The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached or threatened to be breached and that an award of money damages would be inadequate in such event. Accordingly, it is acknowledged that the Parties shall be entitled to equitable relief, without proof of actual damages, to enforce performance of this Agreement in accordance with its terms, including an Order for specific performance, to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement, in addition to any other remedy under this Agreement. Each Party further agrees that neither the other Party nor any other Person shall be required to obtain, furnish or post any bond or similar instrument in connection with or as a condition to obtaining any remedy referred to in this Section 7.11, and each Party hereto irrevocably waives any right it may have to require the obtaining, furnishing or posting of any such bond or similar instrument.

**7.12 Waivers and Amendments; Non-Contractual Remedies; Preservation of Remedies.** This Agreement may be amended, superseded, canceled, renewed or extended only by a written instrument signed by all of the Parties. The provisions hereof may be waived only in writing signed by all of the Parties. No delay on the part of any Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any waiver on the part of any Party of any such right, power or privilege, nor any single or partial exercise of any such right, power or privilege, preclude any further exercise thereof or the exercise of any other such right, power or privilege. Except as otherwise provided herein, the rights and remedies herein provided are cumulative and are not exclusive of any rights or remedies that any Party may otherwise have at Law or in equity.

*[Signatures appear on next page]*

IN WITNESS WHEREOF, intending to be legally bound hereby, the Parties have caused this Agreement to be signed in their respective names by their duly authorized representatives as of the date first above written.

BRICKELL BIOTECH, INC.

By: /s/ Andy Sklawer  
Name: Andy Sklawer  
Title: Vice President, Operations

PANMIRA PHARMACEUTICALS, LLC

By: /s/ Edward O'Sullivan  
Name: Edward O'Sullivan  
Title: CFO

[SIGNATURE PAGE TO ASSET PURCHASE AGREEMENT]

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**EXHIBIT A**

**FORM OF ASSIGNMENT AND ASSUMPTION AGREEMENT**

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**ASSIGNMENT  
AND  
ASSUMPTION AGREEMENT**

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT (this “*Agreement*”) is executed and delivered as of January 30, 2015 by and between PANMIRA PHARMACEUTICALS, LLC, a Delaware limited liability company (“*Seller*”), and BRICKELL BIOTECH, INC., a Delaware corporation (“*Purchaser*”). Seller and Purchaser are each referred to herein as a “Party” and, collectively, as the “Parties.”

**RECITALS**

**WHEREAS**, Seller and Purchaser have entered into that certain Asset Purchase Agreement dated as of January 30, 2015 (the “*Purchase Agreement*”) pursuant to which, among other things, Seller has agreed to sell, convey, transfer, assign and deliver the Purchased Assets to Purchaser, subject to the terms and conditions set forth in the Purchase Agreement, in exchange for the consideration provided for therein, including Purchaser’s assumption of the Assumed Liabilities. All capitalized terms not defined herein shall have the same meanings as set forth in the Purchase Agreement.

**AGREEMENT**

**NOW, THEREFORE**, for good and valuable consideration, receipt of which is hereby acknowledged by the Parties, the Parties hereby agree as follows:

1. Assignment. Subject to and in accordance with the terms and conditions of the Purchase Agreement, Seller hereby sells, conveys, transfers, assigns and delivers to Purchaser and Purchaser hereby assumes all of Seller’s right, title and interest in and to the Purchased Assets.
2. Assumption of Liabilities. Purchaser hereby assumes and agrees to pay, perform and discharge, subject to and in accordance with the terms and conditions of the Purchase Agreement, each of the Assumed Liabilities.
3. Further Assurances. Seller hereby agrees, without further consideration, for a period of sixty (60) days following the Closing Date, to execute and deliver following the Closing such other instruments of transfer and take such other action as Purchaser or its counsel may reasonably request in order to put Purchaser in possession of the Purchased Assets in accordance with this Agreement. In addition to the foregoing, for a period of sixty (60) days following the Closing Date, Seller shall execute and deliver, and shall cause its Affiliates to execute and deliver as applicable, to Purchaser such documentation as shall be reasonably requested and approved by Purchaser, including assignments in substantially the forms as approved by Purchaser, in order to transfer to Purchaser, and put Purchaser in possession of any Assigned Patents in any jurisdiction.

4. Governing Law. THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF [\*\*\*] OTHER THAN CONFLICT OF LAWS PRINCIPLES THEREOF DIRECTING THE APPLICATION OF ANY LAW OTHER THAN THAT [\*\*\*].

5. Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be transferred, conveyed or assigned, in whole or in part, by operation of Law or otherwise, by either Party without the prior written consent of the other Party, except that: (a) Purchaser may assign, in its sole discretion, (i) any or all of its rights, interests and obligations under this Agreement to any of its subsidiaries or Affiliates, but no such assignment shall relieve Purchaser of any of its obligations hereunder, or (ii) provided that the terms and conditions of Section of the Purchase Agreement, if applicable, are satisfied, this Agreement in whole to a Third Party in connection with the transfer or sale of all or substantially all of Purchaser's business related to the Purchased Assets to such third party, whether by merger, sale of stock, sale of assets or otherwise; and (b) Seller may assign, in its sole discretion, this Agreement in whole to a Third Party in connection with the transfer or sale of all or substantially all of Seller's business to such third party, whether by merger, sale of stock, sale of assets or otherwise. Any assignment not in accordance with the foregoing shall be void. Subject to the preceding sentences, this Agreement will be binding upon, inure to the benefit of and be enforceable by, the parties and their respective permitted successors and assigns.

6. Miscellaneous. This Agreement is subject to, and shall be construed in accordance with, the Purchase Agreement, and in the event of a conflict between the provisions of this Agreement and the provisions of the Purchase Agreement (insofar as such provisions relate to the rights and obligations of Purchaser, on the one hand, and Seller, on the other hand), the provisions of the Purchase Agreement shall prevail. This Agreement may be executed and delivered (including by electronic or facsimile transmission) in two or more counterparts, and by the different Parties hereto in separate counterparts, each of which when executed and delivered shall be deemed to be an original but all of which taken together, shall constitute one and the same agreement.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the undersigned have executed this **ASSIGNMENT AND AGREEMENT** as of the date first written above.

**SELLER:**

PANMIRA PHARMACEUTICALS, LLC

By: /s/ Edward O'Sullivan  
Name: Edward O'Sullivan  
Title: CFO

**PURCHASER:**

BRICKELL BIOTECH, INC.

By: /s/ Andy Sklawer  
Name: Andy Sklawer  
Title: Vice President, Operations

[Signature Page to Assignment and Assumption Agreement]

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**EXHIBIT B**  
**FORM 8594**

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**EXHIBIT C**  
**FORM OF PATENT ASSIGNMENT**

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PATENT ASSIGNMENT AGREEMENT

This Patent Assignment Agreement (this "Assignment") is dated as of January 30, 2015 (the "Effective Date"), and is entered into between Panmira Pharmaceuticals, LLC, a Delaware corporation having its place of business at P.O. Box 81946, San Diego, CA 92138, U.S.A. ("Assignor") and Brickell Biotech, Inc., a Delaware corporation, having its place of business at 2600 SW 3rd Avenue, Suite 350, Miami, Florida, 33129, U.S.A. ("Assignee").

WHEREAS, Assignor and Assignee have entered into an Asset Transfer Agreement dated as of January 30, 2015 (the "Asset Transfer Agreement"), whereby Assignor has agreed to sell, assign and transfer to Assignee Transferred Patent Rights (capitalized terms not otherwise defined herein will have the meanings ascribed thereto in the Asset Transfer Agreement); and

WHEREAS, Assignor is the, owner of the entire right, title and interest in, to and under the Transferred Patent Rights; and

WHEREAS, this Assignment is the Patent Assignment Agreement referred to in Section 5.2(b) of the Asset Transfer Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

Assignor hereby sells, assigns, transfers and sets over to Assignee and its successors, assigns and other legal representatives all of Assignor's right, title and interest in and to the certain Transferred Patent Rights disclosed in Schedule A attached hereto ("the "Schedule A Transferred Patent Rights"), including for clarity, [\*\*\*].

Assignor authorizes and requests the United States Commissioner of Patents and Trademarks and any other applicable government authority to record Assignee as the assignee and Owner of the Schedule A Transferred Patent Rights, and issue any and all registrations thereto to Assignee, as assignee of the entire right, title and interest in, to and under the same, for the sole use and enjoyment of Assignee-and its successors, assigns or other legal representatives.

Assignor shall provide to Assignee, its successors, assigns or other legal representatives, cooperation and assistance at Assignee's request and expense but without additional compensation, in connection with (1) execution and delivery, or causing the execution and delivery, of any and all further documentation including country specific assignments, affidavits, declarations, oaths, samples, exhibits, specimens and other documentation as may be reasonably required; (2) preparation and prosecution of arty application within the Schedule A Transferred Patent Rights that Assignee may reasonably deem appropriate that may be secured under the laws now or hereafter in. effect in the United States or any foreign countries; (3) prosecution or defense of any cancellation, opposition, infringement or other proceedings that may arise in connection with any of the Schedule A Transferred Patent Rights, including without limitation, testifying as to any facts relating to the

Schedule A Transferred Patent Rights and this Assignment; (4) enforcement of Assignee's rights in any Schedule A Transferred Patent Rights; and (5) implementation, perfection and/or recording of this Assignment and any foreign country specific assignments required by patent offices of foreign countries.

This Assignment will inure to the benefit of Assignee, its successors and assigns, and will bind Assignor and its successors and permitted assigns, except that Assignor may not assign this Assignment without the consent of Assignee. This Assignment will be governed in all respects, whether as to validity, construction, capacity, performance or otherwise, by the [\*\*\*] without reference to its conflicts of law provisions. If any term or provision of this Assignment will, to any extent or for any reason, be held to be invalid or unenforceable, the remainder of this Assignment will not be affected thereby and will be construed as if such invalid or unenforceable provision had never been contained herein or been applicable in such circumstances. This Assignment may not be amended unless mutually agreed upon in writing by both Assignee and Assignor, and no waiver will be effective unless signed by Assignee.

[The remainder of the page left blank intentionally signature page follows]

IN WITNESS WHEREOF, Assignor has caused this Assignment to be duly executed as of the date first above written.

Date: 1/30, 2015      /s/ Edward O'Sullivan  
Name: Edward O'Sullivan  
Title: CFO

State of California )

) SS:

County of San Diego )

On this the 30 day of January, 2015, Edward O'Sullivan, personally appeared before me, to me known to be the person named in and who executed the above Assignment individually, and acknowledged to me that he executed the same. for the uses and the purposes therein mentioned.

RECEIVED AND AGREED TO BY ASSIGNEE:

Date: January 30, 2015      /s/ Andy Sklawer  
Name: Andy Sklawer  
Title: Vice President, Operations

State of Florida )

) SS:

County of Dade )

On this the 30 day of January, 2015, \_\_\_\_\_, personally appeared before me, to me known to be the person named in and who executed the above Assignment individually, and acknowledged to me that he executed the same. for the uses and the purposes therein mentioned.

SEAL      /s/Merdedes Estevez

[The remainder of the page left blank intentionally; witness signature page follows]

Execution Version

STATEMENT BY WITNESS:

I, Amy Halman Rice (name of witness), whose full post office address is 4401 Eastgate Mall, San Diego CA 92121 (address of witness) was personally present and did see Edward O'Sullivan (name of representative for Assignor) execute the above assignment.

Date: January 30, 2015      /s/ Amy Halman Rice  
[[Name of Witness 1]]

STATEMENT BY WITNESS:

I, Debra Park (name of witness), whose full post office address is 4401 Eastgate Mall, San Diego, CA 92121 (address of witness) was personally present and did see Edward O'Sullivan (name of representative for Assignor) execute the above assignment.

Date: January 30, 2015      /s/ Debra Park  
[[Name of Witness 2]]

STATEMENT BY WITNESS:

I, Richard C. Belmont, Jr. (name of witness), whose full post office address is 888 Baker Log Dr., Miami, FL 33131 (address of witness) was personally present and did see Andy Sklawer (name of representative for Assignor) execute the above assignment.

Date: January 30, 2015      /s/ Richard C. Belmont, Jr.

STATEMENT BY WITNESS:

I, Alfredo Vado (name of witness), whose full post office address is 502 NW 87 Ave., Apt 411, Miami, FL 33172 (address of witness) was personally present and did see Andy Sklawer (name of representative for Assignor) execute the above assignment.

Date: January 30, 2015      /s/ Alfredo Vado  
[The remainder of the page left blank intentionally; Schedule A follows]



- Trustee
- Guardian or Conservator
- Other: \_\_

Signer is representing: \_\_

**EXHIBIT D**  
**ASSIGNED PATENTS**

[\*\*\*]

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**EXHIBIT E-1**

**[\*\*\*] COMPOUND STRUCTURE**

**[\*\*\*]**

**EXHIBIT E-2**

**[\*\*\*] COMPOUND STRUCTURE**

**[\*\*\*]**

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**EXHIBIT F**  
**INVENTORY**

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**EXHIBIT G**

**[\*\*] REFERENCE LETTER**

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[\*\*\*]

Panmira Pharmaceuticals, LLC, P.O. Box 81946, San Diego, CA 92138  
Tel: (858) 216-4541 Fax: (866) 525-2358 Web: [www.panmira.com](http://www.panmira.com)

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**EXHIBIT H**

**[\*\*] REFERENCE LETTER**

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[\*\*\*]

Panmira Pharmaceuticals, LLC, P.O. Box 81946, San Diego, CA 92138  
Tel: (858) 216-4541 Fax: (866) 525-2358 Web: [www.panmira.com](http://www.panmira.com)

**LEASE**

**BMC PROPERTIES, LLC**

**(as Landlord)**

**And**

**BRICKELL BIOTECH, INC.**

**(as Tenant)**

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**LEASE**

THIS LEASE is made the 4<sup>th</sup> day of August, 2016, by and between BMC PROPERTIES, LLC, a Colorado limited liability company (“Landlord”) and BRICKELL BIOTECH, INC., a Delaware corporation (“Tenant”).

W I T N E S S E T H :

**1. DEFINITIONS**

In addition to other terms, which are defined elsewhere in this Lease, the terms defined in the following subparagraphs of this Paragraph 1 shall have the meanings set forth in such subparagraph whenever used in this Lease with the first letter of each word capitalized.

a. “Additional Rent” shall mean Tenant’s Pro Rata Share of Operating Expenses and such other charges as are required to be paid by Tenant to Landlord.

b. “Base Rent” or “Basic Rental” shall have the meaning as set forth in Paragraph 4 hereof.

c. “Brokers” shall mean The Colorado Group, Inc. & Chrisman Commercial, LLC for Landlord and WWR Real Estate Services, LLC for Tenant.

d. “Building” shall mean that certain building and other improvements located at 5777 Central Avenue, Boulder, Colorado 80301, and the real property upon which such building and improvements is located.

e. “Commencement Date” shall mean the date the Lease commences pursuant to Paragraph 3.

f. “Common Areas” shall mean those portions of the Property, which are made available to tenants of the Building, their employees, agents and invitees, on a non-exclusive basis for general use in common, including landscaped areas, sidewalks, lobby, common hallways, restrooms and showers. Landlord shall have the right from time-to-time to change the location or character of and to make alterations or additions to the Common Areas, and to repair and reconstruct the Common Areas.

g. “Consumer Price Index” Intentionally Deleted.

h. The following exhibits, riders and/or addenda are attached to this Lease and expressly incorporated herein by this reference:

Exhibit A Depiction of the Permanent Premises & Space Plan

Exhibit B Rules and Regulations

i. "Landlord's Notice Address" shall mean c/o Chrisman Commercial, LLC, 864 W. South Boulder Road, Suite 200, Louisville, Colorado 80027, Attn: Steven Chrisman, or such other address as Landlord may from time-to-time designate.

j. "Lease Year" shall mean each twelve month period during the Primary Lease Term or extension thereof.

k. "Operating Expenses" shall mean all costs and expenses of every kind and nature paid or incurred by Landlord in the operation, management, repair, maintenance and administration of the Building as set forth in Paragraph 6 below.

l. "Parking Spaces" shall mean ten (10) unassigned and uncovered parking spaces in areas on the Property, which Landlord designates from time-to-time for parking by tenants in the Building.

m. "Premises" shall mean both the Temporary Premises and the Permanent Premises. "Temporary Premises" shall mean Suite 110 in the Building, which is comprised of approximately 2,477 rentable square feet and "Permanent Premises" shall mean Suite 102 in the Building, which is comprised of approximately 3,038 rentable square feet as depicted on Exhibit A attached hereto.

n. "Primary Lease Term." Subject to adjustment as set forth in Paragraph 3b below, the term of the Lease shall commence at 12:01 a.m. on the 1st day of October, 2016 and shall terminate at 12:00 midnight on the 30th day of September, 2021, unless modified pursuant to Paragraph 3b, a term of five (5) years.

o. "Prime Rate" shall mean the rate quoted from time-to-time in the Money Rates section of The Wall Street Journal that leading banks are charging to their most credit-worthy customers.

p. "Property" shall mean that certain real property on which the Building is situated, located in Boulder, Colorado more particularly described as Lot 3, Flatirons Industrial Park Filing No. 4 Replat, County of Boulder, State of Colorado.

q. "Rent" shall mean Base Rent together with all other monetary obligations (or other obligations which are capable of being reduced to a monetary sum) under this Lease.

r. "Rentable Area" shall mean 58,875 square feet which is all rentable space available for lease in the Building. If there is a significant change in the aggregate Rentable Area as a result of an addition to the Building, partial destruction thereof, modification to the design of the Building, or similar cause which causes a reduction or increase thereto on a permanent basis, Landlord shall make such adjustment in the computations as shall be necessary to provide for any such change. Tenant agrees that the Rentable Area may be recalculated in the event that the Building and/or the Premises is re-measured. Notwithstanding such re-measurement, Tenant's Pro Rata Share and Base Rent shall not be increased or decreased during the Primary Lease Term.

s. "Reserve Amount" shall mean a reserve for the replacement of heating, ventilating and air-conditioning unit(s), replacement of the roof, and parking lot in the amount of THIRTY THOUSAND AND NO/100's Dollars (\$30,000.00) for the Building. The Reserve Amount does not include the replacement of any make-up air unit(s) or any dedicated air-conditioning unit(s).

t. "Security Deposit" shall mean the sum of SIX THOUSAND FIVE HUNDRED NINETY AND 43/100's Dollars (\$6,590.43).

u. "Tenant's Notice Address" shall mean the Premises.

v. "Tenant's Permitted Use" shall mean "technical office" pursuant to the Boulder Revised Code.

w. "Tenant's Pro Rata Share" with respect to the Temporary Premises shall mean 4.4287% and with respect to the Permanent Premises shall mean 5.4317%. This percentage is calculated by dividing the Premises square footage by 95% of the Rentable Area. In the event Tenant at any time during the Primary Lease Term, or any extensions thereof, leases additional space in the Building, Tenant's Pro Rata Share shall be recomputed by dividing the total rentable square footage of the Premises then being leased by Tenant (including any additional space) by 95% of the Rentable Area and the resulting percentage shall become Tenant's Pro Rata Share.

2. PREMISES. In consideration of the payment of Rent and the keeping and performance of the covenants and agreements by Tenant, as hereinafter set forth, Landlord hereby leases and demises unto Tenant the Premises, together with a nonexclusive right, subject to the provisions hereof, to use all appurtenances thereto, including the Common Areas.

### 3. COMPLETION OF THE PERMANENT PREMISES AND POSSESSION.

a. Landlord, at its sole cost and expense, except as noted on the Space Plan, will finish the Permanent Premises in accordance with that specific space plan attached hereto as Exhibit A (the "Space Plan"). Other than as set forth on the Space Plan, Landlord shall have no obligations for the completion or remodeling of the Premises, and Tenant shall accept the Premises in their "as is" condition on the date the Primary Lease Term commences, Notwithstanding the foregoing, Landlord shall, at its sole cost and expense, repair any construction defects related to the Space Plan work so long as Tenant provides notice of such defects no later than twelve (12) months after the Commencement Date (the "Warranty Work"). Tenant shall be responsible for any additional costs associated with changes to the Space Plan requested by Tenant. At Landlord's option, Tenant shall have the right, to amortize such additional costs over the term of the Lease at 10% per annum, and paid by Tenant as additional Base Rent. If the Permanent Premises are not "Ready for Occupancy," as hereafter defined, on the date the Primary Lease Term is to begin, Tenant's obligation to pay the Base Rent, its Pro Rata Share of Operating Expenses, and other sums owing hereunder shall not commence until the Permanent Premises are Ready for Occupancy, provided, however, from the effective date hereof, other than the payment of Rent, this Lease, and all of the covenants, conditions, and agreements herein contained shall be in full force and effect. The postponement of Tenant's obligation to pay Rent and other sums herein provided to be paid by Tenant for such period prior to the delivery of the Permanent Premises to Tenant, Ready for

Occupancy, as hereinafter defined, shall be in full settlement of all claims which Tenant might otherwise have by reason of the Permanent Premises not being Ready for Occupancy on the date the Primary Lease Term is scheduled to begin. However, if Tenant takes possession of all or any part of the Permanent Premises prior to the date the Permanent Premises are Ready for Occupancy for the purpose of conducting its usual business therein, all terms and provisions of this Lease shall apply, including the obligations for the payment of all Rent, and other amounts owing hereunder. "Ready for Occupancy" as used herein shall mean the date upon which the last of the following occurs: (a) Landlord has substantially completed the Permanent Premises or any remodeling work therein to be performed by Landlord, to the extent agreed to in the Space Plan; (b) Landlord's architect (or other representative of Landlord) in charge of supervising the completion or remodeling of the Permanent Premises shall have certified that the work has been completed in substantial compliance with the Space Plan; and (c) the City of Boulder has completed its final inspection with respect to the work subject to the Space Plan. If the Permanent Premises is not Ready for Occupancy as of five (5) months after execution of this Lease (except for, and to the extent of, delays caused by unforeseen acts of God, war, riots, fire, hurricanes, tornados, machinery breakdowns, industry-wide labor disputes, material shortages, lockouts, failure by the City of Boulder to timely process permits or any other cause not within reasonable control of Landlord), Tenant at Tenant's sole discretion may elect to terminate the lease and have no further obligation, provided however, any changes to the Space Plan requested by Tenant shall extend the time for completion by the amount of time required to complete said changes. Upon reasonable prior coordination with Landlord (and any contractors in the Permanent Premises), Tenant will be allowed to install phone/data wiring, furniture, fixtures and equipment prior to the date the Permanent Premises are Ready for Occupancy, provided, however, installation of the phone/data wiring, furniture, fixtures and equipment shall not interfere with Landlord's timely completion of the Permanent Premises.

b. If the commencement of the Primary Lease Term is delayed pursuant to Paragraph 3a above, and such commencement occurs on a day other than the first day of the month, the Commencement Date of the Primary Lease Term shall be further delayed until the first day of the following month and Tenant shall pay proportionate Rent at the same monthly rate set forth herein (also in advance) for such partial month. In the event said Commencement Date is so delayed, the expiration of the term hereof shall be extended so that the Primary Lease Term will continue for the full period set forth in Paragraph 1 hereof. As soon as the Primary Lease Term commences, Landlord and Tenant shall execute an addendum to this Lease, if requested by either party, setting forth the exact date on which the Primary Lease Term commenced and the expiration date of the Primary Lease Term.

**4. RENT.** Tenant agrees to pay to Landlord as Base Rent, without prior notice or demand, the following amounts:

Schedule of Base Rent (Permanent Premises):

<u>Month(s)</u>	<u>Monthly Base Rent</u>	<u>Annual Base Rent</u>
October 2016-September 2017	\$4,430.42	\$53,165.04
October 2017-September 2018	\$4,585.48	\$55,025.76
October 2018-September 2019	\$4,745.97	\$56,951.64
October 2019-September 2020	\$4,912.08	\$58,944.96
October 2020-September 2021	\$5,084.00	\$61,008.00
<b>Total Base Rent (Permanent Premises):</b>		<b>\$285,095.40</b>

Base Rent for the Temporary Premises shall equal \$16.50 per rentable square foot, for a monthly Base Rent payment of \$3,405.88.

Tenant shall begin to pay the Base Rent on the date the Primary Lease Term commences and thereafter on the first day of each month during the term hereof. Except as provided herein, all Rents shall be paid in advance, without notice, set off, abatement, counterclaim, deduction or diminution, at The Colorado Group, 3434 47<sup>th</sup> Street, Suite 220, Boulder, Colorado 80301, Attn: Susan Chrisman, or at such place as Landlord, from time-to-time, designates in writing. Tenant shall pay its first installment of Base Rent to Landlord simultaneously with its execution of this Lease. In addition, Tenant shall pay to Landlord Tenant's Pro Rata Share of Operating Expenses as provided herein and such other charges as are required by the terms of this Lease to be paid by Tenant which shall be referred to herein as "Additional Rent." Landlord shall have the same rights as to the Additional Rent as it has in the payment of Base Rent. At no time shall Tenant's Rent obligation be less than the Base Rent amount set forth above.

**5. SECURITY DEPOSIT.** Simultaneously with its execution of this Lease, Tenant shall deposit with Landlord the Security Deposit set forth in Paragraph It above, which shall be held by Landlord as security for the faithful performance by Tenant of all the terms, covenants, and conditions of this Lease to be kept and performed by Tenant during the term hereof. If Tenant defaults with respect to any provision of this Lease, including, but not limited to the provisions relating to the payment of Rent, Landlord may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any Rent or for the payment of any amount which Landlord may spend or become obligated to spend by reason of Tenant's default, or to compensate Landlord for any other loss or damage which Landlord may suffer by reason of Tenant's default. If any portion of said Security Deposit is so used or applied, Tenant shall within five (5) days after written demand therefor, deposit cash with Landlord in an amount sufficient to restore the Security Deposit to its original amount and Tenant's failure to do so shall be an Event of Default under this Lease. Landlord shall not be required to keep the Security Deposit separate from its general funds, and Tenant shall not be entitled to interest on the Security Deposit. If Tenant shall fully and faithfully perform every provision of this Lease to be performed by it, the Security Deposit or any balance thereof shall be returned to Tenant (or at Landlord's option, to the last assignee of Tenant's interest hereunder) within sixty (60) days after the expiration of the Primary Lease Term or any extension period thereof.

**6. OPERATING EXPENSES.**

a. Operating Expenses means all reasonable and necessary costs and expenses of every kind and nature, other than those expressly excluded below, paid or incurred by Landlord in operating, managing, repairing, maintaining and administering the Building including, without limitation:

(1) The cost of all insurance required to be kept by Landlord pursuant to this Lease or by any lender with respect to the Property, and any other insurance customarily procured for other commercial buildings in the same geographical area as the Building or which Landlord may reasonably elect to obtain with respect to the operation or ownership of the Property and the part of any claim required to be paid under the deductible portion of any insurance policies carried by Landlord in connection with the Property.

(2) The cost of general repairs, maintenance and replacements, excluding capital expenditures, made from time-to-time by Landlord to the Property, including costs under mechanical or other maintenance contracts and repairs and replacements of equipment used in connection with such maintenance and repair work.

(3) The cost of pest control, security services, window cleaning, janitorial and snow and ice removal services.

(4) The cost of maintaining and repairing common areas, maintaining and repairing landscaping, and of maintaining and operating fire detection, fire prevention, lighting and communications systems.

(5) The cost of all utilities (including, without limitation, water, sewer, gas and electricity) used or consumed.

(6) Remuneration (including wages, usual expense accounts and fringe benefits, costs to Landlord of workmen's compensation and disability insurance and payroll taxes) and fees of persons and companies to the extent directly engaged in operating, repairing, maintaining, or administering the Property.

(7) The cost of professional property management fees (6% of Basic Rental for the Property) and costs incurred by Landlord or its agents in engaging accountants or other consultants to assist in making the computations required hereunder.

(8) The cost of capital improvements and structural repairs and replacements made in, on or to the Property that are [a] made in order to conform to changes subsequent to the Commencement Date in any applicable laws, ordinances, rules, regulations or orders of any governmental or quasi-governmental authority having jurisdiction over the Property; [b] designed primarily or intended to reduce Operating Expenses or the rate of increase in Operating Expense; or [c] incurred for redecoration, renovation or replacement of floor coverings of Common Areas. The items set forth above in [a] through [c] above shall hereafter be collectively referred to as the "Capital Improvements." The cost of such Capital Improvements shall be charged by Landlord to Operating Expense in equal annual installments over the useful life of such Capital Improvement

(as reasonably determined by Landlord) together with interest on the balance of the unreimbursed cost at 4% above the Prime Rate.

(9) All real property taxes and assessments levied against the Building by any governmental or quasi-governmental authority. The foregoing shall include any taxes, assessments, surcharges, or service or other fees of a nature not presently in effect which shall hereafter be levied on the Building as a result of the use, ownership or operation of the Building or for any other reason, whether in lieu of or in addition to, any current real estate taxes and assessments; provided, however, any taxes which shall be levied on the rentals of the Building shall be determined as if the Building were Landlord's only property and, provided further, that in no event shall the term "taxes or assessments," as used herein, include any net federal or state income taxes levied or assessed on Landlord, unless such taxes are a specific substitute for real property taxes. Such term shall, however, include gross taxes on rentals. Expenses incurred by Landlord for tax consultants and in contesting the amount or validity of any such taxes or assessments shall be included in such computations. The term "assessment" shall include so-called special assessments, license tax, business license fee, business license tax, commercial rental tax, levy, charge, penalty or tax, imposed by any authority having the direct power to tax, including any city, county, state or federal government, or any school, agricultural, lighting, water, drainage or other improvement or special district thereof, against the Premises, the Building, or the Property or any legal or equitable interest of Landlord therein. For the purposes of this Lease, any special assessments shall be deemed payable in such number of installments as is permitted by law, whether or not actually so paid. Tenant shall not be responsible to pay any fines, late charges or penalties assessed against Landlord as a result of Landlord's failure to timely pay such taxes and assessments.

(10) Other costs and expenses, including supplies, not otherwise expressly excluded hereunder attributable to the operation, management, repair, maintenance and administration of the Property.

(11) The Reserve Amount.

b. Operating Expenses shall not, however, include the following:

(1) Any charge for depreciation of the Building and any principal, interest or other finance charge.

(2) The cost of any work, including painting, decorating and work in the nature of tenant finish, which Landlord performs for any tenant in the Building.

(3) The cost of repairs, replacements or other work occasioned by insured casualty or defects in construction or equipment to the extent such cost is reimbursed to Landlord (or not charged to Landlord) by reason of collected insurance proceeds (using Landlord's good faith efforts to collect such proceeds) or any contractors', manufacturers' or suppliers' warranties.

(4) Expenditures required to be capitalized for federal income tax purposes (except as expressly authorized above).

(5) Leasing commissions, advertising expenses and other costs incurred in leasing space in the Building except as otherwise expressly provided in this Lease.

(6) The cost of repairing or rebuilding necessitated by condemnation.

(7) The cost of any damage to the Property or any settlement, payment or judgment incurred by Landlord, resulting from Landlord's tortious act, neglect or breach of this Lease that is not covered by insurance proceeds.

(8) Costs (including, without limitation, attorneys fees) incurred by Landlord in attempting to collect Rent or evict tenants from the Building.

(9) Costs, including, without limitation, any penalties, fines and legal expenses incurred by Landlord or any other tenant in the Building as a result of a violation of any federal, state or local law, code or regulation.

c. Costs for repairs and maintenance of HVAC equipment for the Premises shall be charged to Tenant by Landlord as costs are incurred by Landlord and shall be paid by Tenant concurrently with Tenant's payment of Rent after Landlord receives an invoice for such repairs and maintenance. Repairs and maintenance shall include, but not limited to, the replacement of compressors and motors. Landlord shall use reasonable efforts to allocate such HVAC maintenance charges equitably among the tenants whose Premises are served by such equipment.

d. On the date the Primary Lease Term commences and continuing each month thereafter during the Primary Lease Term (and any extension thereof) Tenant shall pay to Landlord, at the same time as the Base Rent is paid, an amount equal to one-twelfth (1/12) of Landlord's estimate of Tenant's Pro Rata Share of Operating Expenses for the particular calendar year, with a final adjustment to be made between the parties at a later date for said calendar year in accordance with the procedures set forth herein.

(1) As soon as practicable following the end of each calendar year during the Primary Lease Term, or any extension thereof, Landlord shall submit to Tenant a statement prepared by a representative of Landlord setting forth the exact amount of Tenant's Pro Rata Share of the Operating Expenses for the calendar year just completed. Beginning with each subsequent calendar year, it shall also set forth the estimated amount of Tenant's Pro Rata Share of Operating Expenses for the new calendar year. In no event will the Rent to be paid by Tenant hereunder ever be less than the Base Rent set forth in Paragraph 1 above.

(2) To the extent that Tenant's Pro Rata Share of Operating Expenses for the period covered by such statement is different from the estimated amount upon which Tenant paid during the calendar year just completed, Tenant shall pay to Landlord the difference within twenty (20) days following receipt by Tenant of such statement from Landlord or receive a credit on the next months' rental owing hereunder, as the case may be. Upon request, Landlord shall make available to Tenant for its review or audit, Landlord's records of estimated or actual Operating Expenses. Until Tenant receives such statement, Tenant's monthly Rent for the new calendar year shall continue to be paid at the rate paid for the calendar year just completed, but Tenant shall

commence payment to Landlord of the monthly installments of Rent on the basis of said statement beginning on the first day of the month following the month in which Tenant receives such statement. Moreover, Tenant shall pay to Landlord or deduct from the Rent, as the case may be, on the date required for the first payment of Rent, as adjusted, the difference, if any, between the monthly installments of Rent so adjusted for the new calendar year and the monthly installments of Rent actually paid during the new calendar year.

(3) If, during any particular calendar year, there is a change in the information on which Landlord based the estimate upon which Tenant is then making its estimated rental payments so that such estimate furnished to Tenant is no longer accurate, Landlord shall be permitted to revise such estimate by notifying Tenant and there shall be such adjustments made in the monthly rental on the first day of the month following the serving of such statement on Tenant as shall be necessary by either increasing or decreasing, as the case may be, the amount of monthly Rent then being paid by Tenant for the balance of the calendar year as well as an appropriate adjustment in cash based upon the amount theretofore paid by Tenant during such particular calendar year pursuant to the prior estimate (but in no event shall any such decrease result in a reduction of the Base Rent).

e. Landlord's and Tenant's responsibilities with respect to the Operating Expense adjustment described herein shall survive the expiration or early termination of this Lease, and Landlord shall have the right to retain the Security Deposit, or so much thereof as it deems necessary, to secure such payment attributable to the year in which this Lease terminates.

f. If Tenant shall dispute the amount of an adjustment submitted by Landlord or the proposed estimated increase or decrease on the basis of which Tenant's Rent is to be adjusted as provided in Paragraphs 6d(2) or 6d(3) above, Tenant shall give Landlord written notice of such dispute within thirty (30) days after Landlord advises Tenant of such adjustment or proposed increase or decrease. If Tenant does not give Landlord such notice within such time, then Tenant shall be deemed to have waived its right to dispute the amounts so determined. If Tenant timely objects, Tenant shall have the right to engage its own certified public accountants ("Tenant's Accountants") for the purpose of verifying the accuracy of the statement complained of or the reasonableness of the estimated increase or decrease. If Tenant's Accountants determine that an error has been made, Landlord and Tenant's Accountants shall use reasonable efforts to agree upon the matter, failing which the parties shall settle the dispute by arbitration or in such other manner as they agree. Notwithstanding the pendency of any dispute over any particular statement, Tenant shall continue to pay Landlord the amount of the adjusted monthly installments of Rent determined by Landlord until the adjustment has been determined to be incorrect as aforesaid. A delay by Landlord in submitting any statement contemplated herein for any calendar year shall not affect the provisions of this Paragraph 6 or constitute a waiver of Landlord's rights as set forth herein for said calendar year or any subsequent calendar years during the Primary Lease Term and any extensions thereof.

g. Notwithstanding anything contained herein to the contrary, if any lease entered into by Landlord with any tenant in the Building provides for a separate basis of computation for any Operating Expenses with respect to its premises, then, to the extent that Landlord determines that an adjustment should be made in making the computations herein provided for, Landlord shall

be permitted to modify the computation of Operating Expenses and Rentable Area for a particular calendar year, in order to eliminate or otherwise modify any such expenses which are paid for in whole or in part by such tenant. Furthermore, in making any computations contemplated hereby, Landlord shall also be permitted to make such adjustments and modifications to the provisions of this Paragraph 6 as shall be reasonably necessary to achieve a fair and equitable allocation of the costs to the Tenant based upon Tenant's usage of such services and the intention of the parties within this Paragraph 6.

h. As of the date of this Lease, Landlord estimates that Operating Expenses shall equal approximately \$8.53 per rentable square foot of the Premises on an annual basis, resulting in a monthly obligation of \$1,761.15 for the Temporary Premises and \$2,160.01 for the Permanent Premises. A cost breakdown of the 2016 estimated Operating Expenses is as follows:

Taxes	\$168,000.00
Common Area Janitorial	\$15,000.00
Security & Fire Monitoring	\$8,400.00
Water & Sewer'	\$14,000.00
Management Fee	\$36,000.00
Snow Removal	\$27,000.00
Gas & Electric	\$84,000.00
Insurance	\$10,000.00
Trash & Recycling	\$6,800.00
Repairs & Maintenance	\$58,000.00
Reserve for Replacements	\$30,000.00
Landscaping	\$20,000.00
<b>Total</b>	<b>\$477,200.00</b>

7. **USE.** Tenant shall use the Premises 24 hours a day, 7 days a week, 365 days a year for Tenant's Permitted Use and shall not use or permit the Premises to be used for any other purpose without the prior written consent of Landlord. Tenant shall not do or permit anything to be done in or about the Premises nor bring or keep anything therein which will in any way increase the existing rate or affect any fire or other insurance upon the Building or any of its contents, or cause cancellation of any insurance policy covering said Building or any part thereof or any of its contents. Tenant shall not do or permit anything to be done in or about the Premises which will, in any way, obstruct or interfere with the rights of other tenants or occupants of the Building or injure or annoy them or use or allow the Premises to be used for any improper, immoral, unlawful or objectionable purpose, nor shall Tenant cause, maintain or permit any nuisance in, on or about the Premises. Tenant shall not commit or suffer to be committed any waste in or upon the Premises. Tenant shall comply with the Rules and Regulations for the Premises, as further described in Paragraph 18.

8. **COMPLIANCE WITH LAW.** Tenant shall not use the Premises or permit anything to be done in or about the Premises which will, in any way, conflict with any law, statute, ordinance or governmental rule or regulation now in force or which may hereafter be enacted or promulgated. Tenant shall, at its sole cost and expense, promptly comply with all laws, statutes, ordinances and

governmental rules, regulations or requirements now in force or which may hereafter be in force, and with the requirements of any board of fire insurance underwriters or other similar bodies now or hereafter constituted, relating to, or affecting the condition, use or occupancy of the Premises. The judgment against Tenant, whether Landlord be a party thereto or not, that Tenant has violated any law, statute, ordinance or governmental rule, regulation or requirement, shall be conclusive of that fact as between Landlord and Tenant. Landlord shall be responsible for compliance with any law, statute, ordinance or governmental rule or regulation now in force or which may hereafter be enacted or promulgated regarding the Property and the improvements located thereon to the extent that the same are not dependent upon the specific use of the Premises.

**9. ALTERATIONS AND ADDITIONS .** Tenant shall not make or suffer to be made any alterations, additions or improvements (collectively, "Alterations") to or of the Premises or any part thereof without the reasonable prior written consent of Landlord. Any Alterations to or of said Premises, including, but not limited to, wall covering, paneling and built-in cabinet work, but excepting movable furniture and trade fixtures, shall, on the expiration of the term, become a part of the realty and belong to Landlord and shall be surrendered with the Premises. In the event Landlord consents to the making of any Alterations to the Premises by Tenant, the same shall be made by Tenant at its sole cost and expense, and any contractor or person selected by Tenant to make the same, must first be reasonably approved of in writing by Landlord. Upon the expiration or earlier termination of the term hereof, Tenant shall, upon the written demand by Landlord, at Tenant's sole cost and expense, forthwith and with all due diligence, remove any Alterations which have been designated by Landlord to be removed, and repair any damage to the Premises caused by such removal.

**10. REPAIRS.**

a. Subject to Landlord's obligations pursuant to Section 10(b) below, Tenant shall, at its sole cost and expense, keep the Premises and every part thereof in good condition and repair, damage thereto from causes beyond the reasonable control of Tenant and ordinary wear and tear excepted. Tenant shall, upon the expiration or sooner termination of this Lease hereof, surrender the Premises to Landlord in good condition, ordinary wear and tear and damage from causes beyond the reasonable control of Tenant excepted. Except as specifically provided in Section 10(b) below or in an addendum, if any, to this Lease, Landlord shall have no obligation whatsoever to alter, remodel, improve, repair, decorate or paint the Premises or any part thereof, and the parties hereto affirm that Landlord has made no representations to Tenant respecting the condition of the Premises or the Building except as specifically herein set forth.

b. Landlord shall repair and maintain the common areas, exterior of the Building, structural portions of the Building, including the roof, basic plumbing, air conditioning, heating, and electrical and sprinkler systems installed or furnished by Landlord, unless such maintenance and repairs are caused in part or in whole by the act, neglect, fault or omission of any duty by Tenant, its agents, servants, employees or invitees, in which case Tenant shall pay to Landlord the reasonable cost of such maintenance and repairs. The cost of all such repairs (except repairs of structural defects) shall be included in Operating Expenses, except as otherwise provided herein. Landlord shall not be liable for any failure to make any such repairs or to perform any maintenance

unless such failure shall persist for an unreasonable time after written notice of the need of such repairs or maintenance is given to Landlord by Tenant. Except as specifically provided in Paragraph 21 below regarding reconstruction after a casualty, and so long as Tenant's access to, and use and enjoyment of, the Premises shall not be unreasonably interfered with, there shall be no abatement of Rent and no liability of Landlord by reason of any injury to or interference with Tenant's business arising from the making of any repairs, alterations or improvements in or to any portion of the Building or the Premises or in or to fixtures, appurtenances and equipment therein. Except in the event of an emergency involving imminent threat to life or substantial property damage, Tenant waives the right to make repairs at Landlord's expense under any law, statute or ordinance now or hereafter in effect.

c. Notwithstanding the foregoing, if Landlord fails to make any repairs or to perform any maintenance required of Landlord hereunder and within Landlord's reasonable control, and such failure shall persist for an unreasonable time (not less than thirty (30) days) after written notice of the need for such repairs or maintenance is given to Landlord and unless Landlord has commenced such repairs or maintenance during such period and is diligently pursuing the same, Tenant may (but shall not be required to) following a second notice (which notice shall have a heading in at least 12-point type, bold and all caps "FAILURE TO RESPOND SHALL RESULT IN TENANT EXERCISING SELF-HELP RIGHTS") and Landlord's failure to commence repairs within five (5) days after receipt of such second notice, perform such repairs or maintenance in accordance with the provisions of this Lease governing Tenant's repairs and Alterations and Tenant shall be entitled to offset all third party costs and expenses incurred by Tenant therefor against the subsequent monthly installment of Base Rent, provided Tenant delivers to Landlord appropriate invoices and back-up documentation regarding such costs and expenses.

**11. LIENS.** Tenant shall keep the Premises and the Property free from any liens arising out of any work performed, materials furnished or obligations incurred by Tenant. Landlord may require, at Landlord's sole option, that Tenant shall provide to Landlord, at Tenant's sole cost and expense, a lien and completion bond or other security reasonably acceptable to Landlord in an amount equal to one and one-half (1-1/2) times any and all estimated cost of improvements, additions, or alterations in the Premises, to insure Landlord against any liability for mechanics' and materialmen's liens and to insure completion of the work.

**12. ASSIGNMENT AND SUBLETTING.**

a. Except as expressly provided below, Tenant shall not either voluntarily or by operation of law, assign or transfer this Lease or any portion or interest therein, and shall not sublet the said Premises or any part thereof, or any right or privilege appurtenant thereto, or suffer any other person (the employees, agents, servants and invitees of Tenant excepted) to occupy or use the said Premises, or any portion thereof, without the prior written reasonable consent of Landlord. Tenant may not mortgage, pledge or encumber this Lease without Landlord's prior written consent which may be withheld in Landlord's sole and absolute discretion. The consent to one assignment, subletting, occupation or use by any other person shall not be deemed to be a consent to any subsequent assignment, subletting, occupation or use by another person. Any such assignment

or subletting without such consent shall be void, and shall, at the option of Landlord, constitute an Event of Default under this Lease.

b. Tenant may assign this Lease or sublease part or all of the Premises without Landlord's consent to: (i) any corporation, partnership or other business entity that controls, is controlled by, or is under common control with Tenant, (ii) any corporation, partnership or other business entity resulting from a merger or consolidation with Tenant, or (iii) to any entity which acquires substantially all of Tenant's assets or capital stock.

c. Fifty percent (50%) of any Rent or other consideration realized by Tenant under any such assignment, subletting or occupancy in excess of the Basic Rental and other sums payable hereunder, after amortization of the reasonable and documented costs incurred by Tenant for leasing commissions and leasehold improvements in connection with such assignment, subletting or occupancy over the term of such assignment, subletting or occupancy, shall be paid to Landlord by Tenant. Landlord may charge a reasonable fee not to exceed \$1,000 to pay for its expenses to review any proposed assignment, sublease, or encumbrance.

### 13. HOLD HARMLESS.

a. Tenant shall indemnify and hold harmless Landlord against and from any and all claims arising from Tenant's use of the Premises for the conduct of its business or from any activity, work, or other thing done or permitted by Tenant in or about the Property, and shall further indemnify and hold harmless Landlord against and from any and all claims arising from any breach or default in the performance of any obligation on Tenant's part to be performed under the terms of this Lease, or arising from any act or negligence of Tenant, or any officer, agent, employee, guest, or invitee of Tenant, and from all and against all costs, reasonable attorneys' fees, expenses and liabilities incurred in or about any such claim or any action or proceeding brought thereon, and, in any case, action or proceeding be brought against Landlord by reason of any such claim, Tenant, upon notice from Landlord shall defend the same at Tenant's expense. Tenant, as a material part of the consideration to Landlord, hereby assumes all risk of damage to property or injury to persons, in, upon or about the Premises, from any cause other than Landlord's gross negligence or willful and wanton acts. Landlord or its agents shall not be liable for any damage to property entrusted to employees of the Building, nor for loss or damage to any property by theft or otherwise, nor for any injury to or damage to persons or property resulting from fire, explosion, falling plaster, steam, gas, electricity, water or rain which may leak from any part of the Building or from the pipes, appliances or plumbing therein or from the roof, street or subsurface or from any other place resulting from dampness or any other cause whatsoever, unless caused by or due to the gross negligence or willful and wanton acts of Landlord, its agents, servants or employees. So long as Tenant's access to, and use and enjoyment of, the Premises shall not be unreasonably interfered with, Landlord or its agents shall not be liable for interference with the light or other incorporeal hereditament, loss of business by Tenant, nor shall Landlord be liable for any latent defects in the Premises or in the Building, except for the Warranty Work. Tenant shall give prompt notice to Landlord in case of fire or accidents in the Premises or in the Building or of defects therein.

b. Landlord shall indemnify and hold harmless Tenant against and from any and all claims arising from Landlord's activity, work, or other thing done, permitted or suffered by

Landlord in or about the Property, and shall further indemnify and hold harmless Tenant against and from any and all claims arising from any breach or default in the performance of any obligation on Landlord's part to be performed under the terms of this Lease, or arising from the negligence or willful or wanton acts of Landlord, or any officer, agent, or employee of Landlord, and from all and against all costs, reasonable attorneys' fees, expenses and liabilities incurred in or about any such claim or any action or proceeding brought thereon, and, in any case, action or proceeding be brought against Tenant by reason of any such claim, Landlord, upon notice from Tenant shall defend the same at Landlord's expense.

**14. SUBROGATION.** Landlord and Tenant hereby mutually waive their

respective rights of recovery against each other for any loss, damage or claim under any fire, extended coverage and other property insurance policies actually maintained by such party or required to be maintained by such party under the terms of this Lease. Each party shall obtain any special endorsements, if required by their insurer to evidence compliance with the aforementioned waiver.

**15. INSURANCE.**

a. Tenant shall, at Tenant's expense, obtain and keep in force during the term of this Lease a policy of comprehensive general liability insurance with limits not less than \$2,000,000, for each occurrence, with a \$4,000,000 general aggregate, insuring Landlord and Tenant against any liability arising out of the ownership, use, occupancy or maintenance of the Premises and all areas appurtenant thereto, as their interests may appear. The limit of said insurance shall not, however, limit the liability of Tenant hereunder. Tenant may carry said insurance under a blanket policy, providing, however, said insurance by Tenant shall add the Landlord as an additional insured under the Comprehensive General Liability. If Tenant shall fail to procure and maintain said insurance, Landlord may, but shall not be required to, procure and maintain same, but at the expense of Tenant. Tenant shall deliver to Landlord prior to occupancy of the Premises certificates evidencing the existence and amounts of such insurance. No policy shall be cancelable or subject to reduction of coverage except after thirty (30) days' prior written notice to Landlord.

b. Landlord shall obtain and maintain, on a full replacement cost basis, "Special Form" property insurance covering the improvements on the Property, including all of the Building (including the Premises, but excluding Tenant's personal property, furniture, fixtures and equipment), as well as such loss of rents, business interruption, liability or any other insurance, as it reasonably deems appropriate, with such companies and on such terms and conditions as Landlord reasonably deems acceptable. The cost of such insurance shall be an Operating Expense.

**16. SERVICES AND UTILITIES.** Landlord agrees to furnish to the

Premises during reasonable hours of generally recognized business days, electricity for normal lighting and fractional horsepower office machines and heat and air conditioning to keep the Premises in a condition consistent with other similar buildings in the Boulder area. If Tenant wishes to have air conditioning and heat to the Premises between the hours of 6:00 pm and 6:30 am Monday through Friday and the 48 hours of Saturday and Sunday, Tenant agrees to pay for

the cost of the system as estimated by Control Service Center. Landlord shall also maintain and keep lighted the common stairs, common entries and toilet rooms in the Building of which the Premises are a part. Landlord shall not be liable for, and Tenant shall not be entitled to, any reduction of rental by reason of Landlord's failure to furnish any of the foregoing when such failure is caused by accident, breakage, repairs, strikes, lockouts or other labor disturbances or labor disputes of any character, or by any other cause, similar or dissimilar, beyond the reasonable control of Landlord. Landlord shall not be liable under any circumstances for a loss or injury to property, however occurring, through or in connection with or incidental to failure to furnish any of the foregoing, except as to Landlord's gross negligence or willful and wanton acts. Wherever heat generating machines or equipment are used in the Premises which affect the temperature otherwise maintained by the air conditioning system, Landlord reserves the right to install supplementary air conditioning equipment in the Premises and the cost thereof, including the cost of installation, and the cost of operation and maintenance thereof shall be paid by Tenant to Landlord within ten (10) days after demand by Landlord.

Tenant will not, without written consent of Landlord, use any apparatus or device in the Premises, including, but without limitation thereto, electronic data processing machines, punch card machines, and machines using in excess of 120 volts, which will in any way increase the amount of electricity usually furnished or supplied for the use of the Premises as general office space; nor connect with electric current except through existing electrical outlets in the Premises, any apparatus or device, for the purpose of using electric current. If Tenant shall require water or electric current in excess of that usually furnished or supplied for the use of the Premises as general office space, Tenant shall first procure the reasonable prior written consent of Landlord. Landlord may cause a water meter or electrical current meter to be installed in the Premises, so as to measure the amount of water and electric current consumed for any such use. The cost of any such meters and of installation, maintenance and repair thereof shall be paid for by Tenant and Tenant agrees to pay to Landlord promptly upon demand therefor by Landlord for all such water and electric current consumed as shown by said meters at the rates charged for such services by the local public utility furnishing the same, plus an additional expense as reasonably determined by Landlord incurred in keeping account of the water and electric current so consumed. [If a separate meter is not installed, such excess cost for such water and electric current will be established by an estimate made by a utility company or electrical engineer.

**17. PERSONAL PROPERTY TAXES.** Tenant shall pay, or cause to be paid, before delinquency, any and all taxes levied or assessed and which become payable during the term hereof upon all Tenant's leasehold improvements, equipment, furniture, fixtures and personal property located in the Premises; except that which has been paid for by Landlord, and is the standard of the Building. In the event any or all of Tenant's equipment, furniture, fixtures and personal property shall be assessed and taxed with the Building, Tenant shall pay to Landlord its share of such taxes within thirty (30) days after receipt by Tenant from Landlord of a statement in writing setting forth the amount of such taxes applicable to Tenant's property which statement shall include a copy of the tax bill.

**18. RULES AND REGULATIONS.** The current Rules and Regulations for the Premises are attached hereto as Exhibit B and are incorporated herein by this reference. Tenant shall

faithfully observe and comply with the Rules and Regulations that Landlord shall, from time-to-time, promulgate. Landlord reserves the right, from time-to-time, to make all reasonable additions and modifications to said Rules and Regulations, which shall be binding upon Tenant upon delivery of a copy of them to Tenant. Landlord shall not be responsible to Tenant for the nonperformance of any said Rules and Regulations by any other tenants or occupants. Landlord will use commercially reasonable efforts to apply and enforce the Rules and Regulations in a nondiscriminatory manner. In the event of a conflict between the terms of the Rules and Regulations and the terms of the Lease, the terms of this Lease shall control.

**19. HOLDING OVER.** Tenant shall have no right to hold over after the term without the express prior written consent of Landlord which may be withheld in Landlord's sole and absolute discretion. If Tenant remains in possession of the Premises or any part after the expiration of the term hereof, without the express written consent of Landlord, such occupancy shall be on all terms of this Lease except on a month-to-month basis and at a rental in the amount of one and one-half times the last monthly Base Rent.

**20. ENTRY BY LANDLORD .** Landlord reserves, and shall during normal business hours upon reasonable notice to Tenant (which may be verbal to Tenant's on-site manager) the right to enter the Premises, inspect the same, and to supply any service to be provided by Landlord to Tenant hereunder, to submit said Premises to prospective purchasers or during the last six months of the term to prospective tenants, to post notices of non-responsibility, and to alter, improve or repair the Premises and any portion of the Building of which the Premises are a part that Landlord may deem necessary or desirable, without abatement of Rent (so long as Tenant's access to, and use and enjoyment of, the Premises is not unreasonably interfered with) and may for that purpose in connection with any work to be performed by Landlord under this Lease. Landlord shall not be required to give any notice to Tenant in the event of any emergency, for recurring services (e.g., janitorial) or if Tenant has vacated the Premises. Landlord may erect scaffolding and other necessary structures where reasonably required by the character of the work to be performed, always providing that the business of Tenant shall not be interfered with unreasonably. Tenant hereby waives any claim for damages or for any injury or inconvenience to or interference with Tenant's business, any loss of occupancy or quiet enjoyment of the Premises, and any other loss occasioned thereby unless caused by gross negligence or willful and wanton acts of Landlord. For each of the aforesaid purposes, Landlord shall, at all times, have and retain a key with which to unlock all of the doors in, upon and about the Premises, and Landlord shall have the right to use any and all means which Landlord may deem proper to open said doors in an emergency, in order to obtain entry to the Premises without liability to Tenant except for the gross negligence or willful and wanton conduct of Landlord. Any entry to the Premises obtained by Landlord by any of said means, or otherwise shall not, under any circumstances, be construed or deemed to be a forcible or unlawful entry into, or a detainer of, the Premises, or an eviction of Tenant from the Premises or any portion thereof. Tenant shall not change the locks to the Premises without Landlord's written consent.

**21. RECONSTRUCTION.** In the event the Premises, or the Building of which the Premises are a part, are damaged by fire or other perils covered by extended coverage insurance, Landlord agrees to forthwith repair the same to substantially the same condition as existed immediately prior to such damage; and this Lease shall remain in full force and effect, except that

Tenant shall be entitled to a proportionate reduction of the Rent while such repairs are being made, such proportionate reduction to be based upon the extent to which the damage and the making of such repairs shall materially and adversely interfere with the business carried on by Tenant in the Premises. If the damage is due to the fault or neglect of Tenant or its employees, there shall be no abatement of Rent.

In the event the Premises or the Building of which the Premises are a part are damaged as a result of any cause other than the perils covered by fire and extended coverage insurance, then Landlord shall forthwith repair the same within one hundred and fifty (150) days of casualty, provided the extent of the destruction be less than ten percent (10%) of the then full replacement cost of the Premises or the Building of which the Premises are a part. In the event the destruction of the Premises or the Building is to an extent greater than ten percent (10%) of the full replacement cost, then Landlord shall have the option: (1) to repair or restore such damage, this Lease continuing in full force and effect, but the Rent to be proportionately reduced as hereinabove in this Paragraph provided; or (2) give notice to Tenant at any time within thirty (30) days after such damage terminating this Lease as of the date specified in such notice, which date shall be no less than thirty (30) and no more than sixty (60) days after the giving of such notice. In the event of giving such notice, this Lease shall expire and all interest of Tenant in the Premises shall terminate on the date so specified in such notice and the Rent, reduced by a proportionate amount, based upon the extent, if any, to which such damage materially interfered with the business carried on by Tenant in the Premises, shall be paid up to date of said such termination. Notwithstanding anything to the contrary contained in this paragraph, Landlord shall not have any obligation whatsoever to repair, reconstruct or restore the Premises when the damage resulting from any casualty covered under this paragraph occurs during the last twelve (12) months of the term of this Lease or any extension thereof and in the event of such casualty during the last twelve (12) months of the term of this Lease, and Landlord shall have the right to terminate this Lease by giving written notice to Tenant within thirty (30) days of such casualty.

Landlord shall not be required to repair any injury or damage by fire or other cause, or to make any repairs or replacements of any panels, decoration, office fixtures, railings, floor coverings, partitions, or any other property installed in the Premises by Tenant unless covered by Landlord's insurance as part of the Building.

Except as otherwise expressly authorized hereunder, Tenant shall not be entitled to any compensation or damages from Landlord for loss of the use of the whole or any part of the Premises or Tenant's personal property.

**22. DEFAULT.** The occurrence of any one or more of the following events shall constitute an Event of Default:

- a. The vacating or abandonment of the Premises by Tenant, without payment of Rent.
- b. The failure by Tenant to make any payment of Rent or any other payment required to be made by Tenant hereunder, within five (5) days after receipt of written notice that the same is past due.

c. The failure by Tenant to observe or perform any of the covenants, conditions or provisions of this Lease to be observed or performed by Tenant, other than described in Paragraph 22b above, where such failure shall continue for a period of thirty (30) days after written notice thereof by Landlord to Tenant; provided, however, that if the nature of Tenant's default is such that more than thirty (30) days are reasonably required for its cure, then Tenant shall not be deemed to be in default if Tenant commences such cure within said thirty (30) day period and thereafter diligently prosecutes such cure to completion.

d. The making by Tenant of any general assignment or general arrangement for the benefit of creditors; or the filing by or against Tenant of a petition to have Tenant adjudged a bankrupt, or a petition of reorganization or arrangement under any law relating to bankruptcy (unless, in the case of a petition filed against Tenant, the same is dismissed within sixty [60] days); or the appointment of a trustee or a receiver to take possession of substantially all of Tenant's assets located at the Premises or of Tenant's interest in this Lease, where possession is not restored to Tenant within thirty (30) days; or the attachment, execution or other judicial seizure of substantially all of Tenant's assets located at the Premises or of Tenant's interest in this Lease, where such seizure is not discharged in thirty (30) days.

If Landlord is in default in the performance of any obligation under this Lease on the part of Landlord to be performed and such default continues for a period of thirty (30) days after Tenant's written notice to Landlord specifying the nature of the default, then Tenant may exercise any right or remedy it may possess at law or equity, which is not otherwise waived in this Lease. If the default set forth in Tenant's notice cannot reasonably be cured within thirty (30) days, then Landlord shall not be deemed to be in default if (i) Landlord notifies Tenant in writing that it will cure the default, (ii) commences to cure the default within such thirty (30)-day period, and (iii) proceeds diligently and in good faith thereafter to cure such default and does cure such default within a reasonable time.

**23. REMEDIES IN DEFAULT.** In the event of any Event of Default or other breach by Tenant, Landlord may at any time thereafter, with or without notice or demand, and without limiting Landlord in the exercise of a right or remedy which Landlord may have by reason of such Event of Default or breach:

a. Reenter and take possession of the Premises or any part thereof and repossess the same as of Landlord's former estate and expel Tenant and those claiming through or under Tenant and remove the effects of both or either, without being deemed guilty of any manner of trespass and without prejudice to any remedies for arrears of Rent or preceding breach of covenants or conditions. Should Landlord elect to reenter, as provided in this paragraph, or should Landlord take possession pursuant to legal proceedings or pursuant to any notice provided for by law, Landlord may, from time-to-time, without terminating this Lease, relet the Premises or any part thereof, either alone or in conjunction with other portions of the Building of which the Premises are a part, in Landlord's or Tenant's name but for the account of Tenant, for such term or terms (which may be greater or less than the period which would otherwise have constituted the balance of the term of this Lease) and on such conditions and upon such other terms (which may include concessions of free Rent and alteration and repair of the Premises) as Landlord, in its absolute discretion, may determine and Landlord may collect and receive the Rents therefor. Landlord shall in no way be

responsible or liable for any failure to relet the Premises, or any part thereof, or for any failure to collect any Rent due upon such reletting, but Landlord shall use commercially reasonable efforts to mitigate its damages. No such reentry or taking possession of the Premises by Landlord shall be construed as an election on Landlord's part to terminate this Lease unless a written notice of such intention be given to Tenant. No notice from Landlord hereunder or under a forcible entry and detainer statute or similar law shall constitute an election by Landlord to terminate this Lease unless such notice specifically so states. Landlord reserves the right following any such reentry and/or reletting to exercise its right to terminate this Lease by giving Tenant such written notice, in which event the Lease will terminate as specified in said notice.

b. If Landlord elects to take possession of the Premises as provided in Paragraph 23a above without terminating the Lease, Tenant shall pay to Landlord (i) the Rent and other sums as herein provided, which would be payable hereunder if such repossession had not occurred, less (ii) the net proceeds, if any, of any reletting of the Premises after deducting all of Landlord's expenses incurred in connection with such reletting, including, but without limitation, all repossession costs, brokerage commissions, legal expenses, attorneys' fees, expenses of employees, alteration, remodeling, and repair costs and expenses of preparation for such reletting. Unpaid installments of rent or other sums shall bear interest from the date due at the rate of twenty percent (20%) per annum. If, in connection with any reletting, the new lease term extends beyond the existing term or the premises covered thereby include other premises not part of the Premises, a fair apportionment of the Rent received from such reletting and the expenses incurred in connection therewith, as provided aforesaid, will be made in determining the net proceeds received from such reletting. In addition, in determining the net proceeds from such reletting, any Rent concessions will be apportioned over the term of the new lease unless Tenant agrees otherwise. Tenant shall pay such amounts to Landlord monthly on the days on which the Rent and all other amounts owing hereunder would have been payable if possession had not been retaken and Landlord shall be entitled to receive the same from Tenant on each such day;

c. Give Tenant written notice of intention to terminate this Lease on the date of such given notice or on any later date specified therein and, on the date specified in such notice, Tenant's right to possession of the Premises shall cease and the Lease shall thereupon be terminated, except as to Tenant's liability hereunder as hereinafter provided, as if the expiration of the term fixed in such notice were the end of the term herein originally demised. In the event this Lease is terminated pursuant to the provisions of this Paragraph, Tenant shall remain liable to Landlord for damages in an amount equal to the Rent and other sums which would have been owing by Tenant hereunder for the balance of the term had this Lease not been terminated less the net proceeds, if any, of any reletting of the Premises by Landlord subsequent to such termination, after deducting all Landlord's expenses in connection with such reletting, including, but without limitation, the expenses enumerated above. Landlord shall be entitled to collect such damages from Tenant monthly on the days on which the Rent and other amounts would have been payable hereunder if this Lease had not been terminated and Landlord shall be entitled to receive the same from Tenant on each such day. Alternatively, at the option of Landlord, in the event this Lease is terminated, Landlord shall be entitled to recover forthwith against Tenant as damages for loss of the bargain and not as a penalty an amount equal to the worth at the time of termination of the excess, if any, of the amount of Rent reserved in this Lease for the balance of the term hereof over the then Reasonable Rental

Value of the Premises for the same period plus all amounts incurred by Landlord in order to obtain possession of the Premises and relet the same, including attorneys' fees, reletting expenses, alterations and repair costs, brokerage commissions and all other like amounts. It is agreed that the "Reasonable Rental Value" shall be the amount of rental which Landlord can obtain as Rent for the remaining balance of the term. Landlord agrees to use commercially reasonable efforts to mitigate its damages; or

d. Pursue any other remedy now or hereafter available to Landlord under the laws or judicial decision of the State of Colorado.

**24. EMINENT DOMAIN.** If more than twenty-five percent (25%) of the Premises shall be taken or appropriated by any public or quasi-public authority under the power of eminent domain, either party hereto shall have the right, at its option, to terminate this Lease by giving written notice to the other party, and Landlord shall be entitled to any and all income, Rent, award, or any interest therein whatsoever which may be paid or made in connection with such public or quasi-public use or purpose, and Tenant shall have no claim against Landlord or the condemning authority for the value of any unexpired term of this Lease. If less than twenty-five percent (25%) of the premises is taken, or neither party elects to terminate as herein provided, the rental thereafter to be paid shall be proportionately reduced. If more than ten percent (10%) of the Building other than the Premises may be so taken or appropriated, Landlord shall have the right at its option to terminate this Lease by giving thirty (30) days written notice to Tenant and shall be entitled to the entire award as above provided. Tenant shall, however, have the right to pursue a separate claim directly against the condemning authority for any damage suffered as a result of such taking.

**25. ESTOPPEL STATEMENT.** Landlord and Tenant shall at any time and from time-to-time, upon not less than ten (10) business days' prior written notice from the other party, execute, acknowledge, and deliver to the other party a statement in writing, (a) certifying that this Lease is unmodified and in full force and effect (or, if modified, stating the nature of such modification and certifying that this Lease as so modified, is in full force and effect); (b) the date to which the rental and other charges are paid in advance, if any; (c) acknowledging that there are not, to Tenant's or Landlord's knowledge, as appropriate, any uncured defaults on the part of the other party hereunder, or specifying such defaults if any are claimed; and (d) such other items reasonably requested by the other party. Any such statement may be relied upon by any prospective purchaser or encumbrancer of all or any portion of the real property of which the Premises are a part. Tenant Estoppel Statement shall be in a commercially-reasonable form as Landlord's lender may reasonably require.

**26. PARKING.** Tenant shall have the right to use in common with other tenants or occupants of the Building the parking facilities of the Building, subject to the Rules and Regulations. Landlord shall have no liability for any damage to property in or about the parking areas and Tenant hereby waives all claims arising in connection therewith, and agrees to indemnify Landlord for any claims arising out of or in connection with Tenant's use of the Parking Spaces.

**27. AUTHORITY OF PARTIES .** Each individual executing this Lease on behalf of Tenant represents and warrants that he is duly authorized to execute and deliver this Lease on behalf of Tenant, in accordance with a duly adopted resolution or in accordance with the operating

agreement, partnership agreement or other governing entity documentation, and that this Lease is binding upon Tenant in accordance with its terms.

## 28. GENERAL PROVISIONS.

a. Waiver. The waiver by Landlord of any term, covenant, or condition herein contained shall not be deemed to be a waiver of such term, covenant or condition or any subsequent breach of the same or any other term, covenant or condition herein contained. The subsequent acceptance of Rent hereunder by Landlord shall not be deemed to be a waiver of any preceding breach by Tenant of any term, covenant or condition of this Lease, other than the failure of Tenant to pay the particular rental so accepted, regardless of Landlord's knowledge of such preceding breach at the time of the acceptance of such Rent.

b. Notices. All notices and demands which may or are to be required or permitted to be given by either party to the other hereunder shall be in writing, except the verbal notice by Landlord to Tenant as stated in Paragraph 20. All notices and demands by Landlord to Tenant shall be sent by a) United States Mail, postage prepaid, or b) nationally recognized overnight bonded courier, addressed to Tenant at the address set forth in Paragraph 1 u above, or to such other place as Tenant may, from time-to-time, designate in a notice to Landlord. All notices and demands by Tenant to Landlord shall be sent by a) United States Mail, postage prepaid, or b) nationally recognized overnight bonded courier, addressed to Landlord at the address set forth in Paragraph 1i above, or to such other person or place as Landlord may, from time-to-time, designate in a notice to Tenant. Notice shall be deemed effective on the third (3rd) business day after the date postmarked, if sent by United States Mail, and on the next business day if sent by nationally recognized overnight bonded courier.

c. Joint Obligation. If there is more than one entity or individual which comprises Tenant under this Lease, then the obligations hereunder imposed upon Tenant shall be joint and several.

d. Headings and Paragraph Titles. The headings and paragraph titles of this Lease are for reference purposes only and shall have no effect upon the construction or interpretation of any part hereof.

e. Time. Time is of the essence of this Lease and each and all of its provisions.

f. Successors and Assigns. The covenants and conditions herein contained, subject to the provisions as to assignment, apply to and bind the heirs, successors, executors, administrators and assigns of the parties hereto.

g. Recordation. Tenant shall not record this Lease or a short form memorandum hereof or any other document which makes reference to this Lease without the prior written consent of Landlord which may be withheld in Landlord's sole and absolute discretion. Any such recording without Landlord's consent shall be considered an Event of Default.

h. Quiet Possession. Upon Tenant paying the Rent reserved hereunder and observing and performing all of the covenants, conditions and provisions on Tenant's part to be observed and performed hereunder, Tenant shall have quiet possession of the Premises for the entire term hereof against all parties claiming by, through or under Landlord, subject to all the provisions of this Lease.

i. Late Charges. Tenant hereby acknowledges that late payment by Tenant to Landlord of Rent or other sums due hereunder will cause Landlord to incur costs not contemplated by this Lease, the exact amount of which will be extremely difficult to ascertain. Such costs include, but are not limited to, processing and accounting charges, and late charges which may be imposed upon Landlord by terms of any mortgage or trust deed covering the Premises. Accordingly, if any installment of Rent or of a sum due from Tenant shall not be received by Landlord or Landlord's designee within five (5) days after said amount is due, then Tenant shall pay to Landlord a one-time late charge equal to five percent (5%) of such overdue amount. The parties hereby agree that such late charges represent a fair and reasonable estimate of the cost that Landlord will incur by reason of the late payment by Tenant. Acceptance of such late charges by Landlord shall in no event constitute a waiver of Tenant's default with respect to such overdue amount, nor prevent Landlord from exercising any of the other rights and remedies granted hereunder.

j. Prior Agreements. This Lease contains all of the agreements of the parties hereto with respect to any matter covered or mentioned in this Lease, and no prior agreements or understanding pertaining to any such matters shall be effective for any purpose. No provision of this Lease may be amended or added to except by an agreement in writing signed by the parties hereto or their respective successors in interest. This Lease shall not be effective or binding on any party until fully executed by both parties hereto.

k. Attorneys' Fees. In the event of any action or proceeding brought by either party against the other under this Lease, the prevailing party shall be entitled to recover all costs and expenses, including the fees of its attorneys in such action or proceeding in such amount as the court may adjudge reasonable as attorneys' fees.

l. Sale of Premises by Landlord. In the event of any sale of the Building, and assignment of Tenant's Security Deposit to a purchaser, Landlord shall be and is hereby entirely freed and relieved of all liability under any and all of its covenants and obligations contained in or derived from this Lease arising out of any act, occurrence or omission occurring after the consummation of such sale; and the purchaser, at such sale or any subsequent sale of the Premises, shall be deemed, without any further agreement between the parties or their successors in interest or between the parties and any such purchaser, to have assumed and agreed to carry out any and all of the covenants and obligations of Landlord under this Lease.

m. Subordination, Non-Disturbance and Attornment. Within ten (10) days after request of Landlord, Tenant will, in writing, subordinate its rights hereunder to the lien of any first mortgage or first deed of trust to any bank, insurance company or other lending institution, now or hereafter in force against the land and Building of which the Premises are a part, and upon any buildings hereafter placed upon the land of which the Premises are a part, and to all advances made or hereafter to be made upon the security thereof

In the event any proceedings are brought for foreclosure, or in the event of the exercise of the power of sale under any mortgage or deed of trust made by Landlord covering the Premises, Tenant shall attorn to the purchaser upon any such foreclosure or sale and recognize such purchaser as Landlord under this Lease.

Tenant will agree to confirm its subordination and attornment pursuant to a commercially-reasonable subordination, non-disturbance and attornment reasonably requested by Landlord's lender.

n. Name. Tenant shall not use the name of the Building or of the development in which the Building is situated for any purpose other than as an address of the business to be conducted by Tenant in the Premises.

o. Separability. Any provision of this Lease which shall prove to be invalid, void or illegal shall in no way affect, impair or invalidate any other provision hereof and such other provision shall remain in full force and effect.

p. Cumulative Remedies. No remedy or election hereunder shall be deemed exclusive but shall, wherever possible, be cumulative with all other remedies at law or in equity.

q. Choice of Law. This Lease shall be governed by the laws of the State of Colorado.

r. Signs and Auctions. Tenant shall not place any sign upon the Premises or Building or conduct any auction thereon without Landlord's prior written consent which shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, Landlord agrees to provide to Tenant, at Landlord's sole cost and expense, Building standard signage on the monument sign for the Building and Building standard directory signage and Building standard suite entry signage during the term of this Lease if and where applicable. Any future modifications to said signage shall be at Tenant's sole cost and expense.

s. Landlord's Liability. The liabilities of the partners or members of Landlord pursuant to this Lease shall be limited to the assets of the partnership or limited liability company, and Tenant, its successors and assigns hereby waive all right to proceed against any of the partners, members, or the officers, shareholders, or directors of any corporate partner of Landlord. The term "Landlord," as used in this paragraph, shall mean only the owner or owners at the time in question of the fee title or an interest in a ground lease of the Property. Notwithstanding anything to the contrary contained herein, the extent of Landlord's liability under this Lease shall be limited to the Property (including, without limitation, Landlord's real property interest therein and interest in rental income therefrom), and Tenant shall not seek any personal liability against Landlord or any of Landlord's partners or members.

t. Waiver of Jury Trial. Landlord and Tenant waive trial by jury in any action, proceeding or counterclaim brought by either of the parties to this Lease against the other on any matters whatsoever arising out of or in any way connected with this Lease, the relationship of

Landlord and Tenant, Tenant's use of occupancy of the Premises, or any other claims (except claims for personal injury or property damage), and any emergency statutory or any other statutory remedy.

u. Lender/Mortgagees. This Lease, at Landlord's option, shall, subject to typical non-disturbance rights in favor of tenant, be subordinate to any mortgage or deed of trust (now or hereafter placed upon the land and the Building of which the Premises are a part, and upon any buildings hereafter placed upon the land of which the Premises are a part, and to all advances made or hereafter to be made upon the security hereof), including any amendment, modification or restatement of such documents. Tenant agrees that with respect to any of the foregoing documents, no documentation, other than this Lease, shall be required to evidence such subordination and non-disturbance. Notice to Landlord of any such alleged default shall be ineffective unless notice is simultaneously delivered to any holder of a mortgage and/or deed of trust affecting all or any portion of the land and the Building of which the Premises are a part ("Mortgagees"), as hereafter provided. Tenant agrees to give all Mortgagees, by certified mail, return receipt requested, a copy of any notice of default served upon Landlord, provided that prior to such notice Tenant has been notified, in writing (by way of notice of Assignment of Rents and Leases, or otherwise), of the address of such Mortgagees. Tenant further agrees that if Landlord shall have failed to cure such default within the time provided for in this Lease, then the Mortgagees shall have an additional thirty (30) days within which to cure such default or, if such default cannot be cured within that time, then such additional time as may be necessary, if, within such thirty (30) days, any Mortgagee has commenced and is diligently pursuing the remedies necessary to cure such default (including, but not limited to, commencement of foreclosure proceedings, if necessary to effect such cure), in which event this Lease shall not be terminated while such remedies are being so diligently pursued. In no event will Landlord, Tenant or any Mortgagee be responsible for any consequential damages incurred by Tenant as a result of any default, including, but not limited to, lost profits or interruption of business as a result of any alleged default by Landlord or Tenant hereunder.

v. Arbitration. Except for an action to gain possession of the Premises (and any corresponding claim for damages resulting from Tenant's alleged unlawful detainer) and except as provided below, any and all disputes arising under or related to this Lease which cannot be resolved through negotiations between the parties shall be submitted to binding arbitration. If the parties fail to reach a settlement of their dispute within fifteen (15) days after the earliest date upon which one of the parties notified the other(s) of its desire to attempt to resolve the dispute, then the dispute shall promptly be submitted to arbitration by a single arbiter through the Judicial Arbiter Group ("JAG"), any successor of the Judicial Arbiter Group, or any similar arbitration provider who can provide a former judge to conduct such arbitration if JAG is no longer in existence, or an arbiter appointed by the court. The arbiter shall be selected by JAG or the court on the basis, if possible, of his or her expertise in the subject matter(s) of the dispute. The decision of the arbiter shall be final, nonappealable and binding upon the parties, and it may be entered in any court of competent jurisdiction. The arbitration shall take place in Boulder, Colorado. The arbitrator shall be bound by the laws of the State of Colorado applicable to the issues involved in the arbitration and all Colorado rules relating to the admissibility of evidence, including, without limitation, all relevant privileges and the attorney work product doctrine. All such discovery shall be completed in accordance with the time limitations prescribed in the Colorado Rules of Civil Procedure, unless otherwise agreed by the parties or ordered by the arbitrator on the basis of strict necessity adequately demonstrated

by the party requesting an extension or reduction of time. The arbitrator shall have the power to grant equitable relief where applicable under Colorado law. The arbitrator shall issue a written opinion setting forth her or his decision and the reasons therefor within thirty (30) days after the arbitration proceeding is concluded. The obligation of the parties to submit any dispute arising under or related to this Agreement to arbitration as provided in this Paragraph shall survive the expiration or earlier termination of this Agreement. Notwithstanding the foregoing, either party may seek and obtain an injunction or other appropriate relief from a court to preserve or protect the status quo with respect to any matter pending conclusion of the arbitration proceeding, but no such application to a court shall in any way be permitted to stay or otherwise impede the progress of the arbitration proceeding.

w. Financial Statements. Tenant shall provide their most recent annual financial statements, including statements of income and expense and statements of net worth ("financial statements") within fifteen (15) business days following the written request of Landlord. Landlord may request said annual financial statements no more than twice during any twelve (12) month period. Said financial statements shall be verified as being true and correct and Landlord agrees to keep said financial statements confidential, but may use said annual financial statements for purposes of obtaining financing upon or in connection with the sale of the Property. At the time Landlord requests financial statements from Tenant, Landlord shall advise Tenant if the financial statements will be given to a third party and to whom the financial statements will be submitted and Landlord shall, if requested to do so by Tenant, use commercially reasonable efforts to obtain from such individual or entity a written agreement which shall provide that said financial statements will be and shall remain confidential. If Tenant has not previously submitted the required financial statements to Landlord, within fifteen (15) days after the execution of this Lease, Tenant shall submit to Landlord its most recent financial statements.

x. Consents and Approvals. Unless otherwise specifically provided herein, any consent or approval to be given under this Lease shall not be unreasonably withheld, conditioned or delayed by either party.

**29. BROKERS.** Tenant warrants that it has had no dealings with any real estate brokers or agents in connection with the negotiation of this Lease excepting only the Brokers listed in Paragraph 1 c, and it knows of no other real estate broker or agent who is entitled to a commission in connection with this Lease. Tenant hereby agrees to indemnify Landlord for any loss or damage, including defense costs, arising out of claims from brokers or other finders other than the Brokers referenced above.

**30. HAZARDOUS MATERIALS AND ENVIRONMENTAL CONSIDERATIONS.**

a. Tenant covenants and agrees that Tenant and its agents, employees, contractors and invitees shall comply with all Hazardous Materials Laws (as hereinafter defined). Without limiting the foregoing, Tenant covenants and agrees that it will not use, generate, store or dispose of, nor permit the use, generation, storage or disposal of Hazardous Materials (as hereinafter defined) on, under or about the Premises, nor will it transport or permit the transportation of Hazardous Materials to or from the Premises, except in strict and full compliance with any applicable Hazardous Materials Laws. Any Hazardous Materials located on the Premises shall be handled in

an appropriately controlled environment which shall include the use of such equipment (at Tenant's expense) as is necessary to meet or exceed standards imposed by any Hazardous Materials Laws and in such a way as not to interfere with any other tenant's use of its premises. Upon breach of any covenant contained herein, Tenant shall, at Tenant's sole expense, cure such breach by taking all action prescribed by any applicable Hazardous Materials Laws or by any governmental authority with jurisdiction over such matters.

b. Tenant shall inform Landlord at any time of (i) any Hazardous Materials it intends to use, generate, handle, store or dispose of, on or about or transport from, the Premises (other than regular office and cleaning supplies) and (ii) of Tenant's discovery of any event or condition which constitutes a violation of any applicable Hazardous Materials Laws. Tenant shall provide to Landlord copies of all communications to or from any governmental authority or any other party relating to Hazardous Materials affecting the Premises.

c. Tenant shall indemnify and hold Landlord harmless from any and all claims, judgments, damages, penalties, fines, costs, liabilities, expenses or losses (including without limitation, diminution on value of the Premises, damages for loss or restriction on use of all or part of the Premises, sums paid in settlement of claims, investigation of site conditions, or any cleanup, removal or restoration work required by any federal, state or local governmental agency, attorney's fees, consultant fees and expert fees) which arise as a result of or in connection with any breach of the foregoing covenants or any other violation contained herein shall also accrue to the benefit of the employees, agents, officers, directors and/or partners of Landlord.

d. Upon termination of the Lease and/or vacation of the Premises, Tenant shall properly remove all Hazardous Materials and, provided that Landlord reasonably believes that such a report is necessary, shall provide to Landlord an environmental audit report, prepared by a professional consultant satisfactory to Landlord and at Tenant's sole expense, certifying that the Premises have not been subjected to environmental harm caused by Tenant's use and occupancy of the Premises. Landlord shall grant to Tenant and its agents or contractors such access to the Premises as is necessary to accomplish such removal and prepare such report.

e. "Hazardous Materials" shall mean (a) any chemical, material, substance or pollutant which poses a hazard to the Premises or to persons on or about the Premises or would cause a violation of or is regulated by any Hazardous Materials Laws, and (b) any chemical, material or substance defined as or included in the definitions of "hazardous substances", "hazardous wastes", "hazardous materials", "extremely hazardous waste", "restricted hazardous waste", "toxic substances", "regulated substances", or words of similar import under any applicable federal, state or local law or under the regulations adopted or publications promulgated pursuant thereto, including, but not limited to, the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, 42 U.S.C. Sec. 9601, et seq.; the Hazardous Materials Transportation Act, as amended, 49 U.S.C. Sec. 1801, et seq.; the Resource Conservation and Recover Act, as amended, 42 U.S.C. Sec. 6901, et seq.; the Solid Waste Disposal Act, 42 U.S.C. Sec. 6991 et seq.; the Federal Water Pollution Control Act, as amended, 33 U.S.C. Sec. 1251, et seq., of the Colorado Revised Statutes. "Hazardous Materials Laws" shall mean any federal, state or local laws, ordinances, rules, regulations, or policies (including, but not limited to, those laws

specified above) relating to the environment, health and safety or the use, handling, transportation, production, disposal, discharge or storage of Hazardous Materials, or to industrial hygiene or the environmental conditions on, under or about the Premises. Said term shall be deemed to include all such laws as are now in effect or as hereafter amended and all other such laws as may hereafter be enacted or adopted during the term of this Lease.

f. All obligations of Tenant pursuant to this Section 30 shall survive and continue after the expiration of this Lease or its earlier termination for any reason.

g. Tenant further covenants and agrees that it shall not install any storage tank (whether above or below ground) on the Premises without obtaining the prior written consent of Landlord, which consent may be conditioned upon further requirements imposed by Landlord with respect to, among other things, compliance by Tenant with any applicable laws, rules, regulations or ordinances and safety measures or financial responsibility requirements.

**31. OPTION TO RENEW.** If Tenant is not then in default of the terms, covenants and conditions herein contained, Tenant shall have the option to renew this Lease for two (2) additional terms of three (3) years each. In the event Tenant desires to exercise said option, Tenant shall give written notice of such fact to Landlord not less than six (6) months prior to the expiration of the then current term of this Lease. In the event of such exercise, this Lease shall be deemed to be extended for the additional period on the same terms and conditions; provided however, Landlord shall have the option of increasing Basic Rental to the then existing market rate for similar office space in the Boulder vicinity (such market rate to be determined by the mutual agreement of Landlord and Tenant or by an MAI real estate appraiser with at least 10 years of experience appraising similar properties in Boulder, which appraiser shall be jointly engaged by Landlord and Tenant). Basic monthly rental shall increase three and one-half percent (3.5%) each year commencing the second year of the additional term.

### **32. MISCELLANEOUS.**

a. Landlord and Tenant agree to keep the terms and conditions of this Lease confidential, including any proposals and discussions related to this Lease. The foregoing confidentiality obligation shall not apply with respect to the following: (a) information that is publically available; (b) information acquired through a third-party; (c) information required by Landlord or Tenant in connection with an action regarding this Lease; and (d) information required to be disclosed pursuant to court order.

b. If Tenant is not then in default of the terms, covenants and conditions herein contained, Tenant shall have the right-of-first refusal, subject to any right-of-first refusal existing as of the date of this Lease, to lease any contiguous space in the Building, at such time as Landlord receives an offer from a third party to lease the space. Tenant shall have five (5) business days after receipt of written notice from Landlord of an offer to lease the space from a third party to enter into a modification of this Lease to include the additional space under this Lease and on the same terms and conditions of the third party offer.

c. Tenant shall be allowed to use up to four (4) bike storage lockers during the term of the lease at no additional costs to Tenant, provided, however, any bike locker user shall be required to make a \$100 security deposit when a bike locker key is issued to them.

d. Tenant acknowledges that Landlord's Broker Steven Chrisman has an interest in BMC Properties, LLC and Landlord's Brokers, Steven Chrisman and Susan Chrisman, are Managing Members of BMC Properties, LLC and therefore shall be acting in the capacity of the Landlord as well.

e. Tenant shall have a one-time right to terminate this Lease, effective on the last day of the 36th month of the Primary Lease Term, by providing six (6) months prior written notice to Landlord and present to Landlord, within thirty (30) days of such notice, a termination fee equal to the unamortized tenant improvement costs and the unamortized brokerage fees, amortized at 8% per annum. In addition, Tenant shall pay two (2) months Base Rent and Additional Rent, at the then current rates.

f. Notwithstanding anything herein to the contrary, Tenant shall have the right to occupy the Temporary Premises as of September 1, 2016 until such time as the Permanent Premises is Ready for Occupancy. Although the Primary Lease Term shall not commence unless and until Tenant occupies the Permanent Premises as provided herein, the parties shall be subject to the balance of the Lease provisions during Tenant's occupancy of the Temporary Premises. Tenant shall pay the final month's Base Rent and Additional Rent on a prorated basis.

*(signature page follows)*

**LANDLORD:**  
**BMC PROPERTIES, LLC**

By: /s/ Steven P. Chrisman

Steven P. Chrisman  
Manager  
864 W. South Boulder Road, Suite 200  
Louisville, Colorado 80027  
Tax I.D. 84-1322498

**TENANT:**  
**BRICKELL BIOTECH, INC.**

By: /s/ Andrew Sklawer

Andrew Sklawer  
COO  
2600 SW 3rd Avenue, Suite 300  
Miami, FL 33129  
Tax I.D. 270943393

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**EXHIBIT B**

to  
Lease

Rules and Regulations

1. No sign, picture, name, notice or other object shall be displayed or affixed on any part of the Premises (including all common areas) which is visible from outside the Premises without the prior written consent of the Landlord, which consent shall not be unreasonably withheld. Landlord shall have the right to remove any such object without notice and at the expense of Tenant.
2. Landlord may assign a pro rata share of parking spaces to Tenant, but in no event shall Tenant be assigned any less than ten (10) parking spaces. Tenant, its employees and invitees shall not use parking spaces in the Premises assigned to another tenant.
3. Sidewalks, corridors, lobbies and stairways in the Premises shall not be used for storage or be obstructed by bicycles or any other objects. Tenant shall not go upon the roof of the Premises or into any mechanical system.
4. Tenant shall not alter any lock nor install any new or additional locks on any door of the Premises without written consent of Landlord, which consent shall not be unreasonably withheld.
5. Toilets, urinal and wash bowls shall not be used for any purpose other than that for which they were constructed and no foreign substance of any kind shall be thrown therein.
6. Tenant shall not, without the prior consent of Landlord, not to be unreasonably withheld, overload the floor of the Premises, or mark, glue, drive nails or screws, or cut or drill into the partitions, woodwork, walls, ceilings, floor or doors or in any way deface the Premises.
7. No furniture, freight or equipment of any kind shall be brought into the Premises without the consent of Landlord, which consent shall not be unreasonably withheld, and all moving shall be done at such times and in such manner as Landlord may designate, so as not to interfere with other tenants. There shall not be used in any space, or in any public hall, any hand trucks except those equipped with rubber tires and side guards.
8. Tenant shall not permit the Premises to be used in a manner offensive to Landlord or other occupants of the Premises by reason of noise, odors or vibrations, or interfere in any way with other tenants. Tenant shall not discard anything outside of its entrance door or in corridors, lobbies or other common areas unless safely stored in non-combustible containers.
9. Tenant shall not keep in the Premises any combustible fluid or material, except in very small quantities and by verbal agreement by Landlord, and except typical quantities of office cleaning supplies.
10. Landlord will direct electricians as to where and how telephone and electrical wires are to be introduced. No boring or cutting of wires will be allowed without the consent of Landlord, which consent shall not be unreasonably withheld.

Exhibit B

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11. No furniture or merchandise will be received in the Premises or carried up or down in the elevators except between such hours and in such elevators as shall be designated by Landlord. Tenant shall cause its movers to use only the loading facilities and elevator designated by Landlord. Tenant shall obtain Landlord's prior approval of moving time. In the event Tenant's movers damage any part of the Premises, Tenant shall immediately pay to Landlord the amount required to repair damage.
12. Tenant shall see that the doors of the Premises are closed and locked before leaving the Premises and must observe strict care and caution that all water faucets or water apparatus are entirely shut off, and that the electricity is entirely shut off so as to prevent waste, except as necessary for a medical/surgical practice.
13. Tenant shall not solicit any occupant of the Premises and shall cooperate to prevent same.
14. No window shades, blinds, screens or draperies will be attached or detached by Tenant without Landlord's prior consent, which consent shall not be unreasonably withheld. Tenant agrees to abide by Landlord's rules with respect to maintaining uniform curtains, draperies and linings at all windows so that the Premises will present a uniform exterior appearance. The blinds shall be of a light color.
15. Tenant shall furnish chair pads under all chairs or stools in the carpeted areas of the Premises.
16. Subject to the terms of the Lease, Landlord shall at all times have the right to inspect the Premises.
17. Bicycles are not allowed in Premises. When they are not being used, they shall be kept either in the bicycle lockers, if any, or in the bicycle racks furnished by Landlord.
18. Tenant shall have all carpeted areas of the Premises professionally cleaned within five (5) business days after vacating the space.
19. Cigarette or cigar smoking is allowed only in the outdoor designated smoking areas. SMOKING INSIDE OF BUILDINGS IS NOT ALLOWED. Cigarette/cigar butts are to be disposed of only in the butts bins provided in the designated smoking area.

Exhibit B

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## FIRST AMENDMENT TO LEASE

THIS FIRST AMENDMENT TO LEASE (this "**Amendment**") is entered into effective as of the 26<sup>th</sup> day of August 2016 (the "**Effective Date**") by and between BMC PROPERTIES, LLC, a Colorado limited liability company (the "**Landlord**"), and BRICKELL BIOTECH, INC., a Delaware corporation (the "**Tenant**"), collectively, the "**Parties**," and individually, a "**Party**."

### Recitals:

WHEREAS, the Parties are each party to that certain August 4, 2016 Lease regarding space within the building (the "**Building**") located on that certain real property more particularly described as Lot 3, Flatirons Industrial Park Filing No. 4 Replat, County of Boulder, State of Colorado (the "**Lease**");

WHEREAS, capitalized terms not otherwise defined herein shall have the meaning given to such terms by the Lease;

WHEREAS, pursuant to the Lease, the "Temporary Premises" is defined as Suite 110 in the Building ("**Suite 110**"); and WHEREAS, the Parties desire to: (a) change the Temporary Premises to Suite 105 in the Building, which consists of approximately 4,746 rentable square feet ("**Suite 105**"); (b) confirm that Tenant's Pro Rata Share and Rent obligations shall remain unchanged; and (c) amend the Lease to reflect the foregoing and otherwise, all as set forth herein.

### Agreement:

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

#### **1. AMENDMENT TO LEASE.**

1.1 The definition of "Temporary Premises" in the Lease is hereby amended so that it refers to Suite 105, rather than Suite 110. Notwithstanding the fact that Suite 105 contains more rentable square footage than Suite 110, the Parties acknowledge and agree that Tenant's Pro Rata Share with respect to the Temporary Premises and Tenant's Rent obligations with respect to the Temporary Premises (including, without limitation, Base Rent and Operating Expenses) shall be determined based upon the rentable square footage in Suite 110, and therefore shall not change.

1.2 Section 32(f) of the Lease is hereby amended to include the following:

(a) Landlord shall provide the Temporary Premises furnished with the prior tenant's (the "**Prior Tenant**") furniture for use by Tenant; and

(b) Landlord shall use commercially-reasonable efforts to help facilitate the sale to Tenant of some of Prior Tenant's glass white boards (those boards subject to the sale to be designated by Tenant) for an amount equal to the cost to have such boards removed and

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the walls of the Temporary Premises patched, which cost Landlord currently estimates will be approximately \$800.

- 2. ATTORNEYS' FEES.** In the event any action is commenced to enforce the terms of this amendment, the prevailing party in any such action shall be awarded its costs and expenses, including reasonable attorneys' fees through all appeals, in addition to any other remedy awarded in such action.
  - 3. EFFECT OF AMENDMENT.** Unless otherwise modified pursuant to this amendment, the terms of the lease shall remain of full force and effect. In the event of any conflict between the terms of this amendment and the terms of the balance of the lease, the terms of this amendment shall control.
  - 4. COUNTERPARTS, FACSIMILE/ELECTRONIC SIGNATURES.** This amendment may be executed in any number of counterparts, each of which shall be deemed an original with the same effect as if the signatures thereto and hereto were upon the same instrument. Facsimile or electronic signatures shall have the same force and effect as original signatures.
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EXECUTED by the Parties as of the Effective Date.

**LANDLORD:**

BMC PROPERTIES, LLC, a  
Colorado limited liability company

By: /s/ Steven P. Chrisman  
Steven P. Chrisman, Manager

**TENANT:**

BRICKELL BIOTECH, INC., a  
Delaware corporation

By: /s/ Andy Sklawer  
Andy Sklawer, COO

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**SECOND AMENDMENT TO LEASE**

THIS SECOND AMENDMENT TO LEASE (“Amendment”) is made and entered into as of the 19<sup>th</sup> day of January, 2017 by and between BMC PROPERTIES, LLC, a Colorado limited liability company (“Landlord”) and BRICKELL BIOTECH, INC., a Delaware corporation (“Tenant”).

The parties hereto agree to modify that certain August 4, 2016 Lease to which they are both a party, which Lease concerns that certain premises located at 5777 Central Avenue more particularly described in the Lease, as follows:

33. Paragraph In is modified to read as follows:

n. “Primary Lease Term.” The term of the Lease shall commence at 12:01 a.m. on the 1st day of November, 2016 and shall terminate at 12:00 midnight on the 31st day of October, 2021, a term of five (5) years.

34. Paragraph 4 is modified to read as follows:

**RENT.** Tenant agrees to pay to Landlord as Base Rent, without prior notice or demand, the following amounts:

Schedule of Base Rent (Permanent Premises):

<u>Month(s)</u>	<u>Monthly Base Rent</u>	<u>Annual Base Rent</u>
November 2016-October 2017	\$4,430.42	\$53,165.04
November 2017-October 2018	\$4,585.48	\$55,025.76
November 2018-October 2019	\$4,745.97	\$56,951.64
November 2019-October 2020	\$4,912.08	\$58,944.96
November 2020-October 2021	\$5,084.00	\$61,008.00
<b>Total Base Rent (Permanent Premises):</b>		<b>\$285,095.40</b>

Base Rent for the Temporary Premises shall equal \$16.50 per rentable square foot, for a monthly Base Rent payment of \$3,405.88.

Tenant shall begin to pay the Base Rent on the date the Primary Lease Term commences and thereafter on the first day of each month during the term hereof. Except as provided herein, all Rents shall be paid in advance, without notice, set off, abatement, counterclaim, deduction or diminution, at The Colorado Group, 3434 47<sup>th</sup> Street, Suite 220, Boulder, Colorado 80301, Attn: Susan Chrisman, or at such place as Landlord, from time-to-time, designates in writing. Tenant shall pay its first installment of Base Rent to Landlord simultaneously with its execution of this Lease. In addition, Tenant shall pay to Landlord Tenant’s Pro Rata Share of Operating Expenses as provided herein and such other charges as are required by the terms of this Lease to be paid by Tenant which shall be referred to herein as “Additional Rent.” Landlord shall have the same rights as to the Additional Rent as it has in the payment of Base Rent. At no time shall Tenant’s Rent obligation be less than the Base Rent amount set forth above.

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**35.** Tenant hereby acknowledges delivery of possession of the Permanent Premises (as defined in the Lease) on November 1, 2016.

**36.** Other than as modified herein, all terms and conditions of the Lease shall remain unchanged.

**37.** In the event any action is commenced to enforce the terms of this Amendment or the obligations of the parties pursuant hereto, the prevailing party in any such action shall be awarded its costs and expenses, including reasonable attorneys' fees through all appeals, in addition to any other remedy awarded in such action.

**38.** This Amendment may be executed in counterparts which, when taken together, shall constitute but one and the same document. A facsimile or electronic signature of a party on this Amendment shall have the same force and effect as an original signature.

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IN WITNESS WHEREOF, the undersigned have executed this document as of the date above written.

**LANDLORD:**  
**BMC PROPERTIES, LLC**

By: /s/ Steven P. Chrisman\_\_\_\_\_

Steven P. Chrisman  
Manager  
864 W. South Boulder Road, Suite 200  
Louisville, Colorado 80027  
Tax I.D. 84-1322498

**TENANT:**  
**BRICKELL BIOTECH, INC.**

By: /s/ Andy Sklawer\_\_\_\_\_

Andy Sklawer  
COO  
5777 Central Avenue, Suite 102  
Boulder, Colorado 80301  
Tax I.D. 27-0943393

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### THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (“Amendment”) is made and entered into as of January 1, 2018 by and between BMC PROPERTIES, LLC, a Colorado limited liability company (herein called “Landlord”), and BRICKELL BIOTECH, INC., a Delaware corporation (herein called “Tenant”).

The parties hereto agree to modify that certain August 4, 2016 Lease (as previously amended) to which they are both a party (“Lease”), which Lease concerns that certain premises located at 5777 Central Avenue as more particularly described in the Lease, as follows:

**39.** Paragraph 1s is modified to read as follows:

s. “Reserve Amount” shall mean a reserve for the replacement of heating, ventilating and air-conditioning unit(s), replacement of the roof, and replacement of the parking lot in the amount of THIRTY THOUSAND AND NO/100’s Dollars (\$30,000.00) per annum. The Reserve Amount shall not be used to pay costs related to the maintenance, repair or replacement of any Tenant-specific HVAC or other equipment as described in Paragraph 6c below.

**40.** Paragraph 6a(2) is modified to read as follows:

(2) Except for the costs described in Paragraph 6c below, the cost of general repairs, maintenance and replacements, excluding capital expenditures, made from time-to-time by Landlord to the Property, including costs under mechanical or other maintenance contracts and repairs and replacements of equipment used in connection with such maintenance and repair work.

**41.** Paragraph 6c is modified to read as follows:

c. Notwithstanding anything herein to the contrary, costs for repairs and maintenance of Tenant-specific HVAC equipment or other Tenant-specific equipment required for Tenant’s use of the Premises (e.g. supplemental HVAC unit(s), dedicated air-conditioning unit(s), make-up air unit(s), exhaust fan(s), and humidification system(s)) are not included in the general Operating Expenses for the Building but shall be separately charged to Tenant as costs are incurred by Landlord and shall be paid by Tenant concurrently with Tenant’s payment of Rent after Landlord receives an invoice for such repairs and maintenance. Repairs and maintenance shall include, but are not limited to, the replacement of compressors and motors for the above described Tenant-specific HVAC or other equipment.

4. Other than as modified herein, all terms and conditions of the Lease shall remain unchanged.

5. In the event any action is commenced to enforce the terms of this Amendment or the obligations of the parties pursuant hereto, the prevailing party in any such action shall be

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awarded its costs and expenses, including reasonable attorneys' fees through all appeals, in addition to any other remedy awarded in such action.

**1.** This Amendment may be executed in counterparts which, when taken together, shall constitute but one and the same document. A facsimile or electronic signature of a party on this Amendment shall have the same force and effect as an original signature.

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IN WITNESS WHEREOF, the undersigned have executed this document as of the date above written.

**LANDLORD:**  
**BMC PROPERTIES, LLC**

By: /s/ Steven P. Christmas \_\_\_\_\_

Steven P. Chrisman  
Manager  
864 W. South Boulder Road, Suite 200  
Louisville, Colorado 80027  
Tax I.D. 84-1322498

**TENANT:**  
**BRICKELL BIOTECH, INC.**

By: /s/ Andy Sklawer \_\_\_\_\_

Andy Sklawer  
COO  
5777 Central Avenue, Suite 102  
Boulder, Colorado 80301  
Tax I.D. 27-0943393

**EMPLOYMENT AGREEMENT**

**THIS EMPLOYMENT AGREEMENT** (“Agreement”) is made this November 16, 2018 (“Effective Date”) by and between **BRICKELL BIOTECH, INC.**, a Delaware Company with a business address located at 5777 Central Avenue, Suite 102, Boulder, CO 80301 (the “Company”), and **ROBERT BROWN**, an Indiana resident, with an address of 121 3rd St NW, Carmel, IN 46032 (the “Executive”).

**RECITALS:**

**WHEREAS**, the Executive possesses substantial experience in the field of pharmaceutical development;

**WHEREAS**, the Company seeks to employ Executive as Chief Executive Officer of the Company;

**WHEREAS**, the Executive is willing to make his services available to the Company and on the terms and conditions hereinafter set forth.

**NOW, THEREFORE**, in consideration of the recitals, premises and mutual covenants set forth herein, the parties agree as follows:

1 . Employment/Duties of Executive. During the Term of Employment under this Agreement, the Executive shall serve as Chief Executive Officer and as a member of the Board of Directors (“Board”) of the Company and satisfactorily completing the responsibilities commensurate with those duties and responsibilities of such position. Executive shall report to the Company’s Board. Additionally, Executive shall diligently perform all other services and shall exercise such power and authority as may from time to time be delegated to him by the Board. The foregoing shall not limit his right to be involved in other not-for-profit, civic or charitable activities nor limit the Executive’s right to serve as an advisor or board member for other non-competing corporate or not-for-profit entities, provided such outside activities do not conflict or impede Executive’s performance of his duties and responsibilities to the Company. The Board reserves the right to request that the Executive resign from such outside roles in the event that the Board perceives that the Executive is devoting less than his full time attention to his responsibilities at the Company.

2. Term. Executive shall commence employment with the Company on January 1, 2019 (“Start Date”). The Executive’s employment shall be at-will, meaning that the Executive or the Company may terminate the employment relationship at any time, with or without cause, and with or without notice, subject to severance provisions set forth below. The period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement is sometimes referred to in this Agreement as the “Term of Employment”, and the date on which the Term of Employment shall expire, is sometimes referred to in this Agreement as the “Termination Date”).

### 3. Compensation.

3.1 Base Salary. The Company shall pay Executive an initial base salary at the annual rate of Four Hundred Fifty Thousand Dollars (\$450,000) (the "Base Salary"). The Board shall review the Executive's Base Salary from time to time and the Board may, but shall not be required to, increase the Base Salary during the Term of Employment. However, Executive's Base Salary may not be decreased during the Term of Employment other than as part of an across-the-board salary reduction that applies in the same manner to all senior executives of the Company. All salary is payable subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices.

#### 3.2 Equity and Bonuses.

a. Annual Bonus. For each fiscal year of the Term of Employment, Executive shall be eligible to receive a performance bonus of up to 50% of Base Salary (the "Performance Bonus"), based upon the achievement of mutually agreed performance milestones established by the Board, provided nothing herein shall be a guarantee of any amount of bonus, or any bonus at all. Such Performance Bonus, if any, is subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices and is hereby incorporated into this Agreement by reference. Any bonuses payable pursuant to this Section 3.2 are sometimes hereinafter referred to as "Incentive Compensation" and shall be paid by the Company to the Executive within two (2) months after the end of the applicable bonus period in which they are earned.

b. Equity. The Company shall recommend that the Board grant to Executive an option to purchase, pursuant to an option agreement, 400,000 shares of Company Common Stock, (the "Common Stock") at a price per share equal to the fair market value per share of the Common Stock on the date of grant, as determined by the Board (the "Initial Option Grant"). The Initial Option Grant is intended to represent approximately 5% of the Fully Diluted Shares (as defined below) currently outstanding. For the purposes of this Agreement, "Fully Diluted Shares" shall be calculated by adding (x) the number of outstanding shares of capital stock of the Company, plus (y) the number of shares of Company common stock subject to issuance under outstanding options or warrants, plus (z) the number of unallocated shares of Company common stock reserved for issuance pursuant to the Company's stock option plans, in each case, as of the close of the business day preceding the date of determination. Subject to the vesting acceleration terms described in this Agreement, twenty-five percent (25%) of the Initial Option Grant shall vest (or be released from the Company's repurchase right, as applicable) one year from the Effective Date subject to Executive's continuing employment with the Company, and none of the Initial Option Grant shall vest (or be released from the Company's repurchase right, as applicable) before such date. The remaining shares subject to the Initial Option Grant shall vest (or be released from the Company's repurchase right, as applicable) monthly over the next (36) months in equal monthly amounts subject to Executive's continuing employment with the Company. Any shares acquired upon exercise of the Initial Option Grant, will be subject to the terms and conditions of the Company's equity incentive plan and option agreement to be entered into between Executive and the Company.

In addition to the aforementioned Initial Option Grant, as soon as reasonably practicable following the closing of the Company's next equity financing pursuant to which it raises at least twenty million dollars in gross proceeds, which is expected to be a Series D preferred stock financing (the "Series D Financing"), the Company shall grant to Executive an option to purchase, pursuant to an option agreement subject to an early exercise provision, additional shares of Common Stock at a price per share equal to the fair market value per share of the Common Stock on the date of grant, as determined by the Board (collectively, the "Additional Option Grants", and together with the Initial Option Grant, the "Option Grants"), which together with the Initial Option Grant shall represent approximately 5% of the Fully Diluted Shares (as defined above) outstanding immediately following the closing of the Series D Financing, provided that Executive is employed by the Company as its Chief Executive Officer on the date of any such grant. Subject to the vesting acceleration terms described in this Agreement, twenty-five percent (25%) of the Additional Option Grants shall vest (or be released from the Company's repurchase right, as applicable) one year from the Closing of the Series D Financing, subject to Executive's continuing employment with the Company, and none of the Additional Option Grants shall vest (or be released from the Company's repurchase right, as applicable) before such date. The remaining shares subject to the Additional Option Grants shall vest (or be released from the Company's repurchase right, as applicable) monthly over the next thirty-six (36) months in equal monthly amounts subject to Executive's continuing employment with the Company. Any shares acquired upon exercise of the Additional Option Grants, will be subject to the terms and conditions of the equity incentive plan and option agreement(s) to be entered into between Executive and the Company.

Subject to any vesting requirements as set forth below (and in the applicable stock option agreements), the Option Grants may be early exercised at any time after the respective grant dates for all or any part of the shares subject to these Option Grants.

#### 4. Expense Reimbursement and Other Benefits.

4.1 Reimbursement of Expenses. Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

4.2 Compensation/Benefit Programs. During the Term of Employment, the Executive shall be entitled to participate in all medical insurance plans and any and all other plans as are presently and hereinafter offered by the Company to its executives and their spouses, domestic partners and immediate families.

4.3 Relocation Assistance. During the Term of Employment, the Company shall reimburse Executive for up to \$3,000 per month in temporary living expenses toward the costs of maintaining a residence in Boulder County, Colorado for a maximum period of thirty-six (36) months. During the Term of Employment, the Company will reimburse Executive for relocation

expenses associated with purchasing a home in Colorado to serve as Executive's primary residence and movement of Executive's household goods to Colorado up to a maximum amount of \$75,000 ("Relocation Payments"). Expenses eligible for reimbursement as Relocation Payments hereunder, subject to the stated maximum, include the travel and accommodation expenses of house hunting trips and the cost of packing and moving the Executive's household goods from Indiana to Colorado. Should Executive voluntarily resign from the Company without Good Reason (as defined herein) within twelve (12) months of Executive's relocation, Executive agrees to repay to the Company a pro rata portion of all Relocation Payments paid to Executive by the Company. Such amount shall be payable immediately upon resignation of employment. In addition, Executive agrees and authorizes the Company to deduct any amounts owed to the Company pursuant to this **Section 4.3** from Executive's final paycheck and any other amounts that the Company otherwise might pay upon termination. All reimbursements provided pursuant to this **Section 4.3** shall be subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices.

#### 4.4 Other Benefits.

a. Personal Days. The Executive shall be entitled to twenty-eight (28) days of paid personal days annually, including vacation days, sick days and time off for personal matters. Such personal days are to be taken at such times as the Executive and the Company shall mutually determine. Personal days shall not interfere with the duties required to be rendered by the Executive hereunder.

b. Association Dues. During the Term of this Agreement, the Company may pay reasonable initiation fees and dues payable in connection with the Executive's membership(s) in those clubs and activities that in the opinion of the Board are in furtherance and directly related to the active conduct of the Company's business and are consistent with sound financial and tax planning.

c. Miscellaneous Benefits. The Executive shall receive such additional benefits, if any, as the Board shall from time to time determine.

#### 5. Termination.

5.1 Termination for Cause. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, for Cause. For purposes of this Agreement, the term "Cause" shall mean: (i) an action or omission of the Executive which constitutes a willful and material breach of, or failure or refusal (other than by reason of his disability) to perform his duties under this Agreement or any other agreements, including, without limitation, the Company Protection Agreement, between the parties which is not cured within fifteen (15) days after receipt by the Executive of written notice of same; (ii) fraud, embezzlement, misappropriation of funds or breach of trust in connection with his services hereunder; (iii) conviction of any crime which involves dishonesty or a breach of trust; or (iv) gross negligence in connection with the performance of the Executive's duties hereunder, which is not cured within fifteen (15) days after written receipt by the Executive of written notice of same. Any termination for Cause shall be made in writing to the Executive, which notice shall set forth in detail all acts or omissions upon which

the Company is relying for such termination. The Executive shall have the right to address the Board regarding the acts set forth in the notice of termination. Upon any termination pursuant to this **Section 5.1**, the Company shall pay to the Executive his Base Salary to the date of termination. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.2 **Disability.** The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, if the Executive shall become entitled to benefits under the Company's disability plan as then in effect, or, if the Executive shall as the result of mental or physical incapacity, illness or disability, become unable to perform his obligations hereunder for a period of 180 days in any 12-month period. The Company shall have sole discretion based upon competent medical advice to determine whether the Executive continues to be disabled. Upon any termination pursuant to this **Section 5.2**, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; (ii) pay to the Executive or his estate a severance payment equal to three (3) months of the Executive's Base Salary at the time of the termination of the Employee's employment with the Company, such amount to be paid in the manner and at such times as the Base Salary otherwise would have been payable to the Employee; and (iii) pay to the Executive his accrued but unpaid Incentive Compensation, if any, for any Bonus Period ending on or before the date of termination of the Executive's employment with the Company. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.3 **Death.** Upon the death of the Executive during the Term of Employment, the Company shall (i) pay to the estate of the deceased Executive any unpaid Base Salary through the Executive's date of death; (ii) pay to the Executive or his estate a severance payment equal to three (3) months of the Executive's Base Salary at the time of the termination of the Executive's employment with the Company, such amount to be paid in the manner and at such times as the Base Salary otherwise would have been payable to the Employee; and (iii) pay to the estate of the deceased Executive his accrued but unpaid Incentive Compensation, if any, for any Bonus Period ending on or before the Executive's date of death. In addition, in the event that the Executive's spouse and/or children shall be eligible and shall elect to receive continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("**COBRA**"), or, if applicable, state or local insurance laws, the Company shall pay that portion of the Executive's **COBRA** premiums that the Company was paying prior to the Executive's date of death for twelve (12) months following the Executive's death. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of the Executive's death, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.4 **Termination Without Cause.** At any time the Company shall have the right to terminate the Term of Employment by written notice to the Executive. Upon any termination

pursuant to this **Section 5.4**, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive the accrued and/or pro-rated but unpaid Incentive Compensation, if any, for any period ending on or before the date of the termination of the Executive's employment with the Company. Subject to **Section 5.7** below, the Company shall pay to the Executive in a the equivalent of twelve (12) months of Executive's Base Salary in one-lump payment within thirty (30) days of the effective date of termination and reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination ("Severance Benefits"). The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.5 Termination by Executive for Good Reason.

a. The Executive shall at all times have the right, upon fifteen (15) days written notice to the Company, to terminate the Term of Employment. Upon termination of the Term of Employment pursuant to this **Section 5.5(a)** by the Executive, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive his accrued but unpaid Incentive Compensation, if any, for any Bonus Period ending on or before the termination of Executive's employment with the Company.

b. Upon termination of the Term of Employment pursuant to this **Section 5.5** by the Executive for Good Reason, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive the accrued and/or pro-rated but unpaid Incentive Compensation, if any, for any period ending on or before the termination of Executive's employment with the Company. Subject to **Section 5.7** below, the Company shall pay to the Executive in a the equivalent of twelve (12) months of Executive's Base Salary in one-lump payment within thirty (30) days of the effective date of termination and reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination ("Severance Benefits"). The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

c. For purposes of this Agreement, "Good Reason" shall mean (i) the assignment to the Executive of any duties inconsistent in any respect with the Executive's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as contemplated by **Section 1** of this Agreement, or any other action by the Company which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Executive; (ii) any failure by the Company to comply with any of the provisions of **Article 3** of this Agreement, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and which is remedied by the

Company promptly after receipt of notice thereof given by the Executive; *provided however*, that in order to effect resignation for Good Reason all of the following must occur: (x) Executive must provide the Company with written notice within the sixty-day period following the event(s) giving rise to Executive's intent to voluntarily resign his employment for Good Reason (y) such event is not remedied by within thirty (30) days following the Company's receipt of such written notice; and (z) Executive's resignation is effective not later than thirty (30) days after the expiration of such thirty (30) day cure period.

#### 5.6 Change in Control of the Company.

a. Payments. In the event that a termination of employment without Cause or for Good Reason occurs within twelve (12) months following a Change in Control (as defined in paragraph (b) of this **Section 5.6**) in the Company, subject to **Section 5.7** below, the Company shall pay to the Executive in a the equivalent of twelve (12) months of Executive's Base Salary in the form of salary continuation, reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination, and fully accelerate the vesting of all outstanding, unvested options or other equity instruments of Company Common Stock such that all such equity shall be fully vested and exercisable ("Severance Benefits"). The Company shall have no further liability hereunder (other than for (x) reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and (y) payment of compensation for unused paid, personal days that have accumulated during the calendar year in which such termination occurs).

b. For purposes of this Agreement, the term "Change in Control" shall mean approval by the shareholders of the Company of (i) a reorganization, merger, consolidation or other form of corporate transaction or series of transactions, in each case, with respect to which persons who were the shareholders of the Company immediately prior to such reorganization, merger or consolidation or other transaction do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities, in substantially the same proportions as their ownership immediately prior to such reorganization, merger, consolidation or other transaction, or (ii) a liquidation or dissolution of the Company or (iii) the sale of all or substantially all of the assets of the Company (unless such reorganization, merger, consolidation or other corporate transaction, liquidation, dissolution or sale is subsequently abandoned).

5 . 7 Release and Board Resignation Requirement. The Severance Benefits are conditional upon (i) Executive's delivering to the Company and making effective and irrevocable a general release of all claims in favor of the Company, in a form reasonably acceptable to the Company (the "Release"), which release shall be effective not later than 45 days following the date of the applicable termination or resignation; (ii) Executive's complying with the Release including any cooperation, non-disparagement or confidentiality provisions contained therein and continuing to comply with Executive's obligations under the terms of this Agreement, including the non-solicit and non-compete provisions thereof, and the terms of the Protection Agreement; and

(iii) Executive's resignation from the Board, to be effective no later than the date of Executive's termination or resignation date (or such other date as requested by the Board).

5.8 Survival. The provisions of this **Article 5** shall survive the termination of this Agreement, as applicable.

6. Restrictive Covenants.

6.1 Non-Competition. At all times while the Executive is employed by the Company and for a one (1) year period after the termination of the Executive's employment with the Company for any reason other than by the Company without Cause (as defined in **Section 5.1** hereof) or by the Executive for Good Reason (as defined in **Section 5.5** hereof), the Executive shall not, directly or indirectly, engage in or have any interest in any sole proprietorship, partnership, Company or business or any other person or entity (whether as an Executive, officer, director, partner, agent, security holder, creditor, consultant or otherwise) that directly or indirectly (or through any affiliated entity) engages in competition with the Company (for this purpose, any business that engages in the drug development business utilizing those specific pharmaceutical compounds developed, licensed or owned by the Company or any of its subsidiaries during his term of employment to date of Executive's Termination shall be deemed to be in competition with the Company); provided that such provision shall not apply to the Executive's ownership of Common Stock of the Company or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities exchange or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control or, more than five percent of any class of capital stock of such Company.

6.2 Nondisclosure. The Executive shall not at any time divulge, communicate or use to the detriment of the Company or for the benefit of any other person or persons, or misuse in any way, any Confidential Information (as hereinafter defined) pertaining to the business of the Company. Any Confidential Information or data now or hereafter acquired by the Executive with respect to the business of the Company (which shall include, but not be limited to, information concerning the Company's business plan, financial condition, prospects, technology, customers, suppliers, sources of leads and methods of doing business) shall be deemed a valuable, special and unique asset of the Company that is received by the Executive in confidence and as a fiduciary, and Executive shall remain a fiduciary to the Company with respect to all of such information. For purposes of this Agreement, "Confidential Information" means information disclosed to the Executive or known by the Executive as a consequence of or through his employment by the Company (including information conceived, originated, discovered or developed by the Executive) prior to or after the date hereof, and not generally known, about the Company or its business. Notwithstanding the foregoing, nothing herein shall be deemed to restrict the Executive from disclosing Confidential Information to the extent required by law.

6.3 Non-solicitation of Executives and Clients. At all times while the Executive is employed by the Company and for a one (1) year period after the termination of the Executive's employment with the Company for any reason, the Executive shall not, directly or indirectly, for himself or for any other person, firm, Company, partnership, association or other entity (a) employ or attempt to employ or enter into any contractual arrangement with any Executive or former Executive of the Company, unless such Executive or former Executive has not been employed by the Company for a period in excess of six months, and/or (b) call on or solicit any of the actual or targeted prospective clients of the Company on behalf of any person or entity in connection with any business competitive with the business of the Company, nor shall the Executive make known the names and addresses of such clients or any information relating in any manner to the Company's trade or business relationships with such customers, other than in connection with the performance of Executive's duties under this Agreement.

6.4 Books and Records. All books, records, and accounts relating in any manner to the business of the Company, customers, clients or prospects of the Company, reports documents analyses or any information whether prepared by the Executive or otherwise coming into the Executive's possession, shall be the exclusive property of the Company and shall be returned immediately to the Company on termination of the Executive's employment hereunder or on the Company's request at any time.

6.5 Definition of Company. Solely for purposes of this **Article 6**, the term "Company" also shall include any existing or future subsidiaries of the Company that are operating during the time periods described herein and any other entities that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with the Company during the periods described herein.

6.6 Acknowledgment by Executive. The Executive acknowledges and confirms that (a) the restrictive covenants contained in this **Article 6** are reasonably necessary to protect the legitimate business interests of the Company, and (b) the restrictions contained in this **Article 6** (including without limitation the length of the term of the provisions of this **Article 6**) are not overbroad, overlong, or unfair and are not the result of overreaching, duress or coercion of any kind. The Executive further acknowledges and confirms that his full, uninhibited and faithful observance of each of the covenants contained in this **Article 6** will not cause him any undue hardship, financial or otherwise, and that enforcement of each of the covenants contained herein will not impair his ability to obtain employment commensurate with his abilities and on terms fully acceptable to him or otherwise to obtain income required for the comfortable support of him and his family and the satisfaction of the needs of his creditors. The Executive acknowledges and confirms that his special knowledge of the business of the Company is such as would cause the Company serious injury or loss if he were to use such ability and knowledge to the benefit of a competitor or were to compete with the Company in violation of the terms of this **Article 6**. The Executive further acknowledges that the restrictions contained in this **Article 6** are intended to be, and shall be, for the benefit of and shall be enforceable by, the Company's successors and assigns.

6.7 Reformation by Court. In the event that a court of competent jurisdiction shall determine that any provision of this **Article 6** is invalid or more restrictive than permitted

under the governing law of such jurisdiction, then only as to enforcement of this **Article 6** within the jurisdiction of such court, such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

6.8 Extension of Time. If the Executive shall be in violation of any provision of this **Article 6**, then each time limitation set forth in this **Article 6** shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Company seeks injunctive relief from such violation in any court, then the covenants set forth in this **Article 6** shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Executive.

6.9 Survival. The provisions of this **Article 6** shall survive the termination of this Agreement, as applicable.

7 . Mediation. In the event a dispute arises out of or relates to this Agreement, or the breach thereof, and if the dispute cannot be settled through negotiation, the parties hereby agree first to attempt in good faith to settle the dispute by mediation administered by the American Arbitration Association under its Employment Mediation Rules before resorting to litigation or some other dispute resolution procedure.

8 . Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Boulder County, Colorado in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association then in effect (except to the extent that the procedures outlined below differ from such rules or the parties agree otherwise). Within thirty (30) days after written notice by either party has been given that a dispute exists and that arbitration is required, each party must select an arbitrator and those two arbitrators shall promptly, but in no event later than thirty (30) days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The cost and expenses of the arbitration and of enforcement of any award in any court shall be borne by the Company. The cost of any attorney fees shall be borne by each party individually, unless the payment of such fees is awarded to the prevailing party by the arbitrators. If advances are required, each party will advance one-half of the estimated fees and expenses of the arbitrators. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to obtain an injunction to protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

9 . Assignment. This Agreement is personal in nature and accordingly may not be assigned by the Executive, in whole or in part, without the prior written consent of the Company, which may be withheld in its sole discretion. The Company may, in its sole discretion, assign this Agreement and all of its rights, benefits and obligations hereunder, whether by agreement or by operation of law.

10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Colorado without regard to conflict of laws issues.

11. Entire Agreement. This Agreement, including Exhibits A (Protection Agreement) and B (Indemnification Agreement), constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its affiliates) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

12. Notices. All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed e-mail or facsimile transmission addressed as set forth herein. Notices personally delivered, sent by e-mail or facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) days after deposit in the U.S. mail. Notice shall be sent (i) if to the Company, addressed to Brickell Biotech, Inc., 5777 Central Avenue, Suite 102, Boulder, CO 80301, Attention: Chairman of the Board, and (ii) if to the Executive, to his address as reflected on the payroll records of the Company, or to such other address as either party hereto may from time to time give notice of to the other.

13. Benefits; Binding Effect. This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

14. Severability. The invalidity of any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, or section or sections had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area, which would cure such invalidity.

15. Waivers. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

16. Damages. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. In the event that either party hereto brings suit for the collection of any damages resulting from, or the injunction of

any action constituting, a breach of any of the terms or provisions of this Agreement, then the party found to be at fault shall pay all reasonable court costs and attorneys fees of the other.

17. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

18. No Third Party Beneficiary. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and assigns, any rights or remedies under or by reason of this Agreement.

19. Indemnification. The Company will indemnify the Executive pursuant to the terms and conditions of the Indemnification Agreement attached hereto as Exhibit B.

20. Section 409A.

20.1 General Compliance. This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended, ("Section 409A"), or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

20.2 Specified Employees. Notwithstanding any other provision of this Agreement, if any payment or benefit provided to the Executive in connection with his termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Executive is determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of the Termination Date or, if earlier, on the Executive's death (the "Specified Employee Payment Date"). The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date and interest on such amounts calculated based on the applicable federal rate published by the Internal Revenue Service for the month in which the Executive's separation from service occurs shall be paid to the Executive in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

20.3 Reimbursements. To the extent required by Section 409A, each reimbursement or in-kind benefit provided under this Agreement shall be provided in accordance with the following:

(a) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year;

(b) any reimbursement of an eligible expense shall be paid to the Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred; and

(c) any right to reimbursements or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit.

20.4 Tax Gross-ups. Any tax gross-up payments provided under this Agreement shall be paid to the Executive on or before December 31 of the calendar year immediately following the calendar year in which the Executive remits the related taxes.

**IN WITNESS WHEREOF**, the undersigned have executed this Agreement as of the date first above written.

Company:     Executive:

**BRICKELL BIOTECH, INC.**

A Delaware Company

By:       /s/ Reginal Hardy        
Reginal Hardy, CEO

By:       /s/ Robert Brown        
Robert Brown, Individually

**EXHIBIT A - PROTECTION AGREEMENT**

**EXHIBIT B – INDEMNIFICATION AGREEMENT**

**SECOND AMENDED AND RESTATED EMPLOYMENT AGREEMENT**

**THIS SECOND AMENDED AND RESTATED EMPLOYMENT AGREEMENT** (“Agreement”) is made this November 27, 2018 (the “Effective Date”) by and between **BRICKELL BIOTECH, INC.**, a Delaware corporation with a business address located at 5777 Central Avenue, Suite 102, Boulder, CO 80301 (the “Corporation”), and **ANDREW SKLAWER**, a Colorado resident, with an address of 1600 Linden Avenue, Boulder, CO 80304 (the “Executive”).

**RECITALS:**

**WHEREAS**, the Executive and the Corporation entered into an Amended and Restated Employment Agreement dated March 1, 2014 (the “Amended and Restated Employment Agreement”);

**WHEREAS**, the parties desire to amend and restate the Amended and Restated Employment Agreement as amended in full to provide for continuous employment on a going-forward basis with such revised terms as are set forth herein and as may be adopted by the parties in the future;

**WHEREAS**, the Executive is willing to make his services available to the Corporation and on the terms and conditions hereinafter set forth.

**NOW, THEREFORE**, in consideration of the recitals, premises and mutual covenants set forth herein, the parties agree as follows:

1. Employment.

1.1 Employment and Term. The Corporation hereby agrees to employ the Executive and the Executive hereby agrees to serve the Corporation on the terms and conditions set forth herein.

1.2 Duties of Executive. During the Term of Employment under this Agreement, the Executive shall serve as Chief Operating Officer and Corporate Secretary satisfactorily completing the responsibilities commensurate with the duties and responsibilities of those positions. Executive shall report to the Company’s Chief Executive Officer. Additionally, Executive shall diligently perform all other services and shall exercise such power and authority as may from time to time be delegated to him by the Board. The foregoing shall not limit his right to be involved in other not-for-profit, civic or charitable activities nor limit the Executive’s right to serve as an advisor or board member for other non-competing corporate or not-for-profit entities, or as otherwise permitted by the Board.

2. Term. The Executive’s employment shall be at-will, meaning that the Executive or the Corporation may terminate the employment relationship at any time, with or without cause, and with or without notice, subject to severance provisions set forth below. The period during which the Executive shall be employed by the Corporation pursuant to the terms of this Agreement is sometimes referred to in this Agreement as the “Term of Employment”, and the date on which the

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Term of Employment shall expire, is sometimes referred to in this Agreement as the "Termination Date").

3. Compensation.

3.1 Base Salary. The Corporation shall pay Executive an initial base salary at the annual rate of Three Hundred Fifty Thousand Dollars (\$350,000) (the "Base Salary"). Executive's Base Salary shall be reviewed from time to time by the Board and the Board may, but shall not be required to, increase the Base Salary during the Term of Employment. However, Executive's Base Salary may not be decreased during the Term of Employment other than as part of an across-the-board salary reduction that applies in the same manner to all senior executives of the Corporation. All salary is payable subject to standard federal and state payroll withholding requirements in accordance with Corporation's standard payroll practices.

3.2 Bonuses and Equity.

a. Guaranteed Bonus. The Corporation may pay Executive a guaranteed bonus at a rate and for a term to be established. Such guaranteed bonus is subject to standard federal and state payroll withholding requirements in accordance with Corporation's standard payroll practices and is hereby incorporated into this Agreement by reference.

b. Discretionary Bonus. For each fiscal year of the Term of Employment, the Corporation shall pay Executive a performance bonus of up to 35% of Base Salary (the "Performance Bonus"), based upon the achievement of mutually agreed performance milestones established by the Board. Such Performance Bonus is subject to standard federal and state payroll withholding requirements in accordance with Corporation's standard payroll practices and is hereby incorporated into this Agreement by reference.

c. Equity. The Corporation has previously caused Executive to be granted options to purchase shares of common stock of the Corporation. Notwithstanding the previously agreed upon terms of the options or any applicable award agreements, all outstanding unvested options previously granted to the Executive shall be vested in full as of the Effective Date of this Agreement and shall remain exercisable for the remainder of their full term. It is further understood and agreed that any future equity grants from the Corporation to the Executive shall provide for full acceleration of vesting and an exercise period commensurate with the full term of such options or stock awards in the event of a termination without Cause (as defined in **Section 5.1**), resignation for Good Reason (as defined in **Section 5.5(d)**) or a Change of Control (as defined in **Section 5.6(b)**).

Any bonuses payable pursuant to this **Section 3.2** are sometimes hereinafter referred to as "Incentive Compensation" and shall be paid by the Corporation to the Executive within two (2) months after the end of the applicable bonus period in which they are earned. In the event Executive's employment is terminated pursuant to **Section 5.4**, **5.5(b)** or **5.6** during a bonus period and the performance goals are achieved, Executive shall be entitled to a pro-rated portion of the Performance Bonus that would have been paid had the Executive remained employed for the entire bonus period.

4. Expense Reimbursement and Other Benefits.

4.1 Reimbursement of Expenses. Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Corporation may from time to time adopt, the Corporation shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Corporation. The Executive shall account to the Corporation in writing for all expenses for which reimbursement is sought and shall supply to the Corporation copies of all relevant invoices, receipts or other evidence reasonably requested by the Corporation.

4.2 Compensation/Benefit Programs. During the Term of Employment, the Executive shall be entitled to participate in all medical insurance plans and any and all other plans as are presently and hereinafter offered by the Corporation to its executives and their spouses, domestic partners and immediate families, the Corporation shall pay all premiums thereon on behalf of the Executive in accordance with Corporation guidelines.

4.3 Other Benefits.

a. Personal Days. The Executive shall be entitled to twenty eight (28) days of paid personal days annually, including vacation days, sick days and time off for personal matters. Such personal days are to be taken at such times as the Executive and the Corporation shall mutually determine. Personal days shall not interfere with the duties required to be rendered by the Executive hereunder.

b. Association Dues. During the Term of this Agreement, the Corporation may pay reasonable initiation fees and dues payable in connection with the Executive's membership(s) in those clubs and activities that in the opinion of the Board are in furtherance and directly related to the active conduct of the Corporation's business and are consistent with sound financial and tax planning.

c. Miscellaneous Benefits. The Executive shall receive such additional benefits, if any, as the Board shall from time to time determine.

5. Termination.

5.1 Termination for Cause. The Corporation shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, for Cause. For purposes of this Agreement, the term "Cause" shall mean: (i) an action or omission of the Executive which constitutes a willful and material breach of, or failure or refusal (other than by reason of his disability) to perform his duties under this Agreement or any other agreements, including, without limitation, the Company Protection Agreement, between the parties which is not cured within fifteen (15) days after receipt by the Executive of written notice of same; (ii) fraud, embezzlement, misappropriation of funds or breach of trust in connection with his services hereunder; (iii) conviction of any crime which involves dishonesty or a breach of trust; or (iv) gross negligence in connection with the performance of the Executive's duties hereunder, which is not cured within fifteen (15) days after written receipt by the Executive of written notice of same. Any termination for Cause shall be made

in writing to the Executive, which notice shall set forth in detail all acts or omissions upon which the Corporation is relying for such termination. The Executive shall have the right to address the Board regarding the acts set forth in the notice of termination. Upon any termination pursuant to this **Section 5.1**, the Corporation shall pay to the Executive his Base Salary to the date of termination. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.2 **Disability.** The Corporation shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, if the Executive shall become entitled to benefits under the Corporation's disability plan as then in effect, or, if the Executive shall as the result of mental or physical incapacity, illness or disability, become unable to perform his obligations hereunder for a period of 180 days in any 12-month period. The Corporation shall have sole discretion based upon competent medical advice to determine whether the Executive continues to be disabled. Upon any termination pursuant to this **Section 5.2**, the Corporation shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice, (ii) pay to the Executive his accrued but unpaid Incentive Compensation, if any, for any bonus period ending on or before the date of termination of the Executive's employment with the Corporation, (iii) pay to the Executive a severance payment equal to three (3) months of the Executive's Base Salary at the time of the termination of the Executive's employment with the Corporation, such amount to be paid in the manner and at such times as the Base Salary otherwise would have been payable to the Executive. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.3 **Death.** Upon the death of the Executive during the Term of Employment, the Corporation shall (i) pay to the estate of the deceased Executive any unpaid Base Salary through the Executive's date of death, (ii) pay to the estate of the deceased Executive his accrued but unpaid Incentive Compensation, if any, for any bonus period ending on or before the Executive's date of death, (iii) continue to pay to the estate of the deceased Executive the Base Salary the Executive was receiving prior to his death under **Section 3.1** hereof for a period of three (3) months following the Executive's death, in the manner and at such times as the Base Salary otherwise would have been payable to the Executive. In addition, in the event that the Executive's spouse and/or children shall be eligible and shall elect to receive continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), or, if applicable, state or local insurance laws, the Corporation shall pay that portion of the Executive's COBRA premiums that the Corporation was paying prior to the Executive's date of death for twelve (12) months following the Executive's death. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of the Executive's death, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.4 Termination Without Cause. At any time the Corporation shall have the right to terminate the Term of Employment by written notice to the Executive. Upon any termination pursuant to this **Section 5.4** (that is not a termination under any of **Sections 5.1, 5.2, 5.3, 5.5 or 5.6**, and subject to Section 5.7 below, the Corporation shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice, (ii) pay to the Executive the accrued but unpaid Incentive Compensation, if any, for any bonus period ending on or before the date of the termination of the Executive's employment with the Corporation, (iii) pay to the Executive in a lump sum the equivalent of twelve (12) months of Executive's Base Salary, and (iv) reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.5 Termination by Executive.

a. The Executive shall at all times have the right, upon ninety (90) days written notice to the Corporation, to terminate the Term of Employment. Upon termination of the Term of Employment pursuant to this **Section 5.5(a)** (that is not a termination under **Section 5.6**) by the Executive without Good Reason, the Corporation shall pay to the Executive his Base Salary to the date of termination. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

b. Upon termination of the Term of Employment pursuant to this **Section 5.5** (that is not a termination under **Section 5.6**) by the Executive for Good Reason, subject to Section 5.7 below, the Corporation shall pay to the Executive the same amounts that would have been payable by the Corporation to the Executive under **Section 5.4** of this Agreement if the Term of Employment had been terminated by the Corporation without Cause. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused, paid personal days that have accumulated during the calendar year in which such termination occurs).

c. For purposes of this Agreement, "Good Reason" shall mean any of the following: (i) the assignment to the Executive of any duties inconsistent in any respect with the Executive's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as contemplated by **Section 1.2** of this Agreement, or any other action by the Corporation which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Corporation promptly after receipt of notice thereof given by the Executive; (ii) any failure by the Corporation to comply with any of the provisions of **Article 3** of

this Agreement, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and which is remedied by the Corporation promptly after receipt of notice thereof given by the Executive; (iii) any purported termination by the Corporation of the Executive's employment otherwise than for Cause pursuant to **Section 5.1**, or by reason of the Executive's disability pursuant to **Section 5.2** of this Agreement; (iv) the relocation of Executive's principal place of employment by more than thirty (30) miles; or (v) the voluntary resignation of Executive following the determination by Executive, and ninety-day notice to the Corporation that, in his reasonable discretion, Executive's continued employment by the Corporation is a) no longer critical to the success of the Corporation; and b) is no longer aligned with Executive's business or personal goals, *provided however*, that in order to effect resignation for Good Reason under (i), (ii), (iii), or (iv) above, all of the following must occur: (x) Executive must provide the Corporation with written notice within the sixty-day period following the event(s) giving rise to either (i), (ii), (iii) or (iv) of Executive's intent to voluntarily resign his employment for Good Reason (y) such event is not remedied by within thirty (30) days following the Corporation's receipt of such written notice; and (z) Executive's resignation is effective not later than thirty (30) days after the expiration of such thirty (30) day cure period.

#### 5.6 Change in Control of the Corporation.

a. Payments. In the event that a termination of employment without Cause or for Good Reason occurs following a Change in Control (as defined in paragraph (b) of this **Section 5.6**) in the Corporation, and subject to Section 5.7 below, the Corporation shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination, (ii) pay to the Executive the Incentive Compensation, if any, not yet paid to the Executive for any year prior to such termination, at such time as the Incentive Compensation otherwise would have been payable to the Executive, (iii) pay to the Executive within thirty (30) days of the termination of his employment hereunder, a single lump sum payment equal to 200% of the Executive's annual Base Salary at the time of the termination of the Executive's employment with the Corporation, less applicable withholdings and deductions, and (iv) if Executive is participating in the Corporation's group health insurance plans on the effective date of termination, and Executive timely elects and remains eligible for continued coverage under COBRA, or, if applicable, state or local insurance laws, the Corporation shall reimburse Executive's COBRA premiums for eighteen (18) months following the effective date of termination. The Corporation shall have no further liability hereunder (other than for (x) reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and (y) payment of compensation for unused paid, personal days that have accumulated during the calendar year in which such termination occurs).

b. For purposes of this Agreement, the term "Change in Control" shall mean approval by the shareholders of the Corporation and consummation of (i) a reorganization, merger, consolidation or other form of corporate transaction or series of transactions, in each case, with respect to which persons who were the shareholders of the Corporation immediately prior to such reorganization, merger or consolidation or other transaction do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities,

in substantially the same proportions as their ownership immediately prior to such reorganization, merger, consolidation or other transaction, or (ii) a liquidation or dissolution of the Corporation or (iii) the sale of all or substantially all of the assets of the Corporation (unless such reorganization, merger, consolidation or other corporate transaction, liquidation, dissolution or sale is subsequently abandoned).

5.7 Release and Board Resignation Requirement. The Severance Benefits are conditional upon (i) Executive's delivering to the Company and making effective and irrevocable a general release of all claims in favor of the Company, in a form reasonably acceptable to the Company (the "Release"), which release shall be effective not later than 45 days following the date of the applicable termination or resignation and (ii) Executive's complying with the Release including any cooperation, non-disparagement or confidentiality provisions contained therein and continuing to comply with Executive's obligations under the terms of this Agreement, including the non-solicit and non-compete provisions thereof, and the terms of the Protection Agreement.

5.8 Survival. The provisions of this **Article 5** shall survive the termination of this Agreement, as applicable.

6. Restrictive Covenants.

6.1 Non-Competition.

a. At all times while the Executive is employed by the Corporation and for a two (2) year period after the termination of the Executive's employment with the Corporation for any reason other than by the Corporation without Cause (as defined in **Section 5.1** hereof) or by the Executive for Good Reason (as defined in **Section 5.5** hereof), the Executive shall not, directly or indirectly, engage in or have any interest in any sole proprietorship, partnership, corporation or business or any other person or entity (whether as an Executive, officer, director, partner, agent, security holder, creditor, consultant or otherwise) that directly or indirectly (or through any affiliated entity) engages in competition with the Corporation (for this purpose, any business that engages in the drug development business utilizing those specific pharmaceutical compounds developed, licensed or owned by the Corporation or any of its subsidiaries during his term of employment to date of Executive's Termination shall be deemed to be in competition with the Corporation); provided that such provision shall not apply to the Executive's ownership of Common Stock of the Corporation or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities exchange or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control or, more than five percent of any class of capital stock of such corporation.

b. Upon termination of the Term of Employment pursuant to **Section 5.5** by the Executive for Good Reason, the Executive for a period of six (6) months shall not, directly or indirectly, engage in or have any interest in any sole proprietorship, partnership, corporation or

business or any other person or entity (whether as an Executive, officer, director, partner, agent, security holder, creditor, consultant or otherwise) that directly or indirectly (or through any affiliated entity) engages in competition with the Corporation (for this purpose, any business in the hyperhidrosis market or that engages in the drug development business utilizing those specific pharmaceutical compounds developed, licensed or owned by the Corporation or any of its subsidiaries during his term of employment to date of Executive's Termination shall be deemed to be in competition with the Corporation); provided that such provision shall not apply to the Executive's ownership of Common Stock of the Corporation or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities exchange or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control or, more than five percent of any class of capital stock of such corporation.

6.2 Nondisclosure. The Executive shall not at any time divulge, communicate or use to the detriment of the Corporation or for the benefit of any other person or persons, or misuse in any way, any Confidential Information (as hereinafter defined) pertaining to the business of the Corporation. Any Confidential Information or data now or hereafter acquired by the Executive with respect to the business of the Corporation (which shall include, but not be limited to, information concerning the Corporation's business plan, financial condition, prospects, technology, customers, suppliers, sources of leads and methods of doing business) shall be deemed a valuable, special and unique asset of the Corporation that is received by the Executive in confidence and as a fiduciary, and Executive shall remain a fiduciary to the Corporation with respect to all of such information. For purposes of this Agreement, "Confidential Information" means information disclosed to the Executive or known by the Executive as a consequence of or through his employment by the Corporation (including information conceived, originated, discovered or developed by the Executive) prior to or after the date hereof, and not generally known, about the Corporation or its business. Notwithstanding the foregoing, nothing herein shall be deemed to restrict the Executive from disclosing Confidential Information to the extent required by law.

6.3 Non-solicitation of Executives and Clients. At all times while the Executive is employed by the Corporation and for a two (2) year period after the termination of the Executive's employment with the Corporation for any reason, the Executive shall not, directly or indirectly, for himself or for any other person, firm, corporation, partnership, association or other entity (a) employ or attempt to employ or enter into any contractual arrangement with any Executive or former Executive of the Corporation, unless such Executive or former Executive has not been employed by the Corporation for a period in excess of six months, and/or (b) call on or solicit any of the actual or targeted prospective clients of the Corporation on behalf of any person or entity in connection with any business competitive with the business of the Corporation, nor shall the Executive make known the names and addresses of such clients or any information relating in any manner to the Corporation's trade or business relationships with such customers, other than in connection with the performance of Executive's duties under this Agreement.

6.4 Books and Records. All books, records, and accounts relating in any manner to the business of the Corporation, customers, clients or prospects of the Corporation, reports documents analyses or any information whether prepared by the Executive or otherwise coming into the Executive's possession, shall be the exclusive property of the Corporation and shall be returned immediately to the Corporation on termination of the Executive's employment hereunder or on the Corporation's request at any time.

6.5 Definition of Corporation. Solely for purposes of this **Article 6**, the term "Corporation" also shall include any existing or future subsidiaries of the Corporation that are operating during the time periods described herein and any other entities that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with the Corporation during the periods described herein.

6.6 Acknowledgment by Executive. The Executive acknowledges and confirms that (a) the restrictive covenants contained in this **Article 6** are reasonably necessary to protect the legitimate business interests of the Corporation, and (b) the restrictions contained in this **Article 6** (including without limitation the length of the term of the provisions of this **Article 6**) are not overbroad, overlong, or unfair and are not the result of overreaching, duress or coercion of any kind. The Executive further acknowledges and confirms that his full, uninhibited and faithful observance of each of the covenants contained in this **Article 6** will not cause him any undue hardship, financial or otherwise, and that enforcement of each of the covenants contained herein will not impair his ability to obtain employment commensurate with his abilities and on terms fully acceptable to him or otherwise to obtain income required for the comfortable support of him and his family and the satisfaction of the needs of his creditors. The Executive acknowledges and confirms that his special knowledge of the business of the Corporation is such as would cause the Corporation serious injury or loss if he were to use such ability and knowledge to the benefit of a competitor or were to compete with the Corporation in violation of the terms of this **Article 6**. The Executive further acknowledges that the restrictions contained in this **Article 6** are intended to be, and shall be, for the benefit of and shall be enforceable by, the Corporation's successors and assigns.

6.7 Reformation by Court. In the event that a court of competent jurisdiction shall determine that any provision of this **Article 6** is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this **Article 6** within the jurisdiction of such court, such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

6.8 Extension of Time. If the Executive shall be in violation of any provision of this **Article 6**, then each time limitation set forth in this **Article 6** shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Corporation seeks injunctive relief from such violation in any court, then the covenants set forth in this **Article 6** shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Executive.

6.9 Survival. The provisions of this **Article 6** shall survive the termination of this Agreement, as applicable.

7 . Mediation. In the event a dispute arises out of or relates to this Agreement, or the breach thereof, and if the dispute cannot be settled through negotiation, the parties hereby agree first to attempt in good faith to settle the dispute by mediation administered by the American Arbitration Association under its Employment Mediation Rules before resorting to litigation or some other dispute resolution procedure.

8 . Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Boulder County, Colorado in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association then in effect (except to the extent that the procedures outlined below differ from such rules or the parties agree otherwise). Within thirty (30) days after written notice by either party has been given that a dispute exists and that arbitration is required, each party must select an arbitrator and those two arbitrators shall promptly, but in no event later than thirty (30) days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The cost and expenses of the arbitration and of enforcement of any award in any court shall be borne by the Corporation. The cost of any attorney fees shall be borne by each party individually, unless the payment of such fees is awarded to the prevailing party by the arbitrators. If advances are required, each party will advance one-half of the estimated fees and expenses of the arbitrators. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to obtain an injunction to protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

9 . Assignment. This Agreement is personal in nature and accordingly may not be assigned by the Executive, in whole or in part, without the prior written consent of the Corporation, which may be withheld in its sole discretion. The Corporation may, in its sole discretion, assign this Agreement and all of its rights, benefits and obligations hereunder, whether by agreement or by operation of law.

10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Colorado without regard to conflict of laws issues.

11. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Corporation (or any of its affiliates) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Corporation and the Executive.

12. Notices: All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed e-mail or facsimile transmission addressed as set forth herein. Notices personally delivered, sent by e-mail or facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed

given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) days after deposit in the U.S. mail. Notice shall be sent (i) if to the Corporation, addressed to Brickell Biotech, Inc., 5777 Central Avenue, Suite 102, Boulder, CO 80301, Attention: Chairman of the Board, and (ii) if to the Executive, to his address as reflected on the payroll records of the Corporation, or to such other address as either party hereto may from time to time give notice of to the other.

13. Benefits: Binding Effect. This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where applicable, assigns, including, without limitation, any successor to the Corporation, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

14. Severability. The invalidity of any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, or section or sections had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area, which would cure such invalidity.

15. Waivers. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

16. Damages. Nothing contained herein shall be construed to prevent the Corporation or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. In the event that either party hereto brings suit for the collection of any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the party found to be at fault shall pay all reasonable court costs and attorneys fees of the other.

17. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

18. No Third Party Beneficiary. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Corporation, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and assigns, any rights or remedies under or by reason of this Agreement.

19. Indemnification. Subject to limitations imposed by law, the Corporation shall defend, indemnify and hold harmless the Executive to the fullest extent permitted by law from and against any and all claims, damages, expenses (including attorneys fees), judgments, penalties, fines, settlements, and all other liabilities incurred or paid by him in connection with the investigation, defense, prosecution, settlement or appeal of any threatened, pending or completed action, suit or

proceeding, whether civil, criminal, administrative or investigative and to which the Executive was or is a party or is threatened to be made a party by reason of the fact that the Executive is or was an officer, Executive or agent of the Corporation, or by reason of anything done or not done by the Executive in any such capacity or capacities, provided that the Executive acted in good faith, in a manner that was not grossly negligent or constituted willful misconduct and in a manner he reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The Corporation also shall pay any and all expenses (including attorney's fees) incurred by the Executive as a result of the Executive being called as a witness in connection with any matter involving the Corporation and/or any of its officers or directors. The provisions of this **Section 19** shall survive the termination of this Agreement.

20. Section 409A.

20.1 General Compliance. This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended, ("Section 409A"), or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Corporation makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Corporation be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

20.2 Specified Employees. Notwithstanding any other provision of this Agreement, if any payment or benefit provided to the Executive in connection with his termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Executive is determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of the Termination Date or, if earlier, on the Executive's death (the "Specified Employee Payment Date"). The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date and interest on such amounts calculated based on the applicable federal rate published by the Internal Revenue Service for the month in which the Executive's separation from service occurs shall be paid to the Executive in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

20.3 Reimbursements. To the extent required by Section 409A, each reimbursement or in-kind benefit provided under this Agreement shall be provided in accordance with the following:

(a) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year;

(b) any reimbursement of an eligible expense shall be paid to the Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred; and

(c) any right to reimbursements or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit.

20.4 Tax Gross-ups. Any tax gross-up payments provided under this Agreement shall be paid to the Executive on or before December 31 of the calendar year immediately following the calendar year in which the Executive remits the related taxes.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first above written.

Corporation:      Executive:

**BRICKELL BIOTECH, INC.**

A Delaware corporation

By: /s/ Reginal Hardy  
Reginal Hardy, CEO

By: /s/ Andrew Sklawer  
Andrew Sklawer, Individually

**AMENDED AND RESTATED EMPLOYMENT AGREEMENT**

**THIS AMENDED AND RESTATED EMPLOYMENT AGREEMENT** (“Agreement”) is made this August 1, 2016 (“Effective Date”) by and between **BRICKELL BIOTECH, INC.**, a Delaware corporation with a business address located at 2600 Southwest Third Avenue, Ste. 300, Miami, Florida 33129 (the “Corporation”), and **DEEPAK CHADHA**, a Massachusetts resident, with an address of 9 Dutchess Road, Franklin, MA 02038 (the “Employee”).

**RECITALS:**

**WHEREAS**, the Employee possesses substantial experience in the field of pharmaceuticals and business;

**WHEREAS**, the Corporation currently employs Employee as Senior Vice President, Global Regulatory Affairs of the Corporation pursuant to the terms of the Employment Agreement dated December 23, 2015 (the “Original Employment Agreement”);

**WHEREAS**, the Corporation and Employee desire to amend and restate the Original Employment Agreement in its entirety with this Agreement.

**WHEREAS**, the Employee is willing to continue to make his services available to the Corporation and on the terms and conditions hereinafter set forth and as amended and restated by this Agreement.

**NOW, THEREFORE**, in consideration of the recitals, premises and mutual covenants set forth herein, the parties agree as follows:

1. Employment.

1.1 Employment and Term. The Corporation hereby agrees to employ the Employee and the Employee hereby agrees to serve the Corporation on the terms and conditions set forth herein.

1.2 Duties of Employee. During the Term of Employment under this Agreement, the Employee shall serve as Chief Regulatory, Preclinical and Quality Compliance Officer, satisfactorily completing the responsibilities set forth in further detail in Attachment A hereto (“**Attachment A**”). Additionally, Employee shall diligently perform all other services and shall exercise such power and authority as may from time to time be delegated to him by the Corporation. The foregoing shall not limit his right to be involved in other not-for-profit, civic or charitable activities nor limit the Employee’s right to serve as an advisor or board member for other non-competing corporate or not-for-profit entities, or as otherwise permitted by the Board of Directors of the Corporation (the “Board”).

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2. Term.

2.1 Initial Term. Notwithstanding the Effective Date, this Agreement shall commence (the "Initial Term") on January 8th, 2016 (the "Commencement Date") and expire three (3) years from the Commencement Date unless sooner terminated in accordance with **Section 5** hereof.

2.2 Renewal Terms. At the end of the Initial Term, the Term of Employment shall automatically renew for successive one year (1) year terms (subject to earlier termination as provided in **Section 5** hereof) unless the Corporation or the Employee delivers written notice to the other at least ninety (90) days prior to the Expiration Date of its or his election not to renew the Term of Employment or the parties mutually determine otherwise.

2.3 Term of Employment and Expiration Date. The period during which the Employee shall be employed by the Corporation pursuant to the terms of this Agreement is sometimes referred to in this Agreement as the "Term of Employment", and the date on which the Term of Employment shall expire (including the date on which any renewal term shall expire), is sometimes referred to in this Agreement as the "Expiration Date".

3. Compensation.

3.1 Base Salary. The Corporation shall pay Employee a base salary at the annual rate of Two Hundred Eighty Thousand Dollars (\$280,000.00) (the "Base Salary") commencing September 1, 2016 and running through the Term of Employment. All salary is payable subject to standard federal and state payroll withholding requirements in accordance with Corporation's standard payroll practices. The Corporation agrees to undertake a salary and bonus review on an annual basis with adjustments to be made by management in conformity with the achievement of performance goals and objectives.

3.2 Bonuses.

a. Discretionary Bonus. The Corporation expects to pay Employee a discretionary performance bonus target of twenty-five percent (25%) of Base Salary, to be due and payable on an annual basis, upon terms to be determined, provided nothing herein shall be a guarantee of any amount of bonus, or any bonus at all. The bonus, if any, is at the discretion of the Corporation based on factors as the Corporation may determine. Such performance bonus is subject to standard federal and state payroll withholding requirements in accordance with Corporation's standard payroll practices and is hereby incorporated into this Agreement by reference. The date of such bonus, if any is provided, is expected to occur no later than two months following the end of a calendar year.

c. Incentive Compensation. As part of that Consulting Agreement dated September 1, 2015 by and between Employee and Corporation (the "Consulting Agreement"), and on September 1, 2015, the Corporation granted Employee options to purchase 10,000 shares of common stock of the Corporation, vesting as follows: 1,250 shares vested immediately on the date of grant (September 1, 2015), 3,750 will vest one year from the grant date of such options, 2,500

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shares two years from the grant date of such options and 2,500 shares three years from the grant date of such options at \$4.20. As part of the Original Employment Agreement, and on December 23, 2015, the Corporation granted Employee options to purchase 30,000 shares of common stock of the Corporation, vesting as follows: 5,000 shares immediately on the date of grant (December 23, 2015), 8,333 shares one year from the grant date of such options, 8,333 shares two years from the grant date of such options and 8,334 shares three years from the grant date of such options at \$4.20. Notwithstanding the foregoing, 2,000 shares of the most recent unvested tranche of unvested options from the grant on December 23, 2015 are subject to automatic vesting upon the initiation of the first BBI-4000 Phase 3 clinical trial (i.e. the enrollment of the first patient in such study). Furthermore, on June 7, 2016, the Corporation granted Employee options to purchase 5,000 shares of common stock of the Corporation, vesting as follows: 1,666 shares will vest one year from June 7, 2016, 1,667 shares two years from the grant date of such options and 1,667 shares three years from the grant date of such options at \$4.20. All such grants and vesting shall be subject to conditions of continued employment by the Corporation and the related terms and conditions applicable to all participants in the Brickell Biotech, Inc. 2015 Equity Incentive Plan. Notwithstanding the foregoing, after March 1, 2017, any unvested Options shall vest in full upon the date of completion of a Change in Control of the Corporation, if any Change of Control occurs, and as such term is defined in Section 5.6(b) of the Agreement.

d. Special Bonuses. The Corporation shall pay Employee a one-time special bonus of Fifty Thousand Dollars (\$50,000.00) to be due and payable within 30 days of the Corporation's receipt of that Phase 3 Clinical Trial milestone payment by Kaken Pharmaceutical Co, LTD. ("Kaken") as further set forth in that License, Development and Commercialization Agreement by and between the Corporation and Kaken and a one-time special bonus of Twenty- Five Thousand Dollars (\$25,000.00) upon the initiation of the first BBI-4000 Phase 3 clinical trial (i.e. the enrollment of the first patient in such study). Such bonuses are subject to standard federal and state payroll withholding requirements in accordance with Corporation's standard payroll practices and is hereby incorporated into this Agreement by reference.

Any bonuses payable pursuant to this **Section 3.2** are sometimes hereinafter referred to as "Incentive Compensation" and shall be paid by the Corporation to the Employee within two (2) months after the end of the Bonus Period for which it is payable.

For avoidance of doubt, the Consulting Agreement is no longer effective as of January 8, 2016.

4. Expense Reimbursement and Other Benefits.

4.1 Reimbursement of Expenses. Upon the submission of proper substantiation by the Employee, and subject to such rules and guidelines as the Corporation may from time to time adopt, the Corporation shall reimburse the Employee for all reasonable expenses actually paid or incurred by the Employee during the Term of Employment in the course of and pursuant to the business of the Corporation. The Employee shall account to the Corporation in writing for all expenses for which reimbursement is sought and shall supply to the Corporation copies of all relevant invoices, receipts or other evidence reasonably requested by the Corporation.

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4.2 Compensation/Benefit Programs. The Corporation currently permits its full time employees to enroll in the Corporation's healthcare plan, and the Corporation pays the costs of the related premiums, however this policy is subject to change and the Corporation may end this practice and not pay for all or any of its full time employees' healthcare premiums and/or may terminate its healthcare plans at any time. Therefore, currently, and during the Term of Employment, Corporation will directly pay the costs of your medical and vision and dental insurance premiums so long as you enroll in the Corporation's health care and vision/dental plan. However, Corporation reserves the right to eliminate and/or modify all or a portion of this payment or participation in any plan at any time, upon notice to you. In addition, Corporation will reimburse you for pre-approved Corporation expenses as set forth in the Corporation policy manual and as the manual (or related policies) may be adjusted from time to time.

4.3 Location. As part of your employment, Employee agrees to spend a minimum of 5 business days per month in the Corporation's office (Miami, FL or Boulder, CO), as requested by Corporation, and/or at a mutually agreed upon off-site premise, at the reasonable expense of Corporation and subject to its expense and travel policy.

4.4 Other Benefits.

a. Personal Days. The Employee shall be entitled to twenty eight (28) paid personal days annually, including vacation days, sick days and time off for personal matters. Such personal days are to be taken at such times as the Employee and the Corporation shall mutually determine. Personal days shall not interfere with the duties required to be rendered by the Employee hereunder. Additionally, the Employee shall be entitled to paid holidays as the Corporation in its standard holiday schedule may observe.

b. Association Dues. During the Term of this Agreement, the Corporation may pay reasonable initiation fees and dues payable in connection with the Employee's membership(s) in those clubs and activities that in the opinion of the Board are in furtherance and directly related to the active conduct of the Corporation's business and are consistent with sound financial and tax planning.

c. Miscellaneous Benefits. The Corporation agrees to specifically reimburse the Employee for (i) the cost of a cell phone and (ii) any such additional benefits, if any, as the Board of Directors of the Corporation shall from time to time determine.

5. Termination.

5.1 Termination for Cause. The Corporation shall at all times have the right, upon written notice to the Employee, to terminate the Term of Employment, for Cause. For purposes of this Agreement, the term "Cause" shall mean: (i) an action or omission of the Employee which constitutes a willful and material breach of, or failure or refusal (other than by reason of his disability) to perform his duties under this Agreement or any other agreements, including, without limitation, the Company Protection Agreement, between the parties which is not cured within fifteen (15) days after receipt by the Employee of written notice of same; (ii) fraud, embezzlement, misappropriation of funds or breach of trust in connection with his services hereunder; (iii) conviction of any crime

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which involves dishonesty or a breach of trust; or (iv) gross negligence in connection with the performance of the Employee's duties hereunder, which is not cured within fifteen (15) days after written receipt by the Employee of written notice of same. Any termination for Cause shall be made in writing to the Employee, which notice shall set forth in detail all acts or omissions upon which the Corporation is relying for such termination.

The Employee shall have the right to address the Board regarding the acts set forth in the notice of termination. Upon any termination pursuant to this **Section 5.1**, the Corporation shall pay to the Employee his Base Salary to the date of termination. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.2 Disability. The Corporation shall at all times have the right, upon written notice to the Employee, to terminate the Term of Employment, if the Employee shall become entitled to benefits under the Corporation's disability plan as then in effect, or, if the Employee shall as the result of mental or physical incapacity, illness or disability, become unable to perform his obligations hereunder for a period of 90 days in any 12-month period. The Corporation shall have sole discretion based upon competent medical advice to determine whether the Employee continues to be disabled. Upon any termination pursuant to this **Section 5.2**, the Corporation shall

(i) pay to the Employee any unpaid Base Salary through the effective date of termination specified in such notice, (ii) pay to the Employee his accrued but unpaid Incentive Compensation, if any, for any Bonus Period ending on or before the date of termination of the Employee's employment with the Corporation, (iii) pay to the Employee a severance payment equal to six (6) months of the Employee's Base Salary at the time of the termination of the Employee's employment with the Corporation, such amount to be paid in the manner and at such times as the Base Salary otherwise would have been payable to the Employee. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.3 Death. Upon the death of the Employee during the Term of Employment, the Corporation shall (i) pay to the estate of the deceased Employee any unpaid Base Salary through the Employee's date of death, (ii) pay to the estate of the deceased Employee his accrued but unpaid Incentive Compensation, if any, for any Bonus Period ending on or before the Employee's date of death, (iii) continue to pay to the estate of the deceased Employee the Base Salary the Employee was receiving prior to his death under **Section 3.1** hereof for a period of three (3) months following the Employee's death, in the manner and at such times as the Base Salary otherwise would have been payable to the Employee. In addition, in the event that the Employee's spouse and/or children shall be eligible and shall elect to receive COBRA coverage under the Corporation's health plans, the Corporation shall pay the premium payments applicable to such COBRA coverage during the applicable COBRA continuation coverage period. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date

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of the Employee's death, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.4 Termination Without Cause. At any time the Corporation shall have the right to terminate the Term of Employment by written notice to the Employee. Upon any termination pursuant to this **Section 5.4** (that is not a termination under any of **Sections 5.1, 5.2, 5.3, 5.5 or 5.6**, the Corporation shall (i) pay to the Employee any unpaid Base Salary through the effective date of termination specified in such notice, (ii) pay to the Employee the accrued but unpaid Incentive Compensation, if any, for any Bonus Period ending on or before the date of the termination of the Employee's employment with the Corporation, (iii) continue to pay the Employee's Base Salary through six (6) months from the date of termination hereunder (the "Continuation Period"), in the manner and at such time as the Base Salary otherwise would have been payable to the Employee. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.5 Termination by  
Employee.

a. The Employee shall at all times have the right, upon ninety (90) days written notice to the Corporation, to terminate the Term of Employment.

b. Upon termination of the Term of Employment pursuant to this **Section 5.5** (that is not a termination under **Section 5.6**) by the Employee without Good Reason, the Corporation shall (i) pay to the Employee any unpaid Base Salary through the effective date of termination specified in such notice and (ii) pay to the Employee his accrued but unpaid Incentive Compensation, if any, for any Bonus Period ending on or before the termination of Employee's employment with the Corporation. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused, paid personal days that have accumulated during the calendar year in which such termination occurs).

c. Upon termination of the Term of Employment pursuant to this **Section 5.5** (that is not a termination under **Section 5.6**) by the Employee for Good Reason, the Corporation shall pay to the Employee the same amounts that would have been payable by the Corporation to the Employee under **Section 5.4** of this Agreement if the Term of Employment had been terminated by the Corporation without Cause. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused, paid personal days that have accumulated during the calendar year in which such termination occurs).

a. For purposes of this Agreement, "Good Reason" shall mean (i) the assignment to the Employee of duties substantially inconsistent with the Employee's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as contemplated by Section 1.2 of this Agreement, or any other action by the Corporation which results

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in a substantial diminution in such position, authority, duties or responsibilities, provided that, in order to claim relief under this Section, Employee must (1) give Corporation written notice of such Good Reason and (2) allow Corporation 15 days to cure following notice of same from Employee; (ii) any failure by the Corporation to comply with any of the provisions of Article 3 of this Agreement, provided that, in order to claim relief under this Section, Employee must (1) give Corporation written notice of such Good Reason and (2) allow Corporation 15 days to cure following notice of same from Employee; (iii) any purported termination by the Corporation of the Employee's employment otherwise than for Cause pursuant to Section 5.1, or by reason of the Employee's disability pursuant to Section 5.2 of this Agreement, prior to the Expiration Date. A change in job title or reporting lines will not alone qualify as Good Reason. In addition, with regard to (i) above, a diminution in such position, authority, duties or responsibilities for reasons of Cause shall not constitute Good Reason.

5.6 Change in Control of the Corporation.

b. Payments. In the event that a Change in Control (as defined in paragraph (b) of this **Section 5.6**) in the Corporation shall occur during the Term of Employment, the Corporation shall (i) (1) pay to the Employee any unpaid Base Salary through the effective date of termination, (2) pay to the Employee the Incentive Compensation, if any, not yet paid to the Employee for any year prior to such termination, at such time as the Incentive Compensation otherwise would have been payable to the Employee, (3) pay to the Employee his Termination Year Bonus, if any, at the time provided in **Section 3.2** hereof, and (4) pay to the Employee within thirty (30) days of the termination of his employment hereunder, a single lump sum payment equal to 50% of the Employee's annual Base Salary at the time of the termination of the Employee's employment with the Corporation, less applicable withholdings and deductions and (ii) if Employee is participating in the Corporation's group health insurance plans on the effective date of termination, and Employee timely elects and remains eligible for continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), or, if applicable, state or local insurance laws, the Corporation shall pay that portion of the Employee's COBRA premiums that the Corporation was paying prior to the effective date of termination for six (6) months following the effective date of termination or for the continuation period for which the Employee is eligible, whichever is shorter. The Corporation shall have no further liability hereunder (other than for (x) reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and (y) payment of compensation for unused paid, personal days that have accumulated during the calendar year in which such termination occurs).

c. For purposes of this Agreement, the term "Change in Control" shall mean approval by the shareholders of the Corporation of (i) a reorganization, merger, consolidation or other form of corporate transaction or series of transactions, in each case, with respect to which persons who were the shareholders of the Corporation immediately prior to such reorganization, merger or consolidation or other transaction do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities, in substantially the same proportions as their ownership immediately prior to such reorganization, merger, consolidation or other transaction, or (ii) a liquidation or dissolution of the Corporation or (iii) the sale of all or

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substantially all of the assets of the Corporation (unless such reorganization, merger, consolidation or other corporate transaction, liquidation, dissolution or sale is subsequently abandoned).

5.7 Resignation. Upon any termination of employment pursuant to this **Article 5**, the Employee shall be deemed to have resigned as an officer, and if he was then serving as a director of the Corporation, as a director, and if required by the Board, the Employee hereby agrees to immediately execute a resignation letter to the Board.

5.8 Survival. The provisions of this **Article 5** shall survive the termination of this Agreement, as applicable.

6. Restrictive  
Covenants.

6.1 Non-Competition. At all times while the Employee is employed by the Corporation and for a two (2) year period after the termination of the Employee's employment with the Corporation for any reason other than by the Corporation without Cause (as defined in **Section 5.1** hereof) or by the Employee for Good Reason (as defined in **Section 5.5** hereof), the Employee shall not, directly or indirectly, engage in or have any interest in any sole proprietorship, partnership, corporation or business or any other person or entity (whether as an Employee, officer, director, partner, agent, security holder, creditor, consultant or otherwise) that directly or indirectly (or through any affiliated entity) engages in competition with the Corporation (for this purpose, any business that engages in the drug development business utilizing those specific pharmaceutical compounds developed, licensed or owned by the Corporation or any of its subsidiaries during his term of employment to date of Employee's Termination shall be deemed to be in competition with the Corporation); provided that such provision shall not apply to the Employee's ownership of Common Stock of the Corporation or the acquisition by the Employee, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities exchange or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Employee does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control or, more than five percent of any class of capital stock of such corporation.

6.2 Nondisclosure. The Employee shall not at any time divulge, communicate or use to the detriment of the Corporation or for the benefit of any other person or persons, or misuse in any way, any Confidential Information (as hereinafter defined) pertaining to the business of the Corporation. Any Confidential Information or data now or hereafter acquired by the Employee with respect to the business of the Corporation (which shall include, but not be limited to, information concerning the Corporation's business plan, financial condition, prospects, technology, customers, suppliers, sources of leads and methods of doing business) shall be deemed a valuable, special and unique asset of the Corporation that is received by the Employee in confidence and as a fiduciary, and Employee shall remain a fiduciary to the Corporation with respect to all of such information. For purposes of this Agreement, "Confidential Information" means information disclosed to the Employee or known by the Employee as a consequence of or through his employment by the Corporation (including information conceived, originated, discovered or developed by the

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Employee) prior to or after the date hereof, and not generally known, about the Corporation or its business. Notwithstanding the foregoing, nothing herein shall be deemed to restrict the Employee from disclosing Confidential Information to the extent required by law.

6.3 Non-solicitation of Executives and Clients. At all times while the Employee is employed by the Corporation and for a two (2) year period after the termination of the Employee's employment with the Corporation for any reason, the Employee shall not, directly or indirectly, for himself or for any other person, firm, corporation, partnership, association or other entity (a) employ or attempt to employ or enter into any contractual arrangement with any Employee or former Employee of the Corporation, unless such Employee or former Employee has not been employed by the Corporation for a period in excess of six months, and/or (b) call on or solicit any of the actual or targeted prospective clients and/or partners of the Corporation on behalf of any person or entity in connection with any business competitive with the business of the Corporation, nor shall the Employee make known the names and addresses of such clients or any information relating in any manner to the Corporation's trade or business relationships with such customers, other than in connection with the performance of Employee's duties under this Agreement.

6.4 Books and Records. All books, records, and accounts relating in any manner to the business of the Corporation, customers, clients or prospects of the Corporation, reports documents analyses or any information whether prepared by the Employee or otherwise coming into the Employee's possession, shall be the exclusive property of the Corporation and shall be returned immediately to the Corporation on termination of the Employee's employment hereunder or on the Corporation's request at any time.

6.5 Definition of Corporation. Solely for purposes of this **Article 6**, the term "Corporation" also shall include any existing or future subsidiaries of the Corporation that are operating during the time periods described herein and any other entities that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with the Corporation during the periods described herein.

6.6 Acknowledgment by Employee. The Employee acknowledges and confirms that (a) the restrictive covenants contained in this **Article 6** are reasonably necessary to protect the legitimate business interests of the Corporation, and (b) the restrictions contained in this **Article 6** (including without limitation the length of the term of the provisions of this **Article 6**) are not overbroad, overlong, or unfair and are not the result of overreaching, duress or coercion of any kind. The Employee further acknowledges and confirms that his full, uninhibited and faithful observance of each of the covenants contained in this **Article 6** will not cause his any undue hardship, financial or otherwise, and that enforcement of each of the covenants contained herein will not impair his ability to obtain employment commensurate with his abilities and on terms fully acceptable to his or otherwise to obtain income required for the comfortable support of his and his family and the satisfaction of the needs of his creditors. The Employee acknowledges and confirms that his special knowledge of the business of the Corporation is such as would cause the Corporation serious injury or loss if he were to use such ability and knowledge to the benefit of a competitor or were to compete with the Corporation in violation of the terms of this **Article 6**. The Employee further acknowledges that the restrictions contained in this **Article 6** are intended to be, and shall be, for the benefit of and shall be enforceable by, the Corporation's successors and assigns.

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6.7 Reformation by Court. In the event that a court of competent jurisdiction shall determine that any provision of this **Article 6** is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this **Article 6** within the jurisdiction of such court, such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

6.8 Extension of Time. If the Employee shall be in violation of any provision of this **Article 6**, then each time limitation set forth in this **Article 6** shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Corporation seeks injunctive relief from such violation in any court, then the covenants set forth in this **Article 6** shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Employee.

6.9 Survival. The provisions of this **Article 6** shall survive the termination of this Agreement, as applicable.

7. Mediation. In the event a dispute arises out of or relates to this Agreement, or the breach thereof, and if the dispute cannot be settled through negotiation, the parties hereby agree first to attempt in good faith to settle the dispute by mediation administered by the American Arbitration Association under its Employment Mediation Rules before resorting to litigation or some other dispute resolution procedure.

8. Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Miami-Dade County, Florida in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association then in effect (except to the extent that the procedures outlined below differ from such rules or the parties agree otherwise). Within thirty (30) days after written notice by either party has been given that a dispute exists and that arbitration is required, each party must select an arbitrator and those two arbitrators shall promptly, but in no event later than thirty (30) days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The cost and expenses of the arbitration and of enforcement of any award in any court shall be borne equally by both parties. If advances are required, each party will advance one-half of the estimated fees and expenses of the arbitrators. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to obtain an injunction to protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

9. Assignment. This Agreement is personal in nature and accordingly may not be assigned by the Employee, in whole or in part, without the prior written consent of the Corporation, which may be withheld in its sole discretion. The Corporation may, in its sole discretion, assign this Agreement and all of its rights, benefits and obligations hereunder, whether by agreement or by operation of law.

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10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Florida without regard to conflict of laws issues.

12. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Employee and the Corporation (or any of its affiliates) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Corporation and the Employee.

13. Notices: All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed e-mail or facsimile transmission addressed as set forth herein. Notices personally delivered, sent by e-mail or facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) days after deposit in the U.S. mail. Notice shall be sent (i) if to the Corporation, addressed to Brickell Biotech, Inc., 2600 Southwest Third Avenue, Ste. 300, Miami, Florida 33129, Attention: Secretary, and (ii) if to the Employee, to his address as reflected on the payroll records of the Corporation, or to such other address as either party hereto may from time to time give notice of to the other.

14. Benefits; Binding Effect. This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where applicable, assigns, including, without limitation, any successor to the Corporation, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

15. Severability. The invalidity of any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, or section or sections had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area, which would cure such invalidity.

16. Waivers. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

17. Damages. Nothing contained herein shall be construed to prevent the Corporation or the Employee from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. In the event that either party hereto brings suit for the collection of any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the party found to be at fault shall pay all reasonable court costs and attorneys fees of the other.

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18. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

18. No Third Party Beneficiary. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Corporation, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and assigns, any rights or remedies under or by reason of this Agreement.

19. Indemnification. Subject to limitations imposed by law, the Corporation shall defend, indemnify and hold harmless the Employee to the fullest extent permitted by law from and against any and all claims, damages, expenses (including attorneys fees), judgments, penalties, fines, settlements, and all other liabilities incurred or paid by his in connection with the investigation, defense, prosecution, settlement or appeal of any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative and to which the Employee was or is a party or is threatened to be made a party by reason of the fact that the Employee is or was an officer, Employee or agent of the Corporation, or by reason of anything done or not done by the Employee in any such capacity or capacities, provided that the Employee acted in good faith, in a manner that was not grossly negligent or constituted willful misconduct and in a manner she reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The Corporation also shall pay any and all expenses (including attorney's fees) incurred by the Employee as a result of the Employee being called as a witness in connection with any matter involving the Corporation and/or any of its officers or directors. The provisions of this **Section 19** shall survive the termination of this Agreement.

**IN WITNESS WHEREOF**, the undersigned have executed this amended and restated Agreement as of the Effective Date above written.

Corporation:

Employee:

**BRICKELL BIOTECH, INC.**

A Delaware corporation

By: /s/ Patricia S. Walker

Patricia S. Walker MD, PhD

President and Chief Scientific Officer

By: /s/ Deepak Chadha

Deepak Chadha, Individually

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## ATTACHMENT "A"

### **Chief Regulatory, Preclinical and Quality Compliance Officer**

The **Chief Regulatory, Preclinical and Quality Compliance Officer** is responsible for providing strategic leadership and direction for all of Corporation's global product development projects, in addition to, overseeing the execution of activities to support the Corporation's registration goals. The **Chief Regulatory, Preclinical and Quality Compliance** will design, develop and execute long term strategies into short term goals for regulatory/clinical and CMC strategies, in alignment with department, company and commercial goals. The **Chief Regulatory, Preclinical and Quality Compliance** Affairs will report to the Chief Scientific Officer.

#### Key Responsibilities:

- This position will be expected to lead and collaborate with multiple internal stakeholders to ensure that all programs are implemented in accordance with project team strategies and in compliance with global regulatory agencies, and that overall business strategies are translated to guarantee optimal time to market for each of the Corporation's product candidates.

#### Specific Responsibilities:

- Serves as the global regulatory expert within the Corporation.
  - Coordinates and leads meetings with regulatory agencies.
  - Develops preclinical development strategies and policies.
  - Develops robust regulatory and compliance strategies and policies.
  - Ensures effective planning, preparation and submission of IND's, CTA's and NDA's in the U.S. and globally.
  - Develops, implements and assures quality and clinical quality assurance (CQA) policies are in place and followed.
  - Works closely with the CMC, clinical and project teams and partners with project team leaders to ensure all regulatory requirements are met, and all information needed for registration and on going product availability is produced.
  - Serves as the lead for the preclinical and regulatory sub-teams and represent preclinical and regulatory affairs on the project teams.
  - Builds, manages and effectively leads a team of preclinical, regulatory and compliance global professionals and/or consultants.
  - Establishes project related goals and monitors timelines.
  - Manages the preclinical, regulatory and compliance budgets, timelines, including staffing and hiring needs.
  - Establishes and manages relationships with external regulatory authorities and maintains correspondence/communication and other records of interactions.
  - Informs Corporation's senior management of changes in regulatory and compliance directives, guidance, and regulations.
  - Advises staff members and colleagues on regulatory matters and provides guidance in conducting studies that comply with FDA and global requirements.
  - Advises staff members and colleagues on quality and CQA compliance practices and provides guidance and monitoring to assure such practices are adhered to.
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August 28, 2019

Deepak Chadha  
9 Dutchess Road  
Franklin, MA 02038

Dear Mr. Chadha,

You are receiving this letter as an amendment to the employment agreement that you previously signed between you and Brickell Biotech, Inc., a Delaware corporation (the "Corporation") effective August 1, 2016 ("Employment Agreement"). All capitalized terms in this letter agreement not otherwise defined in this letter agreement are defined in the Employment Agreement. The Corporation desires to amend the Employment Agreement as noted below to clarify language in the Change in Control Section of the Employment Agreement as provided below.

First, effective as of the date of this letter agreement, the terms of Section 5.6 of the Employment Agreement are hereby deleted and replaced with the following:

5.6 Change in Control of the Corporation.

a. Payments. Upon termination of the Term of Employment due to a termination by the Corporation without Cause or by the Executive with Good Reason during the twenty-four (24) month period following a Change in Control (as defined in paragraph (b) of this Section 5.6), the Corporation shall (i) (1) pay to the Executive any unpaid Base Salary through the effective date of termination, (2) pay to the Executive the Incentive Compensation, if any, not yet paid to the Executive for any year prior to such termination, at such time as the Incentive Compensation otherwise would have been payable to the Executive, (3) pay to the Executive his Incentive Compensation, if any, at the time provided in Section 3.2 hereof that would otherwise be payable for the year in which such termination occurs, and (4) pay to the Executive within thirty (30) days of the termination of his employment hereunder, a single lump sum payment equal to 50% of the Executive's annual Base Salary at the time of the termination of the Executive's employment with the Corporation, less applicable withholdings and deductions (provided that if such payments of Base Salary would otherwise constitute deferred compensation subject to Section 409A, such payments shall be made at such time and in such form as required to comply with Section 409A), and (ii) if Executive is participating in the Corporation's group health insurance plans on the effective date of termination, and Executive timely elects and remains eligible for continued coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), or, if applicable, state or local insurance laws, the Corporation shall pay that portion of the Executive's COBRA premiums that the Corporation was paying prior to the effective date of termination for twelve (12) months following the effective date of termination or for the continuation period for which the Executive is eligible, whichever is shorter. The Corporation shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of Section 4.1, and payment of compensation for unused

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paid, personal days that have accumulated during the calendar year in which such termination occurs).

b. For purposes of this Agreement, the term “Change in Control” shall mean approval by the shareholders of the Corporation of (i) a reorganization, merger, consolidation or other form of corporate transaction or series of transactions, in each case, with respect to which persons who were the shareholders of the Corporation immediately prior to such reorganization, merger or consolidation or other transaction do not, immediately thereafter, own, directly or indirectly, more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company’s then outstanding voting securities, in substantially the same proportions as their ownership immediately prior to such reorganization, merger, consolidation or other transaction, or (ii) a liquidation or dissolution of the Corporation or (iii) the sale of all or substantially all of the assets of the Corporation (unless such reorganization, merger, consolidation or other corporate transaction, liquidation, dissolution or sale is subsequently abandoned).”

Second, by adding a new Section 20 in the Employment Agreement as follows:

20. Section 409A of the Code.

(a) General. The payments due under this Agreement are intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended (“Section 409A”) or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments of “nonqualified deferred compensation” provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. To the extent Section 409A applies, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments of “nonqualified deferred compensation” to be made under this Agreement by reason of a termination of employment shall only be made if such termination of employment constitutes a “separation from service” under Section 409A. Notwithstanding the foregoing, the Corporation makes no representations that the payments and benefits provided under this Agreement comply with Section 409A and in no event shall the Corporation be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Executive on account of non-compliance with Section 409A

( b ) Specified Employees. Notwithstanding any other provision of this Agreement, if at the time of Executive’s termination of employment, he is a “specified employee”, determined in accordance with Section 409A, any payments and benefits provided under this Agreement that constitute “nonqualified deferred compensation” subject to Section 409A that are provided to Executive on account of his separation from service shall not be paid until the first payroll date to occur following the six (6)-month anniversary of Executive’s termination date (“Specified Employee Payment Date”). The aggregate amount of any payments that would otherwise have been made during such six (6)-month period shall be paid in a lump sum on

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the Specified Employee Payment Date, with interest thereon at one-hundred percent (100%) of the applicable federal funds rate during such period, and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule. If Executive dies during the six (6)-month period, any delayed payments shall be paid to Executive's estate in a lump sum upon Executive's death.

(c) **Reimbursements.** To the extent required by Section 409A, each reimbursement or in-kind benefit provided under this Agreement shall be provided in accordance with the following: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year; (ii) any reimbursement of an eligible expense shall be paid to Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred; and (iii) any right to reimbursements or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit.

You agree and acknowledge that your Employment Agreement remains in full force and effect as amended by this letter agreement. You must sign and return this amendment no later than August 29, 2019. If you do not sign and return this amendment, your Employment Agreement shall remain in full force and effect as drafted without regard to the clarifying changes in this amendment.

Sincerely,

**Corporation:**

Brickell Biotech, Inc.

By:  /s/ Andrew Sklawer

Name: Andrew Sklawer

Title: COO

**Executive:**

/s/ Deepak Chadha

Date: August 28, 2019

**BRICKELL BIOTECH, INC.  
Letter Agreement**

July 10, 2018

Jose Breton  
2973 Bellmeade Way  
Longmont, CO 80503

Re: Brickell Biotech, Inc.  
Offer of Employment

Dear Mr. Breton:

Brickell Biotech, Inc., a Delaware corporation (“Brickell”) is pleased to offer you a position as Chief Accounting Officer. This letter agreement (“Agreement”) sets forth the basic terms and conditions of your at-will employment with Brickell as follows:

1. Responsibilities. Your responsibilities as Chief Accounting Officer are as further detailed in Attachment A to this Agreement. You will report to Brickell’s Chief Operating Officer and Chief Financial Officer or such other designated officer or employee of Brickell, as so determined by Brickell, and shall render professional services in accordance with the job requirements, specific operational directives and Brickell policy. As a material part of your employment relationship, you will be asked to ratify an applicable company protection agreement that sets forth provisions of confidentiality, non-competition and non-interference. An equal opportunity employer, Brickell will also ask you to acknowledge and assent to certain employment policies.
2. Effective Date/Start Date. The effective date of this Agreement shall be July 15, 2018 (“Effective Date”).
3. Salary. In consideration for your services following the Start Date, you shall be paid a salary of \$175,000.00 per annum (“Base Salary”), payable in bi-weekly installments consistent with Brickell’s payroll schedule, subject to applicable withholding and other taxes.
4. Performance Bonus. In addition to the Base Salary, you are eligible for a performance bonus, in Brickell’s sole discretion, of up to 25% of your Base Salary per annum (“Performance Bonus”), subject to applicable tax withholding, in accordance with the goals and objectives of Brickell, as it may establish from time to time, including in any bonus plan to be established. Nothing herein is a guarantee of any Performance Bonus at all.

1. Benefit Plans. Brickell currently permits its full time employees to enroll in its healthcare plan, and Brickell pays the costs of the related premiums, however this policy is subject to change and Brickell may end this practice and not pay for all or any of its full time employees' healthcare premiums and/or may terminate its healthcare plans at any time. Therefore, from the Start Date, and during your full time employment, Brickell will directly pay the costs of your medical and vision and dental insurance premiums so long as you enroll in Brickell's health care and vision/dental plan. However, Brickell reserves the right to eliminate all or a portion of this payment or participation in any plan at any time, upon notice to you. In addition, Brickell will reimburse you for pre-approved Brickell expenses as set forth in the Brickell policy manual and as the manual (or related policies) may be adjusted from time to time.
2. Location. As part of your employment, you agree to be based in Brickell's headquarters (5777 Central Ave. Suite 102, Boulder, CO 80301) on a full-time basis.
3. Paid Time-Off. You are eligible to take up to twenty-one (21) personal days per year to include vacation, sick days and personal time. Additionally, you shall be eligible for paid holidays in accordance with Brickell's holiday schedule.
4. Travel and Expenses. Upon the submission of proper substantiation by you, and subject to such rules and guidelines and policies as Brickell may from time to time adopt, Brickell shall reimburse you for all actual and reasonable travel expenses actually paid or incurred by you during the term of employment in the course of and pursuant to the business of Brickell. You agree to account to Brickell in writing for all expenses for which reimbursement is sought and shall supply to Brickell copies of all relevant invoices, receipts or other evidence reasonably requested by Brickell. In addition, Brickell agrees to specifically reimburse you for the reasonable cost of a cell phone, subject to written approval of plan and model.
5. Assumption of Risk. With this Agreement you acknowledge that you are assuming all risks of being employed in an at-will capacity by a development-stage pharmaceutical corporation with limited capital and resources, highly subject to the volatility of the marketplace. Any contrary representations that may have been made to you are superseded by this Agreement. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for Brickell, or which is in any way inconsistent with the terms of this Agreement.
6. Termination. Following the Effective Date, you are able to terminate your employment from Brickell with or without cause, but two (2) months written notice is appreciated. Likewise, Brickell may terminate your employment at any time with or without cause. If termination is without cause, Brickell will provide you with one hundred eighty (180) days of Base Salary severance. This Agreement shall not be construed as an agreement, either express or implied, to employ you for any stated

term, and shall in no way alter Brickell's policy of employment at-will, under which both Brickell and you remain free to end the employment relationship for any reason, at any time, with or without cause or notice. Although your job duties, title, compensation and benefits, as well as Brickell's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and an executive officer at Brickell that expressly states the intention to modify the at-will nature of your employment.

7. Disputes. Any dispute or controversy arising under or in connection with this Agreement (other than claims you may have for workers' compensation or unemployment insurance benefits), shall be submitted to final and binding arbitration in Boulder County, Colorado or a nearby county of the closest office of the American Arbitration Association ("AAA"), according to the provisions of its Employment Arbitration Rules ("Rules") then in effect (except to the extent that the procedures outlined below differ from such Rules or the parties agree otherwise) and the substantive law of the Federal Arbitration Act ("FAA"). In the event of any inconsistency between the FAA and the Rules, the FAA will prevail. The Rules are available on-line at [www.adr.org](http://www.adr.org) or upon request from Brickell.

Within thirty (30) days after written notice by either party has been given that a dispute exists and that arbitration is required, each party must select an arbitrator and those two arbitrators shall promptly, but in no event later than thirty (30) days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The arbitrators' decision shall be final, conclusive and binding on the parties to arbitration. The arbitrators' award may be enforced in any court of competent jurisdiction.

Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to obtain an injunction to protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

In the event that a court of competent jurisdiction shall determine that any provision of this Agreement is invalid or more restrictive than permitted under the governing law of such jurisdiction, then such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

**BY SIGNING THIS AGREEMENT, PARTIES ARE EACH GIVING UP ITS RIGHT TO A JURY TRIAL AND ITS RIGHT TO BRING OR PARTICIPATE IN A CLASS/COLLECTIVE ACTION, IF ANY, IN COURT. ALL CLAIMS WILL BE RESOLVED EXCLUSIVELY THROUGH ARBITRATION, AS**

**ALLOWED BY LAW.** Nothing in this Agreement shall be construed to prohibit you from filing a charge with or participating in any investigation or proceeding conducted by any governmental agency. Notwithstanding the foregoing, you agree to waive your right to recover monetary damages in any charge, complaint, or lawsuit filed by you or by anyone else on your behalf.

8. Choice of Law. This Agreement, and the terms of your employment, shall each be governed by and construed in accordance with the laws of the State of Colorado without regard to conflict of laws issues.
9. Headings. Any heading used in this Agreement is inserted for convenience and reference only and is to be ignored in the construction and interpretation of the provisions thereof.
10. Miscellaneous. To the extent that language contained in this Agreement is inconsistent with other agreements between Brickell and you, including the company protection agreement, the terms and conditions herein shall prevail.

[Remainder of Page Left Blank Intentionally]

If you believe this Agreement satisfactorily sets forth the terms and conditions as you understand them relative to your proposed employment arrangement, please sign and return this Agreement to Brickell. Upon receipt of your executed Agreement, Brickell will promptly forward information regarding additional aspects of the hiring process.

Thank you for your interest in Brickell. We very much look forward to working with you in the days ahead.

Sincerely,  
**BRICKELL BIOTECH INC.**

By: /s/ Andrew Sklawer  
Its: Chief Operating Officer

Date: July 10, 2018

**ACKNOWLEDGED AND AGREED:**

By: /s/ Jose Breton  
Jose Breton, individually

Date: July 10, 2018

## ATTACHMENT A TO AGREEMENT

### **Chief Accounting Officer / VP of Finance**

The Chief Accounting Officer is responsible for maximizing operating results through oversight of finance, accounting, tax, planning, risk management, and institutional financing. The Chief Accounting Officer will work closely with internal stakeholders to direct the strategic activities and priorities within the finance department. The Chief Accounting Officer will oversee and/or conduct all planning, forecasting, reporting, and management of financials, by providing on-going updates to key financial metrics, financial results to plan/forecast, and providing recommended course of action to such results. The Chief Accounting Officer will monitor and ensure proper capital/cash is in place to support the growth of the business by maintaining various financial models to predict the cash of the business overtime, as well as working with institutional investors/bankers to develop any needed financing structures.

#### Key Responsibilities:

- This position will be expected to lead and collaborate with multiple internal stakeholders to ensure the development of a financial and operational strategy, metrics tied to that strategy, and the ongoing development and monitoring of control systems designed to preserve company assets and report accurate financial results.

#### Specific Responsibilities:

- Monitor compliance with generally accepted accounting principles (GAAP) and company procedures
- Issue timely and complete financial statements under US GAAP
- Review, investigate, and correct errors and inconsistencies in financial entries, documents, and reports
- Assures compliance with federal, state, local and corporate policies, regulations and laws
- Evaluate current accounting practices and policies and drives continuous improvement
- Prepare financial statements and other reports to summarize and interpret current and projected company financial position. Ensure integrity of all financial information
- Coordinate monthly closing process
- Develop and implement various accounting procedures
- Track records, plan, and file all state and federal taxes, along with internal and external financial reports
- Develop, implement and upgrade financial systems and controls

- Direct and coordinate financial planning and budget management functions
- Recommend benchmarks for measuring the financial and operating performance
- Monitor and analyze monthly operating results against budget
- Oversee daily operations of the finance, accounting, and human resources departments
- Manage the preparation of financial outlooks and financial forecasts
- Prepare financial analysis for contract negotiations and investment decisions
- Assist in establishing short- and long-range departmental goals, objectives, policies, and operating procedures
- Design, establish, and maintain an organizational structure to effectively accomplish the departments goals and objectives
- Coordinate financial audits and provide recommendations for procedural improvements
- Direct and monitor the company's contract authorization process.

**EMPLOYMENT AGREEMENT**

**THIS EMPLOYMENT AGREEMENT** ("Agreement") is made this July 1, 2019 ("Effective Date") by and between **BRICKELL BIOTECH, INC.**, a Delaware Company with a business address located at 5777 Central Avenue, Suite 102, Boulder, CO 80301 (the "Company"), and **DAVID R. McAVOY**, an Indiana resident, with an address of 9326 Timber Crest Lane, Indianapolis, IN 46256 (the "Executive").

**RECITALS:**

**WHEREAS**, the Company seeks to employ Executive as General Counsel of the Company; and

**WHEREAS**, the Executive is willing to make his services available to the Company on the terms and conditions hereafter set forth.

**NOW, THEREFORE**, in consideration of the recitals, premises and mutual covenants set forth herein, the parties agree as follows:

1. Employment/Duties of Executive. During the Term of Employment under this Agreement, the Executive shall serve as General Counsel of the Company and satisfactorily complete the legal responsibilities commensurate with those duties and responsibilities of such senior management position. Executive shall report to the Company's Chief Executive Officer ("CEO"). Additionally, Executive shall perform diligently all other services Executive undertakes to assist the Company and shall exercise such power and authority as may from time to time be delegated to him by the Company's CEO. The foregoing shall not limit his right to be involved during business hours in not-for-profit, civic or charitable activities that would benefit the Company's reputation nor limit the Executive's right to serve as an advisor or board member for other non-competing corporate or not-for-profit entities, provided such outside activities do not conflict or impede Executive's performance of his duties and responsibilities to the Company. The Company reserves the right to request that the Executive resign from such outside roles in the event that the Company perceives that the Executive is devoting less than his full-time attention to his responsibilities at the Company.

2. Term/Consulting Period. Executive shall commence employment with the Company on July 1, 2019, unless the Company requests a different start date depending on its ability to complete financing and Executive agrees ("Start Date"); provided, however, that the Start Date in any circumstance will be at least two (2) weeks prior to the Company going public as determined by being listed on any national securities exchange for trading. The Executive's employment shall be at-will, meaning that the Executive or the Company may terminate the employment relationship at any time, with or without cause, and with or without notice, subject to severance provisions set forth below. The period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement is sometimes referred to in the Agreement as the "Term of Employment", and the date on which the Term of Employment shall expire is sometimes referred to in the Agreement as the "Termination Date").

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### 3. Compensation.

3.1 Base Salary. The Company shall pay Executive an initial base salary at the annual rate of Two Hundred Seventy Thousand Dollars (\$270,000.00) (the "Base Salary"). The Company shall review the Executive's Base Salary from time to time and the Company may, but shall not be required to, increase the Base Salary during the Term of Employment. However, Executive's Base Salary may not be decreased during the Term of Employment other than as part of an across-the-board salary reduction that applies in the same manner to all senior executives of the Company. All salary is payable subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices.

#### 3.2 Equity and Bonuses.

a. Annual Bonus. For each fiscal year of the Term of Employment ("Bonus Period"), Executive shall be eligible to receive an annual performance bonus of up to 30% of Base Salary (the "Performance Bonus"), based upon the achievement of mutually agreed performance milestones established by the Board, provided nothing herein shall be a guarantee of any amount of bonus, or any bonus at all. For 2019, the Bonus Period will be prorated from the Effective Date of this Agreement. In order to be eligible to receive a Performance Bonus, Executive must be employed for the full fiscal year to which the Performance Bonus applies, except for 2019 where a Performance Bonus will be calculated pursuant to the foregoing. Except as expressly provided herein, the Company shall have no obligation to provide Executive a pro rata portion of any Performance Bonus and no Performance Bonus is earned unless and until such a determination has been made by the Company at the conclusion of the applicable Bonus Period. Such Performance Bonus, if any, is subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices and is hereby incorporated into this Agreement by reference. Any bonus payable pursuant to this **Section 3.2** shall be paid by the Company to the Executive within two (2) months after the end of the applicable Bonus Period in which they are earned.

4. Equity. The Company shall recommend that the Board grant to Executive an incentive stock option to purchase, pursuant to an option agreement to be given to Executive upon signing this Agreement, 118,000 shares of Company Common Stock, (the "Common Stock") at a price per share equal to the fair market value per share of the Common Stock on the date of grant, as determined by the Board (the "Option Grant"). The Initial Option Grant is intended to represent approximately 1.50% of the Fully Diluted Shares (as defined below) currently outstanding. For the purposes of this Agreement, "Fully Diluted Shares" shall be calculated by adding (x) the number of outstanding shares of capital stock of the Company, plus (y) the number of shares of Company common stock subject to issuance under outstanding options or warrants, plus (z) the number of unallocated shares of Company common stock reserved for issuance pursuant to the Company's stock option plans, in each case, as of the close of the business day preceding the date of determination. Subject to the vesting acceleration terms described in this Agreement, fifteen percent (15%) of the Option Grant shall vest on the Start Date and twenty-percent (25%) of the Option Grant shall vest (or be released from the Company's repurchase right, as applicable) one year from the Start Date subject to Executive's continuing employment with the Company. The remaining shares subject to the Option Grant shall vest (or be released from the Company's

repurchase right, as applicable) monthly over the next (36) months in equal monthly amounts subject to Executive's continuing employment with the Company and any vesting acceleration terms of the Agreement. Any shares acquired upon exercise of the Option Grant, will be subject to the terms and conditions of the Company's equity incentive plan and option agreement to be entered into between Executive and the Company.

Subject to any vesting requirements as set forth herein (and in the applicable stock option agreements), the Option Grant may be exercised early at any time after the respective grant dates for all or any part of the shares subject to this Option Grant.

5. Expense Reimbursement and Other Benefits.

4.1 Reimbursement of Expenses. Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

4.2 Compensation/Benefit Programs. During the Term of Employment, the Executive shall be entitled to participate in all medical insurance plans and any and all other plans as are presently and hereafter offered by the Company to its executives and their spouses, domestic partners and immediate families.

4.3 Relocation Assistance. The Company shall reimburse Executive for up to \$3,000 per month in temporary living expenses toward the costs of maintaining a residence in Boulder County, Colorado for a maximum period of twenty-four (24) months, unless extended by the Company based on then current business needs. Notwithstanding the foregoing, during the Term of Employment, the Company will reimburse Executive for relocation expenses associated with purchasing a home in Colorado to serve as Executive's primary residence and movement of Executive's household goods to Colorado up to a maximum amount of \$40,000 ("Relocation Payments"). Expenses eligible for reimbursement as Relocation Payments hereunder, subject to the stated maximum, include the travel and accommodation expenses of house hunting trips and the cost of packing and moving the Executive's household goods from Indiana to Colorado. Should Executive voluntarily resign from the Company without Good Reason (as defined herein) or should the Company terminate Executive for Cause (as defined herein) within twelve (12) months of Executive's relocation, Executive agrees to repay to the Company a pro rata portion of all Relocation Payments paid to Executive by the Company. If applicable, such amount shall be payable immediately upon resignation or termination of employment, depending on the circumstance. In addition, Executive agrees and authorizes the Company to deduct any amounts owed to the Company pursuant to this **Section 4.3** from Executive's final paycheck and any other amounts that the Company otherwise might pay upon termination. All reimbursements provided pursuant to this **Section 4.3** shall be subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices. The Company shall not be obligated to make any more additional Relocation Payments if and after the Company opens an office in Indiana

during the Term of Employment, unless the Company and Executive agree that the Executive should make his primary work place and residence in Boulder County, Colorado.

#### 4.4 Other Benefits.

a. Personal Days. The Executive shall be entitled to twenty-five (25) days of paid personal days annually, including vacation days, sick days and time off for personal matters. Such personal days are to be taken at such times as the Executive and the Company shall mutually determine. Personal days shall not interfere with the duties required to be rendered by the Executive hereunder.

b. Association and Other Dues. During the Term of Employment, the Company may pay reasonable initiation fees and dues payable in connection with the Executive's membership(s) in those clubs and activities, costs associated with continuing legal education to fulfill the state bar requirements applicable to the Executive, and the annual fees charged by the Indiana judicial system for maintaining attorney licensing in good standing, that in the opinion of the Board are in furtherance and directly related to the active conduct of the Company's business and are consistent with sound financial and tax planning.

c. Miscellaneous Benefits. The Executive shall receive such additional benefits, if any, as the Board shall from time to time determine.

#### 5. Termination.

5.1 Termination for Cause. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, for Cause. For purposes of this Agreement, the term "Cause" shall mean: (i) an action or omission of the Executive which constitutes a willful and material breach of, or failure or refusal (other than by reason of his disability) to perform his duties under this Agreement or any other Company agreements, including without limitation the Company Protection Agreement (see Exhibit A of this Agreement), between the parties which is not cured within fifteen (15) days after receipt by the Executive of written notice of same; (ii) fraud, embezzlement, misappropriation of funds or breach of trust in connection with his services hereunder; (iii) conviction of any crime which involves dishonesty or a breach of trust; or (iv) gross negligence in connection with the performance of the Executive's duties hereunder, which is not cured within fifteen (15) days after written receipt by the Executive of written notice of same. Any termination for Cause shall be made in writing to the Executive, which notice shall set forth in detail all acts or omissions upon which the Company is relying for such termination. The Executive shall have the right to address the Board regarding the acts set forth in the notice of termination. Upon any termination pursuant to this **Section 5.1**, the Company shall pay to the Executive his Base Salary to the date of termination. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.2 Disability. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, if the Executive shall become entitled to

benefits under the Company's disability plan as then in effect, or, if the Executive shall as the result of mental or physical incapacity, illness or disability, become unable to perform his obligations hereunder for a period of 180 days in any 12-month period. The Company shall have sole discretion based upon competent medical advice to determine whether the Executive continues to be disabled. Upon any termination pursuant to this **Section 5.2**, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive his accrued but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the date of termination of the Executive's employment with the Company. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.3 Death. Upon the death of the Executive during the Term of Employment, the Company shall (i) pay to the estate of the deceased Executive any unpaid Base Salary through the Executive's date of death; and (ii) pay to the estate of the deceased Executive his accrued but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the Executive's date of death. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of the Executive's death, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.4 Termination Without Cause. At any time, the Company shall have the right to terminate the Term of Employment by written notice to the Executive. Upon any termination pursuant to this **Section 5.4**, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive the accrued and/or pro-rated but unpaid Performance Bonus, if any, for any period ending on or before the date of the termination of the Executive's employment with the Company. Subject to **Section 5.7** below, the Company shall pay to the Executive the equivalent of six (6) months of Executive's Base Salary in the form of salary continuation commencing on the first regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below and reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for six (6) months following the effective date of termination ("Severance Benefits"). The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.5 Termination by Executive for Good Reason.

a. At all times, the Executive shall have the right, upon fifteen (15) days written notice to the Company, to terminate the Term of Employment. Upon termination of the Term of Employment pursuant to this **Section 5.5(a)** by the Executive, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive his accrued but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the termination of Executive's employment with the Company.

**b. Upon termination of the Term of Employment pursuant to this Section**

**5.5** by the Executive for Good Reason, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive the accrued and/or pro-rated but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the termination of Executive's employment with the Company. Subject to **Section 5.7** below, the Company shall pay to the Executive the equivalent of six (6) months of Executive's Base Salary in the form of salary continuation commencing on the first regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below and reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for six (6) months following the effective date of termination ("Severance Benefits"). The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

c. For purposes of this Agreement, "Good Reason" shall mean (i) the assignment to the Executive of any duties inconsistent in any respect with the Executive's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as contemplated by **Section 1** of this Agreement, or any other action by the Company which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Executive; (ii) any failure by the Company to comply with any of the provisions of **Section 3** of this Agreement, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Executive; *provided however*, that in order to effect resignation for Good Reason all of the following must occur: (i) Executive must provide the Company with written notice within a sixty-day period following the event(s) giving rise to Executive's intent to voluntarily resign his employment for Good Reason (ii) such event is not remedied by Company within thirty (30) days following the Company's receipt of such written notice; and (iii) Executive's resignation is effective no later than thirty (30) days after the expiration of such thirty (30)-day cure period.

**5.6 Change in Control of the Company.**

a. Payments. In the event that a termination of employment without Cause or for Good Reason occurs within twelve (12) months following a Change in Control (as defined in paragraph (b) of this **Section 5.6**) in the Company, subject to **Section 5.7** below, the Company shall pay to the Executive the equivalent of twelve (12) months of Executive's Base Salary in a lump sum, reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination, and fully accelerate the vesting of all outstanding, unvested options or other equity instruments of Company Common Stock such that all such equity shall be vested, immediately and exercisable ("Severance Benefits"). The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject,

however, to the provisions of **Section 4.1**, and payment of compensation for unused paid, personal days that have accumulated during the calendar year in which such termination occurs).

b. For purposes of this Agreement, the term “Change in Control” shall mean approval by the shareholders of the Company of (i) a reorganization, merger, consolidation or other form of corporate transaction or series of transactions, in each case, with respect to which persons who were the shareholders of the Company immediately prior to such reorganization, merger or consolidation or other transaction do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company’s then outstanding voting securities, in substantially the same proportions as their ownership immediately prior to such reorganization, merger, consolidation or other transaction, or (ii) a liquidation or dissolution of the Company, or (iii) the sale of all or substantially all of the assets of the Company (unless such reorganization, merger, consolidation or other corporate transaction, liquidation, dissolution or sale is subsequently abandoned).

**5.7 Release and Resignation Requirement.** The Severance Benefits are conditional upon (i) Executive’s delivering to the Company and making effective and irrevocable a general release of all claims in favor of the Company, in a form reasonably acceptable to the Company (the “Release”), which release shall be effective not later than 45 days following the date of the applicable termination or resignation; (ii) Executive’s complying with the Release including any cooperation, non-disparagement or confidentiality provisions contained therein and continuing to comply with Executive’s obligations under the terms of this Agreement, including any non-solicit and/or non-compete provisions that may be included, and the terms of the Company Protection Agreement; and (iii) Executive’s resignation, to be effective no later than the date of Executive’s termination or resignation date (or such other date as reasonably requested by the Company).

**5.8 Survival.** The provisions of this **Article 5** shall survive the termination or expiration of this Agreement, as applicable.

## **6. Restrictive Covenants.**

**6.1 Non-Competition.** At all times while the Executive is employed by the Company and for a one (1) year period after the termination of the Executive’s employment with the Company for any reason other than by the Company without Cause (as defined in **Section 5.1** hereof) or by the Executive for Good Reason (as defined in **Section 5.5** hereof), the Executive, directly or indirectly, shall not engage in or have any interest in any sole proprietorship, partnership, Company or business or any other person or entity (whether as an Executive, officer, director, partner, agent, security holder, creditor, consultant or otherwise) that directly or indirectly (or through any affiliated entity) engages in direct competition with the Company (for this purpose, any business that engages in the drug development business utilizing those specific pharmaceutical compounds developed, licensed or owned by the Company or any of its subsidiaries during the Executive’s Term of Employment to the Executive’s Termination Date shall be deemed to be in direct competition with the Company); provided that such provision shall not apply to the Executive’s ownership of Common Stock of the Company or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities

exchange or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control or, more than five percent of any class of capital stock of such Company.

persons who were the shareholders of the Company immediately prior to such reorganization, merger or consolidation or other transaction do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities, in substantially the same proportions as their ownership immediately prior to such reorganization, merger, consolidation or other transaction, or (ii) a liquidation or dissolution of the Company, or (iii) the sale of all or substantially all of the assets of the Company (unless such reorganization, merger, consolidation or other corporate transaction, liquidation, dissolution or sale is subsequently abandoned).

**5.7 Release and Resignation Requirement.** The Severance Benefits are conditional upon (i) Executive's delivering to the Company and making effective and irrevocable a general release of all claims in favor of the Company, in a form reasonably acceptable to the Company (the "Release"), which release shall be effective not later than 45 days following the date of the applicable termination or resignation; (ii) Executive's complying with the Release including any cooperation, non-disparagement or confidentiality provisions contained therein and continuing to comply with Executive's obligations under the terms of this Agreement, including any non-solicit and/or non-compete provisions that may be included, and the terms of the Company Protection Agreement; and (iii) Executive's resignation, to be effective no later than the date of Executive's termination or resignation date (or such other date as reasonably requested by the Company).

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## **6. Restrictive Covenants.**

**6.1 Non-Competition.** At all times while the Executive is employed by the Company and for a one (1) year period after the termination of the Executive's employment with the Company for any reason other than by the Company without Cause (as defined in **Section 5.1** hereof) or by the Executive for Good Reason (as defined in **Section 5.5** hereof), the Executive, directly or indirectly, shall not engage in or have any interest in any sole proprietorship, partnership, Company or business or any other person or entity (whether as an Executive, officer, director, partner, agent, security holder, creditor, consultant or otherwise) that directly or indirectly (or through any affiliated entity) engages in direct competition with the Company (for this purpose, any business that engages in the drug development business utilizing those specific pharmaceutical compounds developed, licensed or owned by the Company or any of its subsidiaries during the Executive's Term of Employment to the Executive's Termination Date shall be deemed to be in direct competition with the Company); provided that such provision shall not apply to the Executive's ownership of Common Stock of the Company or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities

exchange or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control or, more than five percent of any class of capital stock of such Company.

6.2 Non-Disclosure. The Executive shall not at any time divulge, communicate or use to the detriment of the Company or for the benefit of any other person or persons, or misuse in any way, any Confidential Information (as hereafter defined) pertaining to the business of the Company. Any Confidential Information or data now or hereafter acquired by the Executive with respect to the business of the Company (which shall include, but not be limited to, information concerning the Company's business plan, financial condition, prospects, technology, customers, suppliers, sources of leads and methods of doing business) shall be deemed a valuable, special and unique asset of the Company that is received by the Executive in confidence and as a fiduciary, and Executive shall remain a fiduciary to the Company with respect to all of such information. For purposes of this Agreement, "Confidential Information" means information disclosed to the Executive or known by the Executive as a consequence of or through his employment by the Company (including information conceived, originated, discovered or developed by the Executive) prior to or after the date hereof, and not generally known, about the Company or its business. Notwithstanding the foregoing, nothing herein shall be deemed to restrict the Executive from disclosing Confidential Information to the extent required by law, that was independently developed by Executive, and/or which Executive has a lawful right to disclose.

6.3 Non-Solicitation of Executives and Clients. At all times while the Executive is employed by the Company and for a one (1) year period after the termination or expiration of the Executive's employment with the Company for any reason, the Executive shall not, directly or indirectly, for himself or for any other person, firm, Company, partnership, association or other entity (a) employ or attempt to employ or enter into any contractual arrangement with any Executive or former Executive of the Company, unless such Executive or former Executive has not been employed by the Company for a period in excess of six months, and/or (b) call on or solicit any of the actual or targeted prospective clients of the Company on behalf of any person or entity in connection with any business competitive with the business of the Company, nor shall the Executive make known the names and addresses of such clients or any information relating in any manner to the Company's trade or business relationships with such customers, other than in connection with the performance of Executive's duties under this Agreement.

6.4 Books and Records. All books, records, and accounts relating in any manner to the confidential business of the Company, customers, clients or prospects of the Company, reports, documents, analyses, or any other such Confidential Information whether prepared by the Executive or otherwise coming into the Executive's possession, shall be the exclusive property of the Company and shall be returned immediately to the Company on termination of the Executive's employment hereunder or on the Company's reasonable request at any time.

6.5 Definition of Company. Solely for purposes of this **Article 6**, the term "Company" also shall include any existing or future subsidiaries of the Company that are operating during the time periods described herein and any other entities that directly or indirectly, through

one or more intermediaries, control, are controlled by, or are under common control with the Company during the periods described herein.

6.6 Acknowledgment by Executive. The Executive acknowledges and confirms that (a) the restrictive covenants contained in this **Article 6** are reasonably necessary to protect the legitimate business interests of the Company, and (b) the restrictions contained in this **Article 6** (including without limitation the length of the term of the provisions of this **Article 6**) are not overbroad, overlong, or unfair and are not the result of overreaching, duress, or coercion of any kind. The Executive further acknowledges and confirms that his full, uninhibited and faithful observance of each of the covenants contained in this **Article 6** will not cause him any undue hardship, financial or otherwise, and that enforcement of each of the covenants contained herein will not impair his ability to obtain employment commensurate with his abilities and on terms fully acceptable to him or otherwise to obtain income required for the comfortable support of him and his family and the satisfaction of the needs of his creditors. The Executive acknowledges and confirms that his special knowledge of the business of the Company is such as would cause the Company serious injury or loss if he were to use such ability and knowledge to the benefit of a competitor or were to compete with the Company in violation of the terms of this **Article 6**. The Executive further acknowledges that the restrictions contained in this **Article 6** are intended to be, and shall be, for the benefit of and shall be enforceable by, the Company's successors and assigns.

6.7 Reformation by Court. In the event that a court of competent jurisdiction shall determine that any provision of this **Article 6** is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this **Article 6** within the jurisdiction of such court, such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

6.8 Extension of Time. If the Executive shall be in violation of any provision of this **Article 6**, then each time limitation set forth in this **Article 6** shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Company seeks injunctive relief from such violation in any court, then the covenants set forth in this **Article 6** shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Executive.

6.9 Survival. The provisions of this **Article 6** shall survive the termination or expiration of this Agreement, as applicable.

7. Mediation. In the event a dispute arises out of or relates to this Agreement, or the breach thereof, and if the dispute cannot be settled through negotiation after a reasonable period, the parties hereby agree first to attempt in good faith and also over a reasonable period to settle the dispute by mediation administered by the American Arbitration Association under its Employment Mediation Rules before resorting to litigation or some other dispute resolution procedure. If the efforts required in this **Article 7** fail to yield a mutually agreed settlement, then the parties will move to **Article 8**.

9. Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Boulder County, Colorado in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration

Association then in effect (except to the extent that the procedures outlined below differ from such rules or the parties otherwise agree). Within thirty (30) days after written notice by either party has been given to the other party that a dispute exists and that arbitration is required, each party must select an arbitrator and those two arbitrators shall promptly, but in no event later than thirty (30) days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The cost and expenses of the arbitration and of enforcement of any award in any court shall be borne by the Company. The cost of any attorney fees shall be borne by each party individually, unless the payment of such fees is awarded to the prevailing party by the arbitrators. If advances are required, each party will advance one-half of the estimated fees and expenses of the arbitrators. Judgment may be entered on the arbitrators' award in any court having jurisdiction. Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to obtain an injunction to protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

10. Assignment. This Agreement is personal in nature and accordingly may not be assigned by the Executive, in whole or in part, without the prior written consent of the Company, which may be withheld in its sole discretion. The Company may, in its sole discretion, assign this Agreement and all of its rights, benefits and obligations hereunder, whether by agreement or by operation of law.

11. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Colorado without regard to conflict of laws issues.

12. Entire Agreement. This Agreement, including Exhibits A (Company Protection Agreement) and B (Indemnification Agreement), constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its affiliates) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

13. Notices. All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested, or sent by confirmed e-mail or facsimile transmission addressed as set forth herein. Notices personally delivered, sent by e-mail or facsimile, or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) days after deposit in the U.S. mail. Notice shall be sent (i) if to the Company, addressed to Brickell Biotech, Inc., 5777 Central Avenue, Suite 102, Boulder, CO 80301, Attention: CEO, and (ii) if to the Executive, to his address as reflected on the payroll records of the Company, or to such other address as either party hereto may from time to time give written notice of to the other.

14. Benefits; Binding Effect. This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives,

successors and, where applicable, assigns, including without limitation any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets, or otherwise.

15. Severability. The invalidity of any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, or section or sections had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

16. Waivers. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

17. Damages. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. In the event that either party hereto brings suit for the collection of any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the party found to be at fault shall pay all reasonable court costs and attorneys' fees of the other.

18. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

19. No Third-Party Beneficiary. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and assigns, any rights or remedies under or by reason of this Agreement.

20. Indemnification. The Company will indemnify the Executive pursuant to the terms and conditions of the Indemnification Agreement attached hereto as Exhibit B.

21. Section  
409A.

20.1 General Compliance. This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended, ("Section 409A"), or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement only may be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement upon a termination of employment only shall be made upon a

"separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

20.2 Specified Employees. Notwithstanding any other provision of this Agreement, if any payment or benefit provided to the Executive in connection with his termination of employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Executive is determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of the Termination Date or, if earlier, on the Executive's death (the "Specified Employee Payment Date"). The aggregate of any payments that otherwise would have been paid before the Specified Employee Payment Date and interest on such amounts calculated based on the applicable federal rate published by the Internal Revenue Service for the month in which the Executive's separation from service occurs shall be paid to the Executive in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

20.3 Reimbursements. To the extent required by Section 409A, each reimbursement or in-kind benefit provided under this Agreement shall be provided in accordance with the following:

(a) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year;

(b) any reimbursement of an eligible expense shall be paid to the Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred; and

(c) any right to reimbursements or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit.

20.4 Tax Gross-ups. Any tax gross-up payments provided by this Agreement shall be paid to the Executive on or before December 31 of the calendar year immediately following the calendar year in which the Executive remits the related taxes. The parties agree to decide when a tax gross-up would be appropriate hereunder such as where the plain intent is to make Executive whole.

**IN WITNESS WHEREOF**, the undersigned have executed this Agreement as of the date first above written.

Corporation:

Employee:

**BRICKELL BIOTECH, INC.**

A Delaware corporation

By: /s/ Robert B. Brown, CEO

Robert B. Brown, CEO

President and Chief Scientific Officer

By: /s/ David R. McAvoy

David R. McAvoy, Individually

**EXHIBIT A – COMPANY PROTECTION AGREEMENT**

(To be attached)

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**EXHIBIT B - INDEMNIFICATION AGREEMENT**

(To be attached)

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August 27, 2019

**David R. McAvoy**  
9326 Timber Crest Lane  
Indianapolis, IN 46256

***Re: Amendment to Employment Agreement***

Dear Mr. McAvoy,

You are receiving this letter as an amendment to the employment agreement that you previously signed between you and Brickell Biotech, Inc., a Delaware corporation (the "Corporation") effective July 1, 2019 ("Employment Agreement"). All capitalized terms in this letter agreement not otherwise defined in this letter agreement are as defined in the Employment Agreement. The Corporation desires to amend the Employment Agreement as noted below to update language in the Bonus Section of the Employment Agreement as follows.

Accordingly, effective as of the date of this letter agreement, the terms of Section 3.2a of the Employment Agreement are hereby deleted and replaced with the ensuing language in quotation marks:

“a. Annual Bonus. For each fiscal year of the Term of Employment ("Bonus Period"), Executive will be eligible to receive an annual target performance bonus of 30% of Base Salary (the "Performance Bonus"), based upon the achievement of mutually agreed performance milestones established by the Board, provided nothing herein shall be a guarantee of any amount of bonus, or any bonus at all. For 2019, the Bonus Period will be calculated based on the annualized Base Salary and will not be pro-rated from the Effective Date of this Agreement. In order to be eligible to receive a Performance Bonus, in addition to the other requirements provided herein, Executive must be employed for the full fiscal year to which the Performance Bonus applies, with the exception of 2019, in which Executive must be employed from the Effective Date through the end of the calendar year. The Company shall have no obligation to provide Executive a Performance Bonus unless and until such a determination has been made by the Company consistent with the criteria described above at the conclusion of the applicable Bonus Period. Such Performance Bonus, if any, is subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices and is hereby incorporated into this Agreement by reference. Any bonus payable pursuant to this **Section 3.2** shall be paid by the Company to the Executive within two (2) months after the end of the applicable Bonus Period in which they are earned.”

You agree and acknowledge that your Employment Agreement remains in full force and

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effect as amended by this letter agreement. You must sign and return this amendment no later than August 27, 2019. If you do not sign and return this amendment, your Employment Agreement shall remain in full force and effect as drafted without regard to the clarifying changes in this amendment.

Sincerely,

**Corporation:**

Brickell Biotech, Inc.  
A Delaware Company

By: /s/ Robert B. Brown

Name: Robert B. Brown  
Title: CEO

**Executive:**

/s/ David R. McAvoy

Name: David R. McAvoy  
Title: General Counsel/Chief Compliance Officer

Date: August 27, 2019

**EMPLOYMENT AGREEMENT**

**THIS EMPLOYMENT AGREEMENT** (“Agreement”) is made this August 1, 2019 (“Effective Date”) by and between **BRICKELL BIOTECH, INC.**, a Delaware Company with a business address located at 5777 Central Avenue, Suite 102, Boulder, CO 80301 (the “Company”), and **ADAM LEVY**, a Colorado resident, with an address of 2481 Tamarack Ave, Boulder, CO 80304 (the “Executive”).

**RECITALS:**

**WHEREAS**, the Executive possesses substantial experience in the field of pharmaceutical development;

**WHEREAS**, the Company seeks to employ Executive initially as Chief Business Officer, and then as Chief Financial Officer, of the Company;

**WHEREAS**, the Executive is willing to make his services available to the Company and on the terms and conditions hereinafter set forth.

**NOW, THEREFORE**, in consideration of the recitals, premises and mutual covenants set forth herein, the parties agree as follows:

1. Employment/Duties of Executive. From the Effective Date through December 31, 2019, Executive shall serve as the Company’s Chief Business Officer. On January 1, 2020, Executive will serve as the Company’s Chief Financial Officer, satisfactorily completing the responsibilities commensurate with those duties and responsibilities of such position. Executive shall report to the Company’s Chief Executive Officer. Additionally, Executive shall diligently perform all other services and shall exercise such power and authority as may from time to time be delegated to him by the Board. The foregoing shall not limit his right to be involved in other not-for-profit, civic or charitable activities nor limit the Executive’s right to serve as an advisor or board member for other non-competing corporate or not-for-profit entities, provided such outside activities do not conflict or impede Executive’s performance of his duties and responsibilities to the Company. The Company reserves the right to request that the Executive resign from such outside roles in the event that the Board perceives that the Executive is devoting less than his full time attention to his responsibilities at the Company.

2. Term. Executive shall commence employment with the Company on August 1, 2019 (“Start Date”). The Executive’s employment shall be at-will, meaning that the Executive or the Company may terminate the employment relationship at any time, with or without cause, and with or without notice, subject to severance provisions set forth below. The period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement is sometimes referred to in this Agreement as the “Term of Employment”, and the date on which the Term of Employment shall expire, is sometimes referred to in this Agreement as the “Termination Date”).

### 3. Compensation.

3.1 Base Salary. The Company shall pay Executive an initial base salary at the annual rate of Four Hundred Thousand Dollars (\$400,000) (the "Base Salary"). The Company shall review the Executive's Base Salary from time to time and the Company may, but shall not be required to, increase the Base Salary during the Term of Employment. However, Executive's Base Salary may not be decreased during the Term of Employment other than as part of an across-the-board salary reduction that applies in the same manner to all senior executives of the Company. All salary is payable subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices.

### 3.2 Equity and Bonuses.

a. Annual Bonus. For each fiscal year of the Term of Employment ("Bonus Period"), Executive will be eligible to receive an annual target performance bonus of 40% of Base Salary (the "Performance Bonus"), based upon the achievement of mutually agreed performance milestones established by the Board, provided nothing herein shall be a guarantee of any amount of bonus, or any bonus at all. For 2019, the Bonus Period will be calculated based on the annualized Base Salary and will not be pro-rated from the Effective Date of this Agreement. In order to be eligible to receive a Performance Bonus, in addition to the other requirements provided herein, Executive must be employed for the full fiscal year to which the Performance Bonus applies, with the exception of 2019, in which Executive must be employed from the Effective Date through the end of the calendar year. The Company shall have no obligation to provide Executive a Performance Bonus unless and until such a determination has been made by the Company consistent with the criteria described above at the conclusion of the applicable Bonus Period. Such Performance Bonus, if any, is subject to standard federal and state payroll withholding requirements in accordance with Company's standard payroll practices and is hereby incorporated into this Agreement by reference. Any bonus payable pursuant to this **Section 3.2** shall be paid by the Company to the Executive within two (2) months after the end of the applicable Bonus Period in which they are earned.

b. Equity. The Company shall recommend that the Board grant to Executive an option to purchase, pursuant to an option agreement, the equivalent of approximately 1.00% of Company Common Stock, (the "Common Stock") on a Fully Diluted basis, at a price per share equal to the fair market value per share of the Common Stock on the date of grant (the "Option Grant"). The Option Grant shall occur immediately upon the next increase to Company's stock option pool, which is expected to occur immediately post-closing of the contemplated merger agreement with Vical Inc. (the "Merger"). In the event the Merger is terminated, the Option Grant will be made on such termination date thereof. In this scenario, dilution protection will be offered through the closing of the Company's next equity financing pursuant to which it raises at least thirty million dollars in gross proceeds.

For the purposes of this Agreement, "Fully Diluted" shall be calculated by adding (x) the number of outstanding shares of capital stock of the Company, plus (y) the number of shares of Company common stock subject to issuance under outstanding options or warrants, plus (z) the number of unallocated shares of Company common stock reserved for issuance pursuant to the

Company's stock option plans, in each case, as of the close of the business day preceding the date of determination. Subject to the vesting acceleration terms described in this Agreement, twenty-five percent (25%) of the Option Grant shall vest (or be released from the Company's repurchase right, as applicable) one year from the Effective Date subject to Executive's continuing employment with the Company (the "Initial Vesting Period"), and none of the Option Grant shall vest (or be released from the Company's repurchase right, as applicable) before such date. The remaining shares subject to the Option Grant shall vest (or be released from the Company's repurchase right, as applicable) monthly over the next (36) months in equal monthly amounts subject to Executive's continuing employment with the Company. Any shares acquired upon exercise of the Option Grant, will be subject to the terms and conditions of the Company's equity incentive plan and option agreement to be entered into between Executive and the Company.

Subject to any vesting requirements as set forth above (and in the applicable stock option agreements), the Option Grant may be early exercised at any time after the respective grant dates for all or any part of the shares subject to the Option Grant.

#### 4. Expense Reimbursement and Other Benefits.

4.1 Reimbursement of Expenses. Upon the submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt, the Company shall reimburse the Executive for all reasonable expenses actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

4.2 Compensation/Benefit Programs. During the Term of Employment, the Executive shall be entitled to participate in all medical insurance plans and any and all other plans as are presently and hereinafter offered by the Company to its executives and their spouses, domestic partners and immediate families.

#### 4.3 Other Benefits.

a. Personal Days. The Executive shall be entitled to twenty-five (25) days of paid personal days annually, including vacation days, sick days and time off for personal matters. Such personal days are to be taken at such times as the Executive and the Company shall mutually determine. Personal days shall not interfere with the duties required to be rendered by the Executive hereunder.

b. Association Dues. During the Term of this Agreement, the Company may pay reasonable initiation fees and dues payable in connection with the Executive's membership(s) in those clubs and activities that in the opinion of the Board are in furtherance and directly related to the active conduct of the Company's business and are consistent with sound financial and tax planning.

c. Miscellaneous Benefits. The Executive shall receive such additional benefits, if any, as the Board shall from time to time determine.

5. Termination.

5.1 Termination for Cause. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, for Cause. For purposes of this Agreement, the term “Cause” shall mean: (i) an action or omission of the Executive which constitutes a willful and material breach of, or failure or refusal (other than by reason of his disability) to perform his duties under this Agreement or any other agreements, including, without limitation, the Company Protection Agreement, between the parties which is not cured within fifteen (15) days after receipt by the Executive of written notice of same; (ii) fraud, embezzlement, misappropriation of funds or breach of trust in connection with his services hereunder; (iii) conviction of any crime which involves dishonesty or a breach of trust; or (iv) gross negligence in connection with the performance of the Executive's duties hereunder, which is not cured within fifteen (15) days after written receipt by the Executive of written notice of same. Any termination for Cause shall be made in writing to the Executive, which notice shall set forth in detail all acts or omissions upon which the Company is relying for such termination. The Executive shall have the right to address the Board regarding the acts set forth in the notice of termination. Upon any termination pursuant to this **Section 5.1**, the Company shall pay to the Executive his Base Salary to the date of termination. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.2 Disability. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment, if the Executive shall become entitled to benefits under the Company's disability plan as then in effect, or, if the Executive shall as the result of mental or physical incapacity, illness or disability, become unable to perform his obligations hereunder for a period of 180 days in any 12-month period. The Company shall have sole discretion based upon competent medical advice to determine whether the Executive continues to be disabled. Upon any termination pursuant to this **Section 5.2**, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive his accrued but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the date of termination of the Executive's employment with the Company. The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.3 Death. Upon the death of the Executive during the Term of Employment, the Company shall (i) pay to the estate of the deceased Executive any unpaid Base Salary through the Executive's date of death; and (ii) pay to the estate of the deceased Executive his accrued but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the Executive's date of death. The Company shall have no further liability hereunder (other than for reimbursement for

reasonable business expenses incurred prior to the date of the Executive's death, subject, however to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.4 Termination Without Cause. At any time, the Company shall have the right to terminate the Term of Employment by written notice to the Executive. Upon any termination pursuant to this **Section 5.4**, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive the accrued but unpaid Performance Bonus, if any, for any period ending on or before the date of the termination of the Executive's employment with the Company. Subject to **Section 5.7** below, the Company shall pay to the Executive in a the equivalent of twelve (12) months of Executive's Base Salary in the form of salary continuation commencing on the first regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below, reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination and accelerated vesting of any unvested Initial Vesting Period stock options, calculated on a pro-rata basis from the Effective Date through the effective date of termination ("Severance Benefits"). The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation for unused vacation days that have accumulated during the calendar year in which such termination occurs).

5.5 Termination by Executive for Good Reason.

a. The Executive shall at all times have the right, upon fifteen (15) days written notice to the Company, to terminate the Term of Employment. Upon termination of the Term of Employment pursuant to this **Section 5.5(a)** by the Executive, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive his accrued but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the termination of Executive's employment with the Company.

b. Upon termination of the Term of Employment pursuant to this **Section 5.5** by the Executive for Good Reason, the Company shall (i) pay to the Executive any unpaid Base Salary through the effective date of termination specified in such notice; and (ii) pay to the Executive the accrued but unpaid Performance Bonus, if any, for any Bonus Period ending on or before the termination of Executive's employment with the Company. Subject to **Section 5.7** below, the Company shall pay to the Executive in a the equivalent of twelve (12) months of Executive's Base Salary in the form of salary continuation commencing on the first regularly scheduled payroll date following the effective date of the Release described in **Section 5.7** below, reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination and accelerated vesting of any unvested Initial Vesting Period stock options, calculated on a pro-rata basis from the Effective Date through the effective date of termination ("Severance Benefits"). The Company shall have no further liability hereunder (other than for reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and payment of compensation

for unused vacation days that have accumulated during the calendar year in which such termination occurs).

c. For purposes of this Agreement, “Good Reason” shall mean (i) the assignment to the Executive of any duties inconsistent in any respect with the Executive's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities as contemplated by **Section 1** of this Agreement, or any other action by the Company which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Executive; (ii) any failure by the Company to comply with any of the provisions of **Section 3** of this Agreement, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Executive; or (iii) relocation of Executive's primary place of work to a location that is more than thirty (30) miles from its current business office at 5777 Central Avenue, Boulder, Colorado; *provided however*, that (1) business travel required for Executive to perform the obligations he has under this Agreement shall not constitute Good Reason; and (2) in order to effect resignation for Good Reason all of the following must occur: (x) Executive must provide the Company with written notice within the sixty-day period following the event(s) giving rise to Executive's intent to voluntarily resign his employment for Good Reason (y) such event is not remedied by within thirty (30) days following the Company's receipt of such written notice; and (z) Executive's resignation is effective not later than thirty (30) days after the expiration of such thirty (30) day cure period.

#### 5.6 Change in Control of the Company.

a. Payments. In the event that a termination of employment without Cause or for Good Reason occurs within twelve (12) months following a Change in Control (as defined in paragraph (b) of this **Section 5.6**) in the Company, subject to **Section 5.7** below, the Company shall pay to the Executive the equivalent of twelve (12) months of Executive's Base Salary in a lump sum, reimburse the Executive for the monthly COBRA premium paid by the Executive for himself and his dependents for twelve (12) months following the effective date of termination, and fully accelerate the vesting of all outstanding, unvested options or other equity instruments of Company Common Stock such that all such equity shall be fully vested and exercisable (“Severance Benefits”). The Company shall have no further liability hereunder (other than for (x) reimbursement for reasonable business expenses incurred prior to the date of termination, subject, however, to the provisions of **Section 4.1**, and (y) payment of compensation for unused paid, personal days that have accumulated during the calendar year in which such termination occurs).

b. For purposes of this Agreement, the term “Change in Control” shall mean approval by the shareholders of the Company of (i) a reorganization, merger, consolidation or other form of corporate transaction or series of transactions, in each case, with respect to which persons who were the shareholders of the Company immediately prior to such reorganization, merger or consolidation or other transaction do not, immediately thereafter, own more than 50% of the combined voting power entitled to vote generally in the election of directors of the reorganized, merged or consolidated company's then outstanding voting securities, in substantially the same

proportions as their ownership immediately prior to such reorganization, merger, consolidation or other transaction, or (ii) a liquidation or dissolution of the Company or (iii) the sale of all or substantially all of the assets of the Company (unless such reorganization, merger, consolidation or other corporate transaction, liquidation, dissolution or sale is subsequently abandoned).

5.7 Release and Resignation Requirement. The Severance Benefits are conditional upon (i) Executive's delivering to the Company and making effective and irrevocable a general release of all claims in favor of the Company, in a form reasonably acceptable to the Company (the "Release"), which release shall be effective not later than 45 days following the date of the applicable termination or resignation; (ii) Executive's complying with the Release including any cooperation, non-disparagement or confidentiality provisions contained therein and continuing to comply with Executive's obligations under the terms of this Agreement, including the non-solicit and non-compete provisions thereof, and the terms of the Protection Agreement; and (iii) Executive's resignation, to be effective no later than the date of Executive's termination or resignation date (or such other date as requested by the Company).

5.8 Survival. The provisions of this **Article 5** shall survive the termination of this Agreement, as applicable.

6. Restrictive Covenants.

6.1 Non-Competition. At all times while the Executive is employed by the Company and for a one (1) year period after the termination of the Executive's employment with the Company for any reason other than by the Company without Cause (as defined in **Section 5.1** hereof) or by the Executive for Good Reason (as defined in **Section 5.5** hereof), the Executive shall not, directly or indirectly, engage in or have any interest in any sole proprietorship, partnership, Company or business or any other person or entity (whether as an Executive, officer, director, partner, agent, security holder, creditor, consultant or otherwise) that directly or indirectly (or through any affiliated entity) engages in competition with the Company (for this purpose, any business that engages in the drug development business utilizing those specific pharmaceutical compounds developed, licensed or owned by the Company or any of its subsidiaries during his term of employment to date of Executive's Termination shall be deemed to be in competition with the Company); provided that such provision shall not apply to the Executive's ownership of Common Stock of the Company or the acquisition by the Executive, solely as an investment, of securities of any issuer that is registered under Section 12(b) or 12(g) of the Securities Exchange Act of 1934, as amended, and that are listed or admitted for trading on any United States national securities exchange or that are quoted on the National Association of Securities Dealers Automated Quotations System, or any similar system or automated dissemination of quotations of securities prices in common use, so long as the Executive does not control, acquire a controlling interest in or become a member of a group which exercises direct or indirect control or, more than five percent of any class of capital stock of such Company.

6.2 Nondisclosure. The Executive shall not at any time divulge, communicate or use to the detriment of the Company or for the benefit of any other person or persons, or misuse in any way, any Confidential Information (as hereinafter defined) pertaining to the business of the Company. Any Confidential Information or data now or hereafter acquired by the Executive with

respect to the business of the Company (which shall include, but not be limited to, information concerning the Company's business plan, financial condition, prospects, technology, customers, suppliers, sources of leads and methods of doing business) shall be deemed a valuable, special and unique asset of the Company that is received by the Executive in confidence and as a fiduciary, and Executive shall remain a fiduciary to the Company with respect to all of such information. For purposes of this Agreement, "Confidential Information" means information disclosed to the Executive or known by the Executive as a consequence of or through his employment by the Company (including information conceived, originated, discovered or developed by the Executive) prior to or after the date hereof, and not generally known, about the Company or its business. Notwithstanding the foregoing, nothing herein shall be deemed to restrict the Executive from disclosing Confidential Information to the extent required by law.

6.3 Non-solicitation of Executives and Clients. At all times while the Executive is employed by the Company and for a one (1) year period after the termination of the Executive's employment with the Company for any reason, the Executive shall not, directly or indirectly, for himself or for any other person, firm, Company, partnership, association or other entity (a) employ or attempt to employ or enter into any contractual arrangement with any Executive or former Executive of the Company, unless such Executive or former Executive has not been employed by the Company for a period in excess of six months, and/or (b) knowingly call on or solicit any of the actual or targeted prospective clients of the Company on behalf of any person or entity in connection with any business competitive with the business of the Company, nor shall the Executive knowingly make known the names and addresses of such clients or any information relating in any manner to the Company's trade or business relationships with such customers, other than in connection with the performance of Executive's duties under this Agreement.

6.4 Books and Records. All books, records, and accounts relating in any manner to the business of the Company, customers, clients or prospects of the Company, reports documents analyses or any information whether prepared by the Executive or otherwise coming into the Executive's possession, shall be the exclusive property of the Company and shall be returned immediately to the Company on termination of the Executive's employment hereunder or on the Company's request at any time.

6.5 Definition of Company. Solely for purposes of this **Article 6**, the term "Company" also shall include any existing or future subsidiaries of the Company that are operating during the time periods described herein and any other entities that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with the Company during the periods described herein.

6.6 Acknowledgment by Executive. The Executive acknowledges and confirms that (a) the restrictive covenants contained in this **Article 6** are reasonably necessary to protect the legitimate business interests of the Company, and (b) the restrictions contained in this **Article 6** (including without limitation the length of the term of the provisions of this **Article 6**) are not overbroad, overlong, or unfair and are not the result of overreaching, duress or coercion of any kind. The Executive further acknowledges and confirms that his full, uninhibited and faithful observance of each of the covenants contained in this **Article 6** will not cause him any undue hardship, financial

or otherwise, and that enforcement of each of the covenants contained herein will not impair his ability to obtain employment commensurate with his abilities and on terms fully acceptable to him or otherwise to obtain income required for the comfortable support of him and his family and the satisfaction of the needs of his creditors. The Executive acknowledges and confirms that his special knowledge of the business of the Company is such as would cause the Company serious injury or loss if he were to use such ability and knowledge to the benefit of a competitor or were to compete with the Company in violation of the terms of this **Article 6**. The Executive further acknowledges that the restrictions contained in this **Article 6** are intended to be, and shall be, for the benefit of and shall be enforceable by, the Company's successors and assigns.

6.7 Reformation by Court. Notwithstanding anything in **Article 14** to the contrary, in the event that a court of competent jurisdiction shall determine that any provision of this **Article 6** is invalid or more restrictive than permitted under the governing law of such jurisdiction, then only as to enforcement of this **Article 6** within the jurisdiction of such court, such provision shall be interpreted and enforced as if it provided for the maximum restriction permitted under such governing law.

6.8 Extension of Time. If the Executive shall be in violation of any provision of this **Article 6**, then each time limitation set forth in this **Article 6** shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Company seeks injunctive relief from such violation in any court, then the covenants set forth in this **Article 6** shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Executive.

6.9 Survival. The provisions of this **Article 6** shall survive the termination of this Agreement, as applicable.

7 . Mediation. In the event a dispute arises out of or relates to this Agreement, or the breach thereof, and if the dispute cannot be settled through negotiation, the parties hereby agree first to attempt in good faith to settle the dispute by mediation administered by the American Arbitration Association under its Employment Mediation Rules before resorting to litigation or some other dispute resolution procedure.

8 . Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in Boulder County, Colorado in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association then in effect (except to the extent that the procedures outlined below differ from such rules or the parties agree otherwise). Within thirty (30) days after written notice by either party has been given that a dispute exists and that arbitration is required, each party must select an arbitrator and those two arbitrators shall promptly, but in no event later than thirty (30) days after their selection, select a third arbitrator. The parties agree to act as expeditiously as possible to select arbitrators and conclude the dispute. The selected arbitrators must render their decision in writing. The cost and expenses of the arbitration and of enforcement of any award in any court shall be borne by the Company. The cost of any attorney fees shall be borne by each party individually, unless the payment of such fees is awarded to the prevailing party by the arbitrators. If advances are required, each party will advance one-half of the estimated fees and expenses of the arbitrators. Judgment may

be entered on the arbitrators' award in any court having jurisdiction. Although arbitration is contemplated to resolve disputes hereunder, either party may proceed to court to seek to obtain an injunction to protect its rights hereunder, the parties agreeing that either could suffer irreparable harm by reason of any breach of this Agreement. Pursuit of an injunction shall not impair arbitration on all remaining issues.

9. Assignment. This Agreement is personal in nature and accordingly may not be assigned by the Executive, in whole or in part, without the prior written consent of the Company, which may be withheld in its sole discretion. The Company may, in its sole discretion, assign this Agreement and all of its rights, benefits and obligations hereunder, whether by agreement or by operation of law.

10. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Colorado without regard to conflict of laws issues.

11. Entire Agreement. This Agreement, including Exhibits A (Protection Agreement) and B (Indemnification Agreement), constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its affiliates) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

12. Notices: All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed e-mail or facsimile transmission addressed as set forth herein. Notices personally delivered, sent by e-mail or facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon the earlier of receipt by the addressee, as evidenced by the return receipt thereof, or three (3) days after deposit in the U.S. mail. Notice shall be sent (i) if to the Company, addressed to Brickell Biotech, Inc., 5777 Central Avenue, Suite 102, Boulder, CO 80301, Attention: Chairman of the Board, and (ii) if to the Executive, to his address as reflected on the payroll records of the Company, or to such other address as either party hereto may from time to time give notice of to the other.

13. Benefits; Binding Effect. This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

14. Severability. The invalidity of any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses or sections contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, or

section or sections had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area, which would cure such invalidity.

15. Waivers. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

16. Damages. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. In the event that either party hereto brings suit for the collection of any damages resulting from, or the injunction of any action constituting, a breach of any of the terms or provisions of this Agreement, then the non-prevailing party shall pay all reasonable court costs and attorneys fees of the other.

17. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

18. No Third Party Beneficiary. Nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the parties hereto and their respective heirs, personal representatives, legal representatives, successors and assigns, any rights or remedies under or by reason of this Agreement.

19. Indemnification. The Company will indemnify the Executive pursuant to the terms and conditions of the Indemnification Agreement attached hereto as Exhibit B.

20. Section 409A.

20.1 General Compliance. This Agreement is intended to comply with section 409A of the Internal Revenue Code of 1986, as amended, ("Section 409A"), or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. Any payments to be made under this Agreement upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A, and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest, or other expenses that may be incurred by the Executive on account of non-compliance with Section 409A.

20.2 Specified Employees. Notwithstanding any other provision of this Agreement, if any payment or benefit provided to the Executive in connection with his termination of

employment is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Executive is determined to be a "specified employee" as defined in Section 409A(a)(2)(b)(i), then such payment or benefit shall not be paid until the first payroll date to occur following the six-month anniversary of the Termination Date or, if earlier, on the Executive's death (the "Specified Employee Payment Date"). The aggregate of any payments that would otherwise have been paid before the Specified Employee Payment Date and interest on such amounts calculated based on the applicable federal rate published by the Internal Revenue Service for the month in which the Executive's separation from service occurs shall be paid to the Executive in a lump sum on the Specified Employee Payment Date and thereafter, any remaining payments shall be paid without delay in accordance with their original schedule.

20.3 Reimbursements. To the extent required by Section 409A, each reimbursement or in-kind benefit provided under this Agreement shall be provided in accordance with the following:

(a) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during each calendar year cannot affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other calendar year;

(b) any reimbursement of an eligible expense shall be paid to the Executive on or before the last day of the calendar year following the calendar year in which the expense was incurred; and

(c) any right to reimbursements or in-kind benefits under this Agreement shall not be subject to liquidation or exchange for another benefit.

20.4 Tax Gross-ups. Any tax gross-up payments provided under this Agreement shall be paid to the Executive on or before December 31 of the calendar year immediately following the calendar year in which the Executive remits the related taxes.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first above written.

Company:     Executive:

**BRICKELL BIOTECH, INC.**  
A Delaware Company

By:     /s/ Robert Brown  
Robert Brown, CEO

By: /s/ Adam Levy  
Adam Levy, Individually

**EXHIBIT A - PROTECTION AGREEMENT**

**EXHIBIT B – INDEMNIFICATION AGREEMENT**

**BRICKELL BIOTECH, INC.  
REGISTRATION RIGHTS AGREEMENT**

This Registration Rights Agreement (this "Agreement") is made and entered into as of August 31, 2019, between Brickell Biotech, Inc., a Delaware corporation (formerly known as Vical Incorporated) (the "Company"), and NovaQuest Co-Investment Fund X (the "Purchaser").

This Agreement is made pursuant to the Funding Agreement, effective as of June 2, 2019, between Brickell Subsidiary, Inc., a Delaware corporation (formerly known as Brickell Biotech, Inc.) ("Brickell Bio"), and the Purchaser (the "Funding Agreement").

Brickell Bio, the Company, and Victory Subsidiary (the "Merger Parties") entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), effective June 2, 2019, whereby the Merger Parties determined that it is in each of their best interests that the Purchaser be granted registration rights by the Company as laid out herein and in order to execute certain key parts of the Funding Agreement from which the Company benefits.

WHEREAS, in consideration of the entry into the Funding Agreement and pursuant to the terms of the Funding Agreement, and as a consequence of the Merger Agreement, the Company is obligated to issue to the Purchaser a Common Stock Purchase Warrant in the form attached as Exhibit B to the Funding Agreement (the "Warrant").

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, from the Merger Agreement, and through the Funding Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Company and the Purchaser agree as follows:

1. Definitions. Capitalized terms used and not otherwise defined herein that are defined in the Funding and Merger Agreements shall have the meanings given such terms in the Funding and Merger Agreements. As used in this Agreement, the following terms shall have the following meanings and shall supersede any other identical term defined in either the Funding or the Merger Agreement(s):

"Advice" shall have the meaning set forth in Section 6(h) herein.

"Affiliate" means, with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with, such Person.

"Agreement" shall have the meaning set forth in the Preamble.

"Allowable Grace Period" shall have the meaning set forth in Section 3(d) of this Agreement.

"Business Day" means a day other than a Saturday or Sunday or other day on which banks located in New York City are authorized or required by law to close.

"Capital Stock" means, with respect to any Person at any time, any and all shares, interests, participations or other equivalents (however designated, whether voting or non-voting) of capital stock, securities convertible into or exchangeable or exercisable for any of its shares, interests, participations or other equivalents, partnership interests (whether general or limited), limited liability company interests, or equivalent ownership interests in or issued by such Person.

"Commission" means the United States Securities and Exchange Commission.

“Common Stock” means the voting common stock of the Company, par value \$0.01 per share, and any securities into which such shares of voting common stock may hereafter be reclassified.

“Company” shall have the meaning set forth in the Preamble.

“Effective Date” means the date that the Registration Statement filed pursuant to Section 2(a) of this Agreement is first declared effective by the Commission. This is not the effective date of this Agreement, which shall be the date last signed by the parties.

“Effectiveness Deadline” means, with respect to the Initial Registration Statement or the New Registration Statement, the date that is seventy-five (75) calendar days after the Filing Deadline.

“Effectiveness Period” shall have the meaning set forth in Section 2(b) herein.

“Event” shall have the meaning set forth in Section 2(c) herein.

“Event Date” shall have the meaning set forth in Section 2(c) herein.

“Exchange Act” means the U.S. Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Filing Deadline” means, with respect to the Initial Registration Statement required to be filed pursuant to Section 2(a) herein, the date that is thirty (30) calendar days after the Warrant is issued, provided, that if the Filing Deadline falls on a Saturday, Sunday or other day that the Commission is closed for business, the Filing Deadline shall be extended to the next business day on which the Commission is open for business.

“FINRA” shall have the meaning set forth in Section 3(k) herein.

“Funding Agreement” shall have the meaning set forth in the Preamble.

“Grace Period” shall have the meaning set forth in Section 3(d) herein.

“Holder” or “Holders” means the holder or holders, as the case may be, from time to time of Registrable Securities.

“Holders Counsel” shall have the meaning set forth in Section 3(a) herein.

“Indemnified Party” shall have the meaning set forth in Section 5(c) herein.

“Indemnifying Party” shall have the meaning set forth in Section 5(c) herein.

“Initial Registration Statement” means shall have the meaning set forth in Section 2(a) herein.

“Liquidated Damages” shall have the meaning set forth in Section 2(c) herein.

“Losses” shall have the meaning set forth in Section 5(a) herein.

“Merger Agreement” shall have the meaning set forth in the Preamble.

“New Registration Statement” shall have the meaning set forth in Section 2(a) herein.

“Non-Responsive Holder” shall have the meaning set forth in Section 6(d) herein.

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Principal Market” means the Trading Market on which the Common Stock is primarily listed on and quoted for trading.

“Proceeding” means an action, claim, suit, investigation or proceeding (including, without limitation, an investigation or partial proceeding, such as a deposition), whether commenced or threatened.

“Prospectus” means the prospectus included in a Registration Statement (including, without limitation, a prospectus that includes any information previously omitted from a prospectus filed as part of an effective registration statement in reliance upon Rule 430A promulgated under the Securities Act), as amended or supplemented by any prospectus supplement, with respect to the terms of the offering of any portion of the Registrable Securities covered by a Registration Statement, and all other amendments and supplements to the Prospectus, including post-effective amendments, and all material incorporated by reference or deemed to be incorporated by reference in such Prospectus.

“Purchaser” shall have the meaning set forth in the Preamble.

“Registrable Securities” means all of the Shares and any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the Shares, provided that Shares shall cease to be Registrable Securities upon the earliest to occur of the following: (A) a sale pursuant to a Registration Statement; (B) becoming eligible for sale without time, volume or manner of sale restrictions by the Holder thereof under Rule 144; or (C) if such Shares have ceased to be outstanding.

“Registration Statements” means any one or more registration statements of the Company filed under the Securities Act that covers the resale of any of the Registrable Securities pursuant to the provisions of this Agreement (including without limitation the Initial Registration Statement, the New Registration Statement and any Remainder Registration Statements), amendments and supplements to such Registration Statements, including post-effective amendments, all exhibits and all material incorporated by reference or deemed to be incorporated by reference in such Registration Statements.

“Remainder Registration Statement” shall have the meaning set forth in Section 2(a) herein.

“Requested Information” shall have the meaning set forth in Section 6(d) herein.

“Required Registration Statement” means any Initial Registration Statement, New Registration Statement or Remainder Registration Statement.

“Rule 144” means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any successor rule thereto.

“Rule 415” means Rule 415 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any successor rule thereto.

“Rule 424” means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended from time to time, or any successor rule thereto.

“SEC Guidance” means (i) any publicly-available written guidance, policy statement, comments, requirements, or requests of the Commission staff and/or (ii) the Securities Act.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Shares” means the shares of Common Stock issued or issuable to the Purchaser pursuant to the Warrant.

“Trading Day” means (i) a day on which the Common Stock is listed or quoted and traded on its Principal Market (other than the OTC Bulletin Board), or (ii) if the Common Stock is not listed on a Trading Market (other than the OTC Bulletin Board), a day on which the Common Stock is traded in the over-the-counter market, as reported by the OTC Bulletin Board, or (iii) if the Common Stock is not quoted on any Trading Market, a day on which the Common Stock is quoted in the over-the-counter market as reported in the “pink sheets” by OTC Markets Group, Inc. (or any similar organization or agency succeeding to its functions of reporting prices); provided, that in the event that the Common Stock is not listed or quoted as set forth in (i), (ii) and (iii) hereof, then Trading Day shall mean a Business Day.

“Trading Market” means whichever of the New York Stock Exchange, the NYSE American LLC, the NASDAQ Global Select Market, the NASDAQ Global Market, the NASDAQ Capital Market, or OTC Bulletin Board on which the Common Stock is listed or quoted for trading on the date in question.

“Warrant” shall have the meaning set forth in the Preamble.

## 2. Mandatory Registration.

(a) On or prior to the Filing Deadline, the Company shall prepare and file with the Commission a Registration Statement covering the resale of all of the Registrable Securities not already covered by an existing and effective Registration Statement for an offering to be made on a continuous basis pursuant to Rule 415 or, if Rule 415 is not available for offers and sales of the Registrable Securities, by such other means of distribution of Registrable Securities as the Company may reasonably determine (the “Initial Registration Statement”). Notwithstanding the registration obligations set forth in this Section 2 of the Agreement, in the event that (i) the Company’s legal counsel determines that all such Registrable Securities cannot, as a result of the application of Rule 415, be registered for resale as a secondary offering on a single registration statement prior to filing the Initial Registration Statement, or (ii) the Commission informs the Company that all such Registrable Securities cannot, as a result of the application of Rule 415, be registered for resale as a secondary offering on a single registration statement, the Company agrees promptly to (A) inform each of the Holders thereof and, as applicable, file the Initial Registration Statement, or use its reasonable efforts to file amendments to the Initial Registration Statement as required by the Commission and/or (B) withdraw the Initial Registration Statement and file a new registration statement (a “New Registration Statement”), in each case covering the maximum number of such Registrable Securities permitted to be registered thereon, on the Commission’s Form S-3 or, if Form S-3 is not available for such purpose, on such form available to the Company to register for resale the Registrable Securities as a secondary offering. Notwithstanding any other provision of this Agreement, if the opinion of the Company’s legal counsel or any SEC Guidance sets forth a limitation of the number of Registrable Securities permitted to be registered on a particular Registration Statement as a secondary offering, the number of Registrable Securities to be registered on such Registration Statement will be reduced pro rata on the basis of the aggregate number of Registrable Securities owned by each applicable Holder. In the event the Company amends the Initial Registration Statement or files a New Registration Statement, as the case may be, under clauses (A) or (B) above, the Company will use its reasonable efforts to file with the Commission, as promptly as allowed by Commission or SEC Guidance provided to the Company or to registrants of securities in general, one or

more registration statements on such form available to the Company to register for resale those Registrable Securities that were not registered for resale on the Initial Registration Statement, as amended, or the New Registration Statement (the "Remainder Registration Statements"). No Holder shall be named as an "underwriter" in any Registration Statement without such Holder's prior written consent.

(b) The Company shall use its reasonable efforts to cause each Required Registration Statement to be declared effective by the Commission as soon as practicable, and, with respect to the Initial Registration Statement or the New Registration Statement, as applicable, no later than the Effectiveness Deadline, and shall use its reasonable efforts to keep each Required Registration Statement continuously effective under the Securities Act (excluding during an Allowable Grace Period) until the earlier of (i) such time as all of the Registrable Securities covered by such Required Registration Statement have been sold publicly by the Holders or (ii) the date that all Registrable Securities covered by such Required Registration Statement may be sold by the Holders without volume or manner of sale restrictions under Rule 144, as determined by counsel to the Company pursuant to a written opinion letter to such effect, addressed and reasonably acceptable to the Company's transfer agent (the "Effectiveness Period"). The Company promptly shall notify the Holders via facsimile or electronic mail of a ".pdf" format data file of the effectiveness of a Registration Statement within one (1) Business Day of the Effective Date. The Company shall file a final Prospectus for a Required Registration Statement with the Commission, as required by Rule 424(b) as promptly as reasonably practicable following the Effective Date.

(c) If: (i) the Initial Registration Statement is not filed with the Commission on or prior to the Filing Deadline, (ii) the Initial Registration Statement or the New Registration Statement, as applicable, is not declared effective by the Commission (or otherwise does not become effective) for any reason on or prior to the Effectiveness Deadline, or (iii) after its Effective Date, (A) such Registration Statement ceases to be effective for any reason (including without limitation by reason of a stop order, or the Company's failure to update the Registration Statement), to remain continuously effective as to all Registrable Securities for which it is required to be effective, or (B) the Holders are not permitted to utilize the Prospectus therein to resell such Registered Securities (other than during an Allowable Grace Period), or (iv) a Grace Period applicable to a Required Registration Statement exceeds the length of an Allowable Grace Period (any such failure or breach in clauses (i) through (iv) above being referred to as an "Event," and, for purposes of clauses (i), (ii) or (iii), the date on which such Event occurs, or for purposes of clause (iv) the date on which such Allowable Grace Period is exceeded, being referred to as an "Event Date"), then in addition to any other rights the Holders may have hereunder or under applicable law, on each such Event Date and on each monthly anniversary of each such Event Date (if the applicable Event shall not have been cured by such date) until the applicable Event is cured, the Company shall pay to each Holder, pro rata on the basis of the aggregate number of Registrable Securities owned by each applicable Holder, an amount in cash, as liquidated damages and not as a penalty ("Liquidated Damages"), an amount equal to \$500.00 per day on which the Company is not in compliance with the Filing Deadline, the Effectiveness Deadline and the Effectiveness Period. The parties agree that notwithstanding anything to the contrary herein or in the Funding or Merger Agreement(s), no Liquidated Damages shall be payable (i) to a Holder if as of the relevant Event Date, all Registrable Securities held by it may be sold by the Holder without volume or manner of sale restrictions under Rule 144, as determined by counsel to the Company pursuant to a written opinion letter to such effect, addressed and reasonably acceptable to the Company's transfer agent, (ii) to a Holder causing an Event that relates to or is caused by any action or inaction taken by such Holder, (iii) to a Holder in the event it is unable to lawfully sell any of its Registrable Securities (including, without limitation, in the event a Grace Period exceeds the length of an Allowable Grace Period) because of possession of material non-public information

or (iv) with respect to any period after the expiration of the Effectiveness Period (it being understood that this clause shall not relieve the Company of any Liquidated Damages accruing prior to the expiration of the Effectiveness Period). If the Company fails to pay any Liquidated Damages pursuant to this Section 2(c) of the Agreement in full within ten (10) Business Days after the date payable, the Company will pay interest on the amount of Liquidated Damages then owing to the Holder at a rate of 1.0% per month on an annualized basis (or such lesser maximum amount that is permitted to be paid by applicable law) to the Holder, accruing daily from the date such Liquidated Damages are due until such amounts, plus all such interest thereon, are paid in full. The Liquidated Damages pursuant to the terms hereof shall apply on a daily pro-rata basis for any portion of a month prior to the cure of an Event, except in the case of the first Event Date. With respect to a Holder, the Effectiveness Deadline for a Required Registration Statement shall be extended without default or Liquidated Damages hereunder in accordance with Section 3(k) of the Agreement in the event that the Company's failure to obtain the effectiveness of the Registration Statement on a timely basis results from the failure of such Holder timely to provide the Company with information requested by the Company and necessary to complete the Registration Statement in accordance with the requirements of the Securities Act.

### 3. Registration Procedures.

In connection with the Company's registration obligations hereunder:

(a) The Company shall, not less than one Trading Day prior to the filing of a Registration Statement or any related Prospectus or any amendment or supplement thereto (except for Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, proxy statements and Current Reports on Form 8-K, and any similar or successor reports), furnish to one legal counsel designated by a majority of the outstanding Registrable Securities ("Holder's Counsel"), copies of such Registration Statement, Prospectus, or amendment or supplement thereto, as proposed to be filed, which document will be subject to the reasonable review and comment of Holder's Counsel; provided that each Holder shall have the right to review and comment on, prior to filing, its selling shareholder information.

(b) (i) The Company shall prepare and file with the Commission such amendments, including post-effective amendments and supplements, to each Registration Statement and the Prospectus used in connection therewith as may be necessary to keep such Registration Statement continuously effective as to the applicable Registrable Securities for its Effectiveness Period (except during an Allowable Grace Period); (ii) the Company shall cause the related Prospectus to be amended or supplemented by any required Prospectus supplement (subject to the terms of this Agreement), and, as so supplemented or amended, to be filed pursuant to Rule 424 (except during an Allowable Grace Period); (iii) the Company shall respond as promptly as reasonably practicable to any comments received from the Commission with respect to each Registration Statement or any amendment thereto and, as promptly as reasonably possible, provide the Holder's Counsel true and complete copies of all correspondence from and to the Commission relating to such Registration Statement that pertains to the Holders as "Selling Shareholders"; and (iv) the Company shall comply in all material respects with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by a Registration Statement until such time as all of such Registrable Securities shall have been disposed of (subject to the terms of this Agreement) in accordance with the intended methods of disposition by the Holders thereof as set forth in such Registration Statement as so amended or in such Prospectus as so supplemented; provided, that each Holder shall be responsible for the delivery of the Prospectus to the Persons to whom such Holder sells any of the Registrable Securities (including in accordance with Rule 172 under the Securities Act), and each Holder agrees to dispose of Registrable

Securities in compliance with applicable federal and state securities laws. In the case of amendments and supplements to a Registration Statement that are required to be filed pursuant to this Agreement (including pursuant to this Section 3(b)) by reason of the Company filing a report on Form 10-K, Form 10-Q, or Form 8-K, or any analogous report under the Exchange Act, the Company shall have incorporated such report by reference into such Registration Statement, if applicable, or shall file such amendments or supplements with the Commission as promptly as practicable.

(c) The Company shall notify the Holders (which notice shall, pursuant to clauses (ii) through (iv) hereof, be accompanied by an instruction to suspend the use of the Prospectus until the requisite changes have been made, if applicable) as promptly as reasonably practicable following the day (i)(A) when a Prospectus or any Prospectus supplement or post-effective amendment to a Registration Statement has been filed with the Commission (except for Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, proxy statements and Current Reports on Form 8-K and any similar or successor reports); and (B) with respect to each Registration Statement or any post-effective amendment, when the same has become effective; (ii) of the issuance by the Commission or any other federal or state Governmental Entity of any stop order suspending the effectiveness of a Registration Statement covering any or all of the Registrable Securities or the initiation of any Proceedings for that purpose; (iii) of the receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Registrable Securities for sale in any jurisdiction, or the initiation or threatening of any Proceeding for such purpose; and (iv) of the occurrence of any event or passage of time that makes the financial statements included in a Registration Statement ineligible for inclusion therein or any statement made in such Registration Statement or Prospectus or any document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires any revisions to such Registration Statement, Prospectus or other documents so that, in the case of such Registration Statement or the Prospectus, as the case may be, it will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, form of prospectus or supplement thereto, in light of the circumstances under which they were made), not misleading.

(d) Notwithstanding anything to the contrary herein, at any time after the Registration Statement has been declared effective by the Commission, the Company may delay the disclosure of material non-public information concerning the Company if the disclosure of such information at the time is not, in the good faith judgment of the Company, in the best interests of the Company (such delay, a “Grace Period”). During the Grace Period, the Company shall not be required to maintain the effectiveness of any Registration Statement filed hereunder and, in any event, Holders shall suspend sales of Registrable Securities pursuant to such Registration Statements during the pendency of the Grace Period provided, the Company shall promptly (i) notify the Holders of the existence of material non-public information giving rise to a Grace Period or the need to file a post-effective amendment, as applicable, and the date on which such Grace Period will begin, (ii) use reasonable efforts to terminate a Grace Period as promptly as practicable provided that such termination is, in the good faith judgment of the Company, in the best interest of the Company, and (iii) notify the Holders in writing of the date on which the Grace Period ends; provided, further, that, with respect to a Required Registration Statement only, no single Grace Period shall exceed sixty (60) consecutive calendar days, and during any three hundred sixty-five (365) calendar day period, the aggregate of all Grace Periods shall not exceed an aggregate of ninety (90) calendar days (each Grace Period complying with this provision being an “Allowable Grace Period”). For purposes of determining the length of a Grace Period, the Grace Period shall be deemed to begin on and include the date the Holders receive the notice referred to in clause (i) above and shall end on and include the later of the date the Holders receive the notice referred

to in clause (iii) above and the date referred to in such notice; provided, that no Grace Period shall be longer than an Allowable Grace Period. Notwithstanding anything to the contrary, the Company shall use reasonable best efforts to cause the Transfer Agent to deliver unlegended Shares to a transferee of a Holder in connection with any sale of Registrable Securities with respect to which a Holder has entered into an irrevocable contract for sale prior to the Holder's receipt of the notice of a Grace Period and for which the Holder has not yet settled.

(e) The Company shall use reasonable efforts to avoid the issuance of, or, if issued, obtain the withdrawal of (i) any order suspending the effectiveness of a Registration Statement, or (ii) any suspension of the qualification (or exemption from qualification) of any of the Registrable Securities for sale in any jurisdiction, as soon as practicable.

(f) The Company shall, if requested by a Holder, furnish to such Holder, without charge, at least one (1) conformed copy of each Registration Statement and each amendment thereto and all exhibits to the extent requested by such Holder (including those previously furnished or incorporated by reference) promptly after the filing of such documents with the Commission; provided, that the Company shall have no obligation to provide any document pursuant to this clause that is available on the Commission's EDGAR or successor system.

(g) The Company agrees to deliver promptly to each Holder whose Registrable Securities are included in the applicable Registration Statement, without charge, a PDF electronic copy of each Prospectus or Prospectuses (including each form of prospectus) and each amendment or supplement thereto as such Persons may reasonably request. The Company will provide hard copies to such Persons upon request. The Company hereby consents to the use of such Prospectus and each amendment or supplement thereto by each of the selling Holders in connection with the offering and sale of Registrable Securities covered by such Prospectus and any amendment or supplement thereto.

(h) The Company shall, prior to any resale of Registrable Securities by a Holder, use its reasonable efforts to register or qualify or cooperate with the selling Holders in connection with the registration or qualification (or exemption from the registration or qualification) of such Registrable Securities for the resale by the Holder under the securities or Blue Sky laws of such jurisdictions within the United States as any Holder reasonably requests in writing, to keep each registration or qualification (or exemption therefrom) effective during the Effectiveness Period and to do any and all other acts or things reasonably necessary to enable the disposition in such jurisdictions of the Registrable Securities covered by each Registration Statement; provided, that the Company shall not be required to qualify generally to do business in any jurisdiction where it is not then so qualified, subject the Company to any general tax in any such jurisdiction where it is not then so subject, or file a consent to service of process in any such jurisdiction.

(i) The Company shall reasonably cooperate with the Holders to facilitate the timely preparation and delivery of certificates representing Registrable Securities to be delivered to a transferee pursuant to the Registration Statement, which certificates shall be free, to the extent permitted by the Funding Agreement and under law, of all restrictive legends, and to enable such Registrable Securities to be in such denominations and registered in such names as any such Holders may reasonably request. Certificates for Registrable Securities free from all restrictive legends may be transmitted by the transfer agent to a Holder by crediting the account of such Holder's prime broker with DTC as directed by such Holder.

(j) The Company shall following the occurrence of any event contemplated by Sections 3(c)(ii)-(iv), as promptly as reasonably practicable, as applicable: (i) use its reasonable efforts to

prevent the issuance of any stop order or obtain its withdrawal at the earliest possible moment if the stop order have been issued, or (ii) taking into account the Company's good faith assessment of any adverse consequences to the Company and its shareholders of the premature disclosure of such event, prepare and file a supplement or amendment, including a post-effective amendment, to the affected Registration Statements or a supplement to the related Prospectus or any document incorporated or deemed to be incorporated therein by reference, and file any other required document so that, as thereafter delivered, no Registration Statement nor any Prospectus will contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, form of prospectus or supplement thereto, in light of the circumstances under which they were made), not misleading.

(k) The Company may require each selling Holder to furnish to the Company a certified statement as to (i) the number of securities of the Company beneficially owned by such Holder and any Affiliate thereof, (ii) any Financial Industry Regulatory Authority ("FINRA") affiliations, (iii) any natural persons who have the power to vote or dispose of the Common Stock and (iv) any other information as may be requested by the Commission, FINRA, any state securities commission or any other government or regulatory body with jurisdiction over the Company or its activities. During any periods that the Company is unable to meet its obligations hereunder with respect to the registration of Registrable Securities because any Holder fails to furnish such information, any Liquidated Damages that are accruing at such time as to such Holder shall be tolled and any Event that may otherwise occur solely because of such delay shall be suspended as to such Holder only, until such information is delivered to the Company.

(l) The Company shall cooperate with any registered broker through which a Holder proposes to resell its Registrable Securities in effecting a filing with FINRA pursuant to FINRA Rule 5110 as requested by any such Holder and the Company shall pay the filing fee required for the first such filing (but not additional filings) within five (5) Business Days of the request therefore.

(m) If requested by a Holders Counsel, the Company shall (i) promptly incorporate in a Prospectus supplement or post-effective amendment to the Registration Statement such information as the Company reasonably agrees (upon advice of legal counsel) is required to be included therein and (ii) make all required filings of such Prospectus supplement or such post-effective amendment as soon as reasonably practicable after the Company has received notification of the matters to be incorporated in such Prospectus supplement or post-effective amendment.

4 . Registration Expenses. All fees and expenses incident to the Company's performance of or compliance with its obligations under this Agreement (excluding any selling commissions, stock transfer taxes and fees of legal counsel for the Holders) shall be borne by the Company whether or not any Registrable Securities are sold pursuant to a Registration Statement. The fees and expenses referred to in the foregoing sentence that are the Company's responsibility shall include, without limitation, (i) all registration and filing fees (including, without limitation, fees and expenses (A) with respect to filings required to be made with any Trading Market on which the Common Stock is then listed for trading, (B) with respect to compliance with applicable state securities or Blue Sky laws (including, without limitation, fees and disbursements of legal counsel for the Company in connection with Blue Sky qualifications or exemptions of the Registrable Securities and determination of the eligibility of the Registrable Securities for investment under the laws of such jurisdictions as requested by the Holders) and (C) if not previously paid by the Company in connection with an issuer filing, with respect to any filing that may be required to be made by any broker through which a Holder intends to make sales of Registrable Securities with FINRA pursuant to FINRA Rule 5110, so long

as the broker is receiving no more than a customary brokerage commission in connection with such sale, (ii) printing expenses (including, without limitation, expenses of printing certificates for Registrable Securities and of printing prospectuses if the printing of prospectuses is reasonably requested by the Holders of a majority of the Registrable Securities included in the Registration Statement), (iii) messenger, telephone and delivery expenses of the Company, (iv) fees and disbursements of legal counsel for the Company, and (v) fees and expenses of all other Persons retained by the Company in connection with the consummation of the transactions contemplated by this Agreement. In addition, the Company shall be responsible for all of its internal expenses incurred in connection with the consummation of the transactions contemplated by this Agreement (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit, and the fees and expenses incurred in connection with the listing of the Registrable Securities on any securities exchange as required hereunder.

5. Indemnification.

(a) Indemnification by the Company. The Company shall, notwithstanding any termination of this Agreement, indemnify, defend and hold harmless each Holder and each of their respective officers, directors, agents, general partners, managing members, managers, Affiliates and employees, each Person who controls any such Holder (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) and the officers, directors, general partners, managing members, managers, agents and employees of such controlling Person, to the fullest extent permitted by applicable law, from and against any and all losses, claims, damages, liabilities, costs (including, without limitation, reasonable costs of preparation and investigation and reasonable and documented attorneys' fees) and expenses (collectively, "Losses"), as incurred, that arise out of or are based upon (i) any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus or any form of prospectus or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus or form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading, or (ii) any violation or alleged violation by the Company of the Securities Act, Exchange Act or any state securities law or any rule or regulation thereunder, in connection with the performance of its obligations under this Agreement, except to the extent, but only to the extent, that (A) such untrue statements, alleged untrue statements, omissions or alleged omissions are based solely upon information regarding such Holder furnished to the Company by such Holder or on behalf of such Holder expressly for use therein, or to the extent that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and approved by such Holder or Holders Counsel expressly for use in the Registration Statement, such Prospectus or such form of Prospectus or in any amendment or supplement thereto, (B) Holder's failure to deliver or cause to be delivered the Prospectus or any amendment or supplement thereto made available by the Company in compliance with Section 6(g), or (C) in the case of an occurrence of an event of the type specified in Sections 3(c)(ii)-(iv), related to the use by a Holder of an outdated or defective Prospectus after the Company has notified such Holder that the Prospectus is outdated or defective and prior to the receipt by such Holder of the Advice contemplated and defined in Section 6(h) below, but only if and to the extent that following the receipt of the Advice the misstatement or omission giving rise to such Loss would have been corrected. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of an Indemnified Party (as defined in Section 5(c) below) and shall survive the transfer of the Registrable Securities by the Holders.

(b) Indemnification by Holders. Each Holder shall, notwithstanding any termination of this Agreement, severally and not jointly, indemnify and hold harmless the Company, its directors, officers, agents and employees, each Person who controls the Company (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, agents or employees of such controlling Persons, to the fullest extent permitted by applicable law, from and against all Losses, as incurred, arising out of or are based upon (i) any untrue or alleged untrue statement of a material fact contained in any Registration Statement, any Prospectus, or any form of prospectus, or in any amendment or supplement thereto or in any preliminary prospectus, or arising out of or relating to any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein (in the case of any Prospectus, or any form of prospectus or supplement thereto, in light of the circumstances under which they were made) not misleading (A) to the extent, but only to the extent, that such untrue statements or omissions are based solely upon information regarding such Holder furnished to the Company by or on behalf of such Holder expressly for use therein, or (B) to the extent, but only to the extent, that such information relates to such Holder or such Holder's proposed method of distribution of Registrable Securities and was reviewed and approved by such Holder or Holders Counsel expressly for use in a Registration Statement, such Prospectus or such form of Prospectus or in any amendment or supplement thereto or (C) in the case of an occurrence of an event of the type specified in Sections 3(c)(ii)-(iv), to the extent, but only to the extent, related to the use by such Holder of an outdated or defective Prospectus after the Company has notified such Holder that the Prospectus is outdated or defective and prior to the receipt by such Holder of the Advice contemplated in Section 6(h), but only if and to the extent that following the receipt of the Advice the misstatement or omission giving rise to such Loss would have been corrected, or (ii) Holder's failure to deliver or cause to be delivered the Prospectus or any amendment or supplement thereto made available by the Company in compliance with Section 6(g) herein. In no event shall the liability of any selling Holder hereunder be greater in amount than the dollar amount of the net proceeds received by such Holder upon the sale of the Registrable Securities giving rise to such indemnification obligation.

(c) Conduct of Indemnification Proceedings. If any Proceeding shall be brought or asserted against any Person entitled to indemnity hereunder (an "Indemnified Party"), such Indemnified Party shall promptly notify the Person from whom indemnity is sought (the "Indemnifying Party") in writing, and the Indemnifying Party shall have the right to assume the defense thereof, including the employment of one (1) legal counsel reasonably satisfactory to the Indemnified Party and the payment of all reasonable and documented fees and expenses incurred in connection with defense thereof; provided, that the failure of any Indemnified Party to give such written notice within a reasonable time of commencement of any such Proceeding shall not relieve the Indemnifying Party of its obligations or liabilities pursuant to this Agreement, except (and only) to the extent that such failure shall have materially and adversely prejudiced the Indemnifying Party in its ability to defend such Proceeding.

An Indemnified Party shall have the right to employ separate legal counsel in any such Proceeding and to participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Indemnified Party or Indemnified Parties unless: (1) the Indemnifying Party has agreed in writing to pay such fees and expenses; (2) the Indemnifying Party shall have failed promptly to assume the defense of such Proceeding and to employ legal counsel reasonably satisfactory to such Indemnified Party in any such Proceeding; or (3) the named parties to any such Proceeding (including any impleaded parties) include both such Indemnified Party and the Indemnifying Party, and such Indemnified Party shall have been advised by legal counsel in writing that a conflict of interest exists if the same counsel were to represent such Indemnified Party and the Indemnifying Party; provided, that the Indemnifying Party shall

not be liable for the fees and expenses of more than one separate firm of attorneys plus local legal counsel at any time for all Indemnified Parties. The Indemnifying Party shall not be liable for any settlement of any such Proceeding effected without its written consent, which consent shall not be unreasonably withheld, delayed or unreasonably conditioned. No Indemnifying Party shall, without the prior written consent of the Indemnified Party, effect any settlement of any pending Proceeding in respect of which any Indemnified Party is a party, unless such settlement includes an unconditional release of such Indemnified Party from all liability on claims that are the subject matter of such Proceeding.

Subject to the terms of this Agreement, all documented fees and expenses of the Indemnified Party (including reasonable fees and expenses to the extent incurred in connection with investigating or preparing to defend such Proceeding in a manner not inconsistent with this Section 5(c) of the Agreement) shall be paid to the Indemnified Party, as incurred, within twenty (20) Trading Days of written notice thereof to the Indemnifying Party; provided, that the Indemnified Party shall promptly reimburse the Indemnifying Party for that portion of such fees and expenses applicable to such actions for which such Indemnified Party is finally judicially determined to not be entitled to indemnification hereunder.

(d) Contribution. If a claim for indemnification under Section 5(a) or 5(b) of the Agreement is unavailable to an Indemnified Party (other than in accordance with its terms) or insufficient to hold an Indemnified Party harmless for any Losses, then each Indemnifying Party, in lieu of indemnifying such Indemnified Party, shall contribute to the amount paid or payable by such Indemnified Party as a result of such Losses, in such proportion as is appropriate to reflect the relative fault of the Indemnifying Party, on the one hand, and the Indemnified Party, on the other hand, in connection with the actions, statements or omissions that resulted in such Losses as well as any other relevant equitable considerations. The relative fault of such Indemnifying Party, on the one hand, and such Indemnified Party, on the other hand, shall be determined by reference to, among other things, whether any action in question, including any untrue or alleged untrue statement of a material fact or omission or alleged omission of a material fact, has been taken or made by, or relates to information supplied by, such Indemnifying Party or Indemnified Party, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such action, statement or omission. The amount paid or payable by a party as a result of any Losses shall be deemed to include, subject to the limitations set forth in this Agreement, any reasonable attorneys' or other reasonable fees or expenses incurred by such party in connection with any Proceeding to the extent such party would have been indemnified for such fees or expenses if the indemnification provided for in this Section 5(d) was available to such party in accordance with its terms. The parties hereto agree that it would not be just and equitable if contribution pursuant to this Section 5(d) were determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to in the immediately preceding paragraph. Notwithstanding the provisions of this Section 5(d), no Holder shall be required to contribute, in the aggregate, any amount in excess of the amount by which the net proceeds actually received by such Holder from the sale of the Registrable Securities subject to the Proceeding exceeds the amount of any damages that such Holder has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation.

The indemnity and contribution agreements contained in this Section 5 of the Agreement are in addition to any liability that the Indemnifying Parties may have to the Indemnified Parties and are not in diminution or limitation of the indemnification provisions under the Funding and Merger Agreements.

6. Miscellaneous.

(a) Remedies. In the event of a breach by the Company or by a Holder of any of their obligations under this Agreement, each Holder or the Company, as the case may be, in addition to being entitled to exercise all rights granted by law and under this Agreement, including recovery of damages, will be entitled to specific performance of its rights under this Agreement. The Company and each Holder agree that monetary damages would not provide adequate compensation for any losses incurred by reason of a breach by it of any of the provisions of this Agreement and hereby further agrees that, in the event of any action for specific performance in respect of such breach, it shall waive the defense that a remedy at law would be adequate.

(b) Rule 144 Requirements. For so long as the Company is subject to the reporting requirements of the Exchange Act, the Company will use its reasonable efforts to timely file with the Commission such reports and information required to be filed by it under the Securities Act and the Exchange Act and the rules and regulations adopted by the Commission thereunder and as the Commission may require. The Company shall furnish to any Holder of Registrable Securities forthwith upon request a written statement as to its compliance with the reporting requirements of Rule 144 (or any successor exemptive rule), the Securities Act and the Exchange Act (at any time that it is subject to such reporting requirements); and such reports and documents as such Person may reasonably request in availing itself of any rule or regulation of the Commission allowing it to sell any such securities without registration.

(c) Obligations of Holders and Others in a Registration. Each Holder agrees timely to furnish in writing such information regarding such Person, the securities sought to be registered, and the intended method of disposition of the Registrable Securities held by it, as shall reasonably be required to effect the registration of such Registrable Securities (the "Requested Information") and shall take such other action as the Company may reasonably request in connection with the registration, qualification or compliance or as otherwise provided herein. At least ten (10) Business Days prior to the first anticipated filing date of a Registration Statement, the Company shall notify each Holder of the information the Company requires from such Holder. If at least five (5) business days prior to the filing date, the Company has not received the Requested Information from a Holder (a "Non-Responsive Holder"), then the Company may exclude from any Registration Statement the Registrable Securities of such Non-Responsive Holder.

(d) Limitations on Subsequent Registration Rights. The Company will not enter into any agreements with any holder or prospective holder of any securities of the Company which would grant such holder or prospective holder registration rights with respect to the securities of the Company that would have priority over the Registrable Securities with respect to the inclusion of such securities in any registration. If the Company enters into an agreement that contains terms more favorable, in form or substance, to any shareholders than the terms provided to the Holders under this Agreement, then the Company will modify or revise the terms of this Agreement in order to reflect any such more favorable terms for the benefit of the Holders.

(e) Compliance. Each Holder covenants and agrees that it will comply with the prospectus delivery requirements of the Securities Act as applicable to it (unless an exemption therefrom is available) in connection with sales of Registrable Securities pursuant to the Registration Statement and shall sell the Registrable Securities only in accordance with a method of distribution described in the Registration Statement.

(f) Discontinued Disposition. By its acquisition of Registrable Securities, each Holder agrees that, upon receipt of a notice from the Company of the occurrence of any event of the kind described in Sections 3(c)(ii)-(iv) of the Agreement, such Holder will forthwith discontinue disposition of such Registrable Securities under a Registration Statement until it is advised in writing (the "Advice") by the Company that the use of the applicable Prospectus (as it may have been supplemented or amended) may be resumed. The Company may provide appropriate stop orders to enforce the provisions of this paragraph.

(g) No Inconsistent Agreements. Neither the Company nor any of its Subsidiaries has entered, as of the date hereof, nor shall the Company or any of its Subsidiaries, on or after the date hereof, enter into any agreement with respect to its securities, that would have the effect of impairing the rights granted to either party in this Agreement or otherwise conflicts with the provisions hereof.

(h) Amendments and Waivers. The provisions of this Agreement, including the provisions of this sentence, may not be amended, modified or supplemented, or waived unless the same shall be in writing and signed by the Company and Holders of a majority of the then outstanding Registrable Securities; provided that any such amendment, modification, supplement or waiver that materially, adversely and disproportionately effects the rights or obligations of any Holder vis-a-vis the other Holders shall require the prior written consent of such Holder.

(i) Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of (a) the date of transmission, if such notice or communication is delivered via facsimile or e-mail (provided the sender receives a machine-generated confirmation of successful facsimile transmission or e-mail notification or confirmation of receipt of an e-mail transmission) at the facsimile number or e-mail address specified in this Section prior to 5:00 p.m., New York City time, on a Trading Day, (b) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile at the facsimile number specified in this Section on a day that is not a Trading Day or later than 5:00 p.m., New York City time, on any Trading Day, (c) the Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service with next day delivery specified, or (d) upon actual receipt by the party to whom such notice is required to be given.

The address for such notices and communications shall be as follows:

If to the Company:                   Brickell Biotech, Inc.  
5777 Central Avenue, Suite 102  
Boulder, CO 80301  
Attention: Andy Sklawer  
Telephone: 305-582-4657  
E-mail:  
asklawer@brickellbio.com

With a copy to:                       Mayer Brown LLP  
1221 Avenue of the Americas  
New York, NY 10020  
Attention: Anna T. Pinedo  
Telephone: 212-506-2275  
E-mail:  
apinedo@mayerbrown.com

If to the Purchaser: NovaQuest Co-Investment Fund X  
4208 Six Forks Road, Suite 920  
Raleigh, NC 27609  
Attention: Jonathan Tunncliffe  
Email: jonathan.tunncliffe@nqcapital.com  
Facsimile: 919-516-0580

With a copy to: Wyrick Robbins Yates & Ponton LLP  
4101 Lake Boone Trail, Suite 300  
Raleigh, NC 27607  
Attention: Daniel S. Porper  
Email: dporper@wyrick.com  
Facsimile: 919-781-4865

If to a Holder who is not the Purchaser, then to such address as may be designated in writing hereafter, in the same manner, by such Person.

(j) Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective permitted successors and assigns any rights, remedies, obligations, or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. The Company may not assign its rights (except by merger or in connection with another entity acquiring all or substantially all of the Company's assets) or obligations hereunder without the prior written consent of all of the Holders of the then outstanding Registrable Securities. The rights to have the Company register Registrable Securities pursuant to this Agreement shall be automatically assigned by a Holder to any transferee of the Shares only if: (i) the Holder agrees in writing with the transferee or assignee to assign such rights; (ii) the Company is, within a reasonable time after such transfer or assignment, furnished with written notice of (A) the name and address of such transferee or assignee and (B) the securities with respect to which such registration rights are being transferred or assigned; and (iii) at or before the time the Company received the written notice contemplated by clause (ii) of this sentence, the transferee or assignee agrees in writing with the Company to be bound by all of the provisions contained herein with respect to a Holder. In the event of any delay in filing or effectiveness of the Registration Statement as a result of such assignment by a Holder or its transferee, the Company shall not be liable for any damages arising from such delay.

(k) Execution and Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which when so executed shall be deemed to be an original and, all of which taken together shall constitute one and the same Agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a “.pdf” format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or “.pdf” signature were the original thereof.

(l) Governing Law and Jurisdiction. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to contracts made and

to be performed entirely within such State. The parties hereby agree that all actions or proceedings arising out of or related to this Agreement shall be subject to the exclusive jurisdiction of the state and federal courts in the State of New York. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be determined in accordance with the provisions of the Funding Agreement.

(m) Cumulative Remedies. Except as provided in Section 2(c) of the Agreement with respect to Liquidated Damages, the remedies provided herein are cumulative and not exclusive of any other remedies provided by law.

(n) Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their good faith reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

(o) Headings. The headings in this Agreement are for convenience only and shall not limit or otherwise affect the meaning hereof.

(p) Independent Nature of Holders' Obligations and Rights. The obligations of each Holder under this Agreement are several and not joint with the obligations of any other Holder hereunder, and no Holder shall be responsible in any way for the performance of the obligations of any other Holder hereunder. Nothing contained herein or in any other agreement or document delivered at any closing, and no action taken by any Holder pursuant hereto or thereto, shall be deemed to constitute the Holders as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Holders are in any way acting in concert with respect to such obligations or the transactions contemplated by this Agreement. Each Holder shall be entitled to protect and enforce its rights, including, without limitation, the rights arising out of this Agreement, and it shall not be necessary for any other Holder to be joined as an additional party in any Proceeding for such purpose. It is expressly understood and agreed that each provision contained in this Agreement is between the Company and a Holder, solely, and not between the Company and the Holders collectively and not between and among the Holders.

(q) Entire Agreement. This Agreement, the Warrant, the Funding Agreement, the Merger Agreement, and the Security Agreement constitute the entire agreement among the parties hereto with respect to the subject matter hereof. There are no restrictions, promises, warranties or undertakings, other than as set forth or referred to herein and in the Warrant, the Funding Agreement, the Merger Agreement, and the Security Agreement. For purposes of this Agreement only, this Agreement supersedes all prior agreements and understandings among the parties hereto with respect to the subject matter hereof.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

BRICKELL BIOTECH, INC.

By: /s/ Robert Brown

Name: Robert Brown

Title: Chief Executive Officer

*[Signature Page to Registration Rights Agreement]*

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IN WITNESS WHEREOF, the parties have executed this Registration Rights Agreement as of the date first written above.

**NovaQuest Co-Investment Fund X, L.P.**

By: **NQ POF V GP, LTD., its general partner**

By: /s/ John L. Bradley, Jr.  
Name: John L. Bradley, Jr.  
Title: Director

*[Signature Page to Registration Rights Agreement]*

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

## U.S. SECURITY AGREEMENT

THIS U.S. SECURITY AGREEMENT (as the same may be amended, restated, supplemented or otherwise modified from time to time, this “*Security Agreement*”) is entered into as of August 31, 2019 by Brickell Subsidiary, Inc., a Delaware corporation (formerly known as Brickell Biotech, Inc.) (“*Brickell*” or “*Grantor*” and together with any additional obligors that are hereafter joined as parties hereto, the “*Grantors*”, and each individually, a “*Grantor*”) and NovaQuest Co-Investment Fund X, L.P., a Delaware limited partnership (“*Secured Party*”).

## PRELIMINARY STATEMENT

Brickell and Secured Party have entered into a Funding Agreement, dated as of June 2, 2019 (the “*Funding Agreement*”), pursuant to which Secured Party has agreed to provide funding for Brickell’s development of the Product (as defined in the Funding Agreement) and for Brickell to make certain payments to Secured Party as set forth in the Funding Agreement;

Brickell is entering into this Security Agreement in order to induce Secured Party to enter into and extend credit to Brickell under the Funding Agreement;

ACCORDINGLY, Grantors and Secured Party hereby agree as follows:

## ARTICLE I

### DEFINITIONS

1.1 **Terms Defined in UCC.** Terms defined in the UCC which are not otherwise defined in this Security Agreement are used herein as defined in the UCC, and if defined in more than one article of the UCC shall have the meaning specified in Article 9 thereof.

1.2 **Terms Defined in the Funding Agreement.** All capitalized terms used herein and not otherwise defined herein or in the UCC shall have the meanings assigned to such terms in the Funding Agreement.

1.3 **Definitions of Certain Terms Used Herein.** As used in this Security Agreement, in addition to the terms defined in the preamble and the Preliminary Statement, the following terms shall have the following meanings:

“*Article*” means a numbered article of this Security Agreement, unless another document or statute is specifically referenced.

“*Collateral*” shall have the meaning set forth in Article II.

“**Control**” shall have the meaning set forth in Section 8-106 of Article 8, Section 9-104, 9-105, 9-106 or 9-107 of Article 9 of the UCC, as applicable.

“**Copyright Security Agreement**” shall mean an agreement substantially in the form of the agreement attached hereto as Exhibit IV.

“**Copyrights**” means, with respect to any Grantor, all of such Grantor’s right, title, and interest in and to the following: (a) all copyrights, works protectable by copyright, copyright registrations, and copyright applications; (b) all extensions and renewals of any of the foregoing; (c) all income, royalties, damages, claims and payments now or hereafter due and/or payable under any of the foregoing, including, without limitation, damages or payments for past or future infringements for any of the foregoing; (d) the right to sue for past, present, and future infringements or violations of any of the foregoing; and (e) all rights corresponding to any of the foregoing throughout the world.

“**Domain Names**” means all internet domain names and associated URL addresses in or to which any Person now or hereafter has any right, title or interest.

“**Event of Default**” is defined in Section 5.1.

“**Excluded Accounts**” means (a) any trust or fiduciary account, (b) any payroll account or payroll taxes account, (c) any employee wage and benefit accounts, (d) any deposit account or securities account established or currently maintained for the sole purpose of holding cash or cash equivalents that serve as collateral or security under any letter of credit or other obligation not prohibited by the Funding Agreement, (e) withholding tax and fiduciary accounts and (f) any account that does not hold Product Assets or the proceeds of Product Assets.

“**Excluded Assets**” means (a) any assets that are not Product Assets or proceeds thereof, (b) any governmental licenses or state or local franchises, charters and authorizations, to the extent a security interest in any such license, franchise, charter or authorization is prohibited or restricted thereby (other than to the extent that any such prohibition or restriction would be rendered ineffective pursuant to the UCC of any relevant jurisdiction or any other Applicable Law), (c) nonassignable licenses or contracts, which by their terms require the consent of the licensor thereof or another party (other than to the extent that any such prohibition would be rendered ineffective pursuant to the UCC of any relevant jurisdiction or any other Applicable Law), (d) any applications for trademarks or service marks filed in the United States Patent and Trademark Office, or any successor office thereto pursuant to 15 U.S.C. §1051 Section 1(b) unless and until evidence of use of the mark in interstate commerce is submitted to the United States Patent and Trademark Office pursuant to 15 U.S.C. §1051 Section 1(c) or Section 1(d), and (e) Excluded Accounts.

“**Insolvency Event**” means in relation to any Grantor:

(a) if such Grantor (i) files a petition seeking to take advantage of any laws relating to bankruptcy, insolvency, reorganization, winding up or composition for adjustment of debts; (ii)

consents to, or fails to contest within sixty (60) calendar days and in appropriate manner, any petition filed against it in an involuntary case under such bankruptcy laws or other laws; (iii) applies for, consents to, or fails to contest within sixty (60) calendar days and in appropriate manner the appointment of, or the taking of possession by, a receiver, custodian, trustee, or liquidator of itself or of a substantial part of its property; (iv) admits in writing its inability to pay its debts as they become due; (v) makes a general assignment for the benefit of creditors; or (vi) takes any corporate action for the purpose of authorizing any of the foregoing; or

(b) if a case or other proceeding is commenced against such Grantor in any court of competent jurisdiction seeking (i) relief under any laws relating to bankruptcy, insolvency, reorganization, winding up, or adjustment of debts or (ii) the appointment of a trustee, receiver, custodian, liquidator, or the like for such Grantor for all or any substantial part of its assets; and under either clause (b)(i) or (b)(ii) of this definition, such case or proceeding has continued without dismissal or stay for a period of sixty (60) consecutive calendar days, or an order granting the relief requested in such case or proceeding (including an order for relief under such federal bankruptcy laws) is entered.

**“Intellectual Property”** means the collective reference to all rights, priorities and privileges relating to all Patents, Trademarks, Copyrights, Domain Names, trade secrets, Licenses and any other intellectual property, and all rights to sue or otherwise recover for any past, present and future infringement, dilution, misappropriation, or other violation or impairment thereof, including the right to receive all proceeds therefrom, including without limitation license fees, royalties, income payments, claims, damages and proceeds of suit, now or hereafter due and/or payable with respect thereto.

**“Licenses”** means (a) any and all licenses, agreements or similar arrangements providing for the grant to or from any Grantor of any right in and to Patents, Copyrights, or Trademarks or other Intellectual Property, and (b) all rights to sue for past, present, and future breaches thereof.

**“Non-Contingent Obligations”** means (i) if U.S. Approval has occurred, the Milestone Payment Obligation, and (ii) if a Non-Technical Termination has occurred, the Non-Technical Termination Payment.

**“Patent Security Agreement”** shall mean an agreement substantially in the form of the agreement attached hereto as Exhibit II.

**“Patents”** means, with respect to any Grantor, all of such Grantor’s right, title, and interest in and to: (a) any and all patents and patent applications; (b) all inventions and improvements described and claimed therein; (c) all reissues, divisions, continuations, renewals, extensions, and continuations-in-part thereof; (d) all income, royalties, damages, claims, and payments now or hereafter due or payable under and with respect thereto, including, without limitation, damages and payments for past and future infringements thereof; (e) all rights to sue for past, present, and future infringements thereof; and (f) all rights corresponding to any of the foregoing throughout the world.

**“Permitted Liens”** means the security interest in or lien on its assets granted by Brickell in favor of Hercules Technology Growth Capital, Inc., a Maryland corporation, but only for a period of time not to exceed seven (7) Business Days after the Closing Date.

**“Schedule”** refers to a specific schedule to this Security Agreement, unless another document is specifically referenced.

**“Section”** means a numbered section of this Security Agreement, unless another document or statute is specifically referenced.

**“Secured Obligations”** means all obligations of Brickell to make any Milestone Installment Payment, any Non-Technical Termination Payment, or any Revenue Share Payment pursuant to the Funding Agreement.

**“Software”** means with respect to any Grantor, all of such Grantor’s right, title, and interest in and to computer programs, object code, source code and supporting documentation, including, without limitation, “software” as such term is defined in the UCC and computer programs that may be construed as included in the definition of “goods” in the UCC.

**“Supplement to U.S. Security Agreement”** means a supplement to this Security Agreement in the form of Exhibit I (with such modifications as shall be reasonably acceptable to Secured Party).

**“Termination Date”** shall have the meaning set forth in Section 7.11.

**“Trademark Security Agreement”** shall mean an agreement substantially in the form of the agreement attached hereto as Exhibit III.

**“Trademarks”** means, with respect to any Grantor, all of such Grantor’s right, title, and interest in and to the following: (a) all trademarks (including service marks), trade names, trade styles, trade dress and the registrations and applications for registration thereof and the goodwill of the business symbolized by the foregoing; (b) all renewals of the foregoing; (c) all income, royalties, damages, claims and payments now or hereafter due or payable with respect thereto, including, without limitation, damages, claims, and payments for past and future infringements thereof; (d) all rights to sue for past, present, and future infringements of the foregoing, including the right to settle suits involving claims and demands for royalties owing; and (e) all rights corresponding to any of the foregoing throughout the world.

**“UCC”** means the Uniform Commercial Code as from time to time in effect in the State of New York; provided, however, that, in the event that, by reason of mandatory provisions of any Applicable Law, any of the attachment, perfection or priority of Secured Party’s security interest in any Collateral is governed by the Uniform Commercial Code of a jurisdiction other than the State of New York, “UCC” shall mean the Uniform Commercial Code as in effect in such other jurisdiction

for purposes of the provisions hereof relating to such attachment, perfection or priority and for purposes of the definitions related to or otherwise used in such provisions.

Section 11.12 of the Funding Agreement shall apply to this Security Agreement as if set out herein in full, mutatis mutandis.

## ARTICLE II

### GRANT OF SECURITY INTEREST

For value received and to secure the prompt and complete payment and performance of the Secured Obligations, each Grantor hereby grants to Secured Party a continuing security interest in and lien upon all of the following, in each case, to the extent located in the United States: Grantor's accounts, equipment, inventory, goods, fixtures, cash and currency, chattel paper, instruments, investment property, documents, letter-of-credit rights, deposit accounts, insurance claims and proceeds, contract rights, general intangibles, goodwill, and Intellectual Property rights, wherever located, whether now owned or hereafter acquired, and any additions, replacements, accessions, or substitutions thereof, all cash and non-cash proceeds and products thereof and all supporting obligations related thereto, but only to the extent such aforementioned property comprises the Product Assets as defined in the Funding Agreement, together with all books and records, customer lists, credit files, programs, printouts and other computer materials and records related thereto (the "*Collateral*"); *provided* that Collateral shall exclude Excluded Assets.

For the avoidance of doubt, the reaffirmation and grant of a security interest herein shall not be deemed to be an outright absolute assignment of Intellectual Property rights owned by such Grantor.

## ARTICLE III

### REPRESENTATIONS AND WARRANTIES

As of the Effective Date, each Grantor represents and warrants, and each Grantor that becomes a party to this Security Agreement pursuant to the execution of a Supplement to U.S. Security Agreement in substantially the form of Exhibit I represents and warrants (after giving effect to supplements to each of the Schedules hereto with respect to such subsequent Grantor as attached to such Supplement to U.S. Security Agreement as of the date of such Supplement to U.S. Security Agreement), to Secured Party that:

3.1 **Title, Authorization, Validity and Enforceability.** Such Grantor has good and valid rights in and the power to transfer the Collateral owned by it and title to the Collateral with respect to which it has purported to grant a security interest hereunder, free and clear of all Liens except for Permitted Liens, and has full corporate, limited liability company or partnership, as applicable, power and authority to grant to Secured Party the security interest in such Collateral

pursuant hereto. The execution and delivery by such Grantor of this Security Agreement (or any supplement hereto) and the performance of its obligations hereunder have been duly authorized by proper corporate, limited liability company, limited partnership or partnership, as applicable, proceedings, and this Security Agreement constitutes a legal, valid and binding obligation of such Grantor and creates a security interest which is enforceable against such Grantor in all of its right, title and interest in all Collateral it now owns or hereafter acquires, subject to applicable bankruptcy, insolvency, reorganization or moratorium and subject to general principles of equity, regardless of whether considered in a proceeding in equity or at law. When financing statements have been filed in the appropriate offices against such Grantor in the locations listed in Schedule C, Secured Party will have a fully perfected first priority security interest in the Collateral owned by such Grantor to the extent that a security interest may be perfected by filing of a financing statement under the UCC, subject only to Permitted Liens.

**3.2 Conflicting Laws and Contracts.** Neither the execution and delivery by such Grantor of this Security Agreement, the creation and perfection of the security interest in the Collateral granted hereunder, nor compliance with the terms and provisions hereof will (i) violate the charter, by-laws or other organizational documents of such Grantor, (ii) violate any Applicable Law or regulation or any order of any Governmental Authority that applies to such Grantor or the Collateral except as could not result in a Material Adverse Effect, (iii) violate in any material respect or result in a default under any material indenture, material agreement or other material instrument binding upon such Grantor or its assets, or give rise to a right thereunder to require any payment to be made by such Grantor except where such defaults would not reasonably be expected to result in a Material Adverse Effect, or (iv) result in the creation or imposition of any Lien on the Collateral of such Grantor, other than Liens created under this Security Agreement or the Funding Agreement.

**3.3 Principal Location.** As of the date such Person becomes a Grantor hereunder, such Grantor's location of its chief executive office is disclosed in Schedule A.

**3.4 No Other Names; Etc.** Within the five-year period ending as of the date such Person becomes a Grantor hereunder, such Grantor has not conducted business under any other name, changed its jurisdiction of organization, merged with or into or consolidated with any other Person, except as disclosed on Schedule A (as may be updated at the time such Person becomes a Grantor hereunder). The name in which such Grantor has executed this Security Agreement (or any Supplement to U.S. Security Agreement, as applicable) is the exact name as it appears in such Grantor's organizational documents, as amended, as filed with such Grantor's jurisdiction of organization as of the date such Person becomes a Grantor hereunder.

**3.5 Filing Requirements.** As of the date such Person becomes a Grantor hereunder, none of the Collateral owned by such Grantor is of a type for which security interests or liens may be perfected by filing under any U.S. federal statute except for Patents, Trademarks and Copyrights held by such Grantor and described in Schedule B.

**3.6 No Financing Statements, Security Agreements.** No UCC financing statement or security agreement describing all or any portion of the Collateral which has not lapsed or been

terminated naming such Grantor as debtor has been filed or is of record in any jurisdiction except UCC financing statements (i) naming Secured Party as the secured party and (ii) in respect of Permitted Liens.

3.7 **Federal Employer Identification Number; State Organization Number; Jurisdiction of Organization.** As of the date such Person becomes a Grantor hereunder, such Grantor's federal employer identification number (if applicable) is, and if such Grantor is a registered organization, such Grantor's state of organization, type of organization and state of organization identification number (if any) are, listed in Schedule E.

3.8 **Intellectual Property.** Schedule B contains a complete and accurate listing as of the date such Person becomes a Grantor hereunder of the following Intellectual Property licensed or owned by such Grantor in connection with the Product Assets: (i) U.S. trademark registrations and applications for trademark registration, (ii) U.S. patents and patent applications, (iii) U.S. copyright registrations and applications for registration, and (iv) Domain Names and (B) Licenses for all forms of Intellectual Property described in clauses (A)(i)-(iii) above that are owned by a Third Party and licensed to such Grantor or otherwise used by such Grantor under contract that are material to the business of the Grantor other than off-the-shelf Software and Software subject to shrink-wrap, click-wrap and other generally commercially available licenses. Notwithstanding anything in this Section 3.8 to the contrary, this Section 3.8 shall only apply to those items of Intellectual Property that constitute Product Assets.

3.9 **[Reserved].**

3.10 **Deposit and Securities Accounts.** Schedule F contains a list of all Deposit Accounts and Securities Accounts that constitute Collateral of each Grantor as of the date such Person becomes a Grantor hereunder.

## ARTICLE IV

### COVENANTS

Each of the Grantors agrees, and from and after the effective date of any Supplement to U.S. Security Agreement applicable to any Grantor (and after giving effect to supplements to each of the Schedules hereto with respect to such subsequent Grantor as attached to such Supplement to U.S. Security Agreement) and thereafter until the Termination Date, each such subsequent Grantor agrees:

#### 4.1 **General.**

(a) Financing Statements and Other Actions; Defense of Title. Each Grantor hereby authorizes Secured Party to file, and if requested will execute and deliver to Secured Party, all financing statements describing the Collateral owned by such Grantor and other documents and take such other actions as may from time to time reasonably be requested by Secured Party in order to maintain a perfected security interest in the Collateral owned by such Grantor. Such financing

statements may describe the Collateral in the same manner as described herein. At least ten (10) Business Days prior to opening any new Deposit Account or Securities Account that constitutes Collateral, the Grantor establishing such account shall provide written notice thereof to Secured Party, such notice to include the name, location, intended purpose and anticipated balance of funds to be held in such Deposit Account or Securities Account. Except with respect to Encumbrances that are permitted pursuant to the Funding Agreement, each Grantor agrees that it shall not execute any agreement for the benefit of any Person other than Secured Party that would have the effect of establishing Control of any Collateral provided that the foregoing shall not preclude Grantor from executing documentation with a depository bank, securities intermediary, or the like with respect to establishment of a deposit account or securities account or similar arrangement in the ordinary course of business.

(b) Change in Corporate Existence, Type or Jurisdiction of Organization, Location, Name. Each Grantor will:

(i) preserve its existence and organizational structure as in effect on the Effective Date (or as of the date such Person becomes a Grantor hereunder), except as otherwise permitted under the Funding Agreement; and

(ii) within thirty (30) calendar days (or such later date as may be agreed to by Secured Party in its sole discretion) before such Grantor makes any change in its (A) legal name or (B) jurisdiction of organization after the Effective Date, provide written notice to Secured Party of such action, clearly describing such change and providing such other information in connection therewith as Secured Party may reasonably request.

(c) Other UCC Financing Statements. Prior to the Termination Date, each Grantor acknowledges that it is not authorized to file any UCC financing statement or amendment or termination statement with respect to any UCC financing statement filed in connection herewith without the prior written consent of Secured Party, subject to such Grantor's rights under Section 9-509(d)(2) of the UCC.

(d) Disposition of Collateral. No Grantor shall sell, lease or otherwise dispose, discount or factor, with or without recourse, any Collateral except as permitted under the Funding Agreement.

**4.2 Intellectual Property.** If, after the date hereof, any Grantor obtains ownership rights to, including, but not limited to filing and acceptance of a statement of use or an amendment to allege use with the United States Patent and Trademark Office, or applies for or seeks registration of (other than applications for Trademarks filed in the United States Patent and Trademark Office, or any successor office thereto pursuant to 15 U.S.C. §1051 Section 1(b)), any new patentable invention, Trademark or Copyright in addition to the Patents, Trademarks and Copyrights described in Schedule B, in each case that constitutes Collateral, such Grantor shall give Secured Party written notice thereof as part of each Quarterly Report delivered to Secured Party under the Funding Agreement. Each Grantor agrees to execute and deliver to Secured Party, within thirty (30) days (or such later date as may be agreed to by Secured Party) of delivery of the applicable Quarterly

Report, any Supplement to U.S. Security Agreement, any Copyright Security Agreement, any Patent Security Agreement, any Trademark Security Agreement and any other document reasonably requested by Secured Party to evidence Secured Party's security interest in such new application or registration in a form appropriate for recording in the applicable federal office.

4.3 **[Reserved]**.

4.1 **Foreign Intellectual Property.** In the event any Grantor acquires any material Intellectual Property in the Territory constituting Collateral that is not located, registered or arising in the United States, such Grantor agrees to provide prompt written notice thereof to Secured Party and take such actions as may be required by Secured Party to create and perfect a security interest in such Collateral in favor of Secured Party.

4.2 **Termination of Hercules Lien.** Brickell agrees to cause the security interest in its assets granted to Hercules Technology Growth Capital, Inc. to be released within three (3) Business Days following the Closing Date and to have promptly terminated, but in any event within seven (7) business days after the Closing Date, all financing statements, control agreements and notices of record with respect thereto.

4.3 **Further Assurances.** Each Grantor agrees that from time to time such Grantor will promptly execute and deliver all further instruments and documents, and take all further action, that Secured Party may reasonably request, in order to perfect and protect the security interests granted hereby, to create, perfect or protect the security interests purported to be granted hereby or to enable Secured Party to exercise and enforce its rights and remedies hereunder with respect to any of the Collateral; provided that, (i) no action will be required of any Grantor to the extent such action would (A) result in (1) a breach of Applicable Laws that apply to such Grantor relating to corporate benefit, financial assistance, fraudulent preference, related or connected persons transactions, thin capitalization, capital maintenance or other Applicable Laws that apply to such Grantor, or (2) any material risk to the officers of the relevant Grantor of breach of fiduciary duties or civil or criminal liability, (B) result in costs that are materially disproportionate to the benefit obtained by Secured Party by reference to the costs of creating or perfecting such Liens versus the value of the assets being secured (as reasonably determined by Secured Party), or (C) impose an undue administration burden on, or material inconvenience to the ordinary course of operations of, such Grantor of such Lien, in each case which is materially disproportionate to the benefit obtained by Secured Party (as reasonably determined by Secured Party). Each Grantor shall furnish to Secured Party from time to time statements and schedules further identifying and describing the Collateral and such other reports in connection with the Collateral as Secured Party reasonably requests, all in reasonable detail and in form and substance reasonably satisfactory to Secured Party.

## ARTICLE V

### DEFAULT AND REMEDIES

5.1 **Events of Default.** The occurrence of any one or more of the following events shall be an event of default hereunder (each, an “*Event of Default*”):

(a) Payments. Brickell fails to pay any Milestone Installment Payment or Revenue Share Payment when due and does not cure such breach within thirty (30) calendar days after the earlier of (i) provision of written notice of such breach by Brickell to Secured Party in accordance with Section 8.1 of the Funding Agreement, or (ii) Secured Party becoming aware of such breach.

(b) Non-Technical Termination. Any Non-Technical Termination shall have occurred and Brickell shall have failed to pay the Non-Technical Termination Payment when due in accordance with Section 3.3(c) of the Funding Agreement.

(c) Minimum Cash Balance. Brickell shall fail to satisfy its obligation to maintain a minimum cash balance in accordance with Section 8.4(d) of the Funding Agreement.

(d) Insolvency. An Insolvency Event occurs with respect to any Grantor.

Upon the occurrence and during the continuance of an Event of Default, Secured Party may, by written notice to the Grantors, accelerate any Non-Contingent Obligations and thereupon any such Non-Contingent Obligations shall immediately become due and payable without presentment, demand, protest or notice of any kind, all of which are hereby expressly waived; provided that in the event of an Event of Default under Section 5.1(d), all Non-Contingent Obligations shall automatically and without written notice from Secured Party become due and payable without presentment, demand, protest or notice of any kind, all of which are hereby waived by each Grantor. For the avoidance of doubt, (i) the Milestone Payment Obligation (i.e., Thirty-Seven Million, Five Hundred Thousand Dollars (\$37,500,000)) would not be accelerated by an Event of Default that occurs prior to the Milestone Payment Obligation accruing, and being irrevocably earned by NovaQuest, on the Milestone Date, pursuant to Section 4.1(a) of the Funding Agreement and (ii) a Non-Technical Termination Payment would not be accelerated by an Event of Default that occurs prior to the occurrence of a Non-Technical Termination pursuant to Section 3.3(c) of the Funding Agreement.

## 5.2 Remedies.

(a) Secured Party may, upon the occurrence and during the continuation of any Event of Default, exercise any or all of the following rights and remedies:

(i) Those rights and remedies provided in this Security Agreement or the Funding Agreement; provided that this clause (i) shall not be construed to limit any rights or remedies available to Secured Party prior to or after an Event of Default.

(ii) Those rights and remedies available to a secured party under the UCC (whether or not the UCC applies to the affected Collateral) or under any other Applicable Law or in equity when a debtor is in default under a security agreement.

(iii) Without notice except as specifically provided in Section 7.1 hereof or elsewhere herein, sell, lease, assign, grant an option or options to purchase or otherwise dispose of, deliver, or realize upon, the Collateral or any part thereof in one or more parcels at public or private sale or sales (which sales may be adjourned or continued from time to time with or without notice and may take place at any Grantor's premises or elsewhere), for cash, on credit or for future delivery without assumption of any credit risk, and upon such other terms as Secured Party may deem commercially reasonable. Secured Party shall be entitled to credit bid and use and apply the Secured Obligations (or any portion thereof) as a credit on account of the purchase price for any Collateral payable by Secured Party at such sale. Each purchaser at any such sale shall hold the property sold absolutely free from any claim or right on the part of any Grantor, and each Grantor hereby waives (to the extent permitted by Applicable Law) all rights of redemption, stay and/or appraisal which it now has or may at any time in the future have under any rule of law or statute now existing or hereafter enacted.

(iv) Transfer and register in its name or in the name of its nominee the whole or any part of the Collateral, to exchange certificates or instruments representing or evidencing Collateral for certificates or instruments of smaller or larger denominations, to exercise the voting and all other rights as a holder with respect thereto, to collect and receive all dividends, interest, principal and other distributions made thereon and to otherwise act with respect to the Collateral as though Secured Party was the outright owner thereof.

(b) Secured Party may comply with any applicable state or federal law requirements in connection with a disposition of the Collateral and such compliance will not be considered to adversely affect the commercial reasonableness of any sale of the Collateral.

(c) Secured Party, after the occurrence and during the continuance of an Event of Default, shall be entitled to exercise the power of attorney provided in Section 7.4 hereof to execute, and cause to be acknowledged and notarized, an assignment of the entire right, title, and interest of any Grantor in and to the Intellectual Property included in the Collateral, and record said assignment with the applicable agency or registrar.

(d) Secured Party shall have the right upon any such public sale or sales and, to the extent permitted by law, upon any such private sale or sales, to purchase all or any part of the Collateral so sold, free of any right or equity of redemption, which right or equity of redemption each Grantor hereby expressly waives and releases. Secured Party may sell the Collateral without giving any warranties as to the Collateral. Secured Party may specifically disclaim or modify any warranties of title or the like.

(e) Until Secured Party is able to effect a sale, lease, or other disposition of Collateral, Secured Party shall have the right to hold or use Collateral, or any part thereof, to the extent that it deems appropriate for the purpose of preserving Collateral or its value or for any other purpose deemed appropriate by Secured Party. Secured Party may, if it so elects, seek the appointment of a receiver or keeper to take possession of Collateral and to enforce any of Secured Party's remedies, with respect to such appointment without prior notice or hearing as to such appointment.

(f) Notwithstanding the foregoing, Secured Party shall not be required to (i) make any demand upon, or pursue or exhaust any of its rights or remedies against, any Grantor, any other obligor, guarantor, pledgor or any other Person with respect to the payment of the Secured Obligations or to pursue or exhaust any of its rights or remedies with respect to any Collateral therefor or any direct or indirect guarantee thereof, (ii) marshal the Collateral or any guarantee of the Secured Obligations or to resort to the Collateral or any such guarantee in any particular order, or (iii) effect a public sale of any Collateral.

5 . 3 **Grantors' Obligations Upon Event of Default.** Upon the request of Secured Party after the occurrence and during the continuance of an Event of Default, each Grantor will:

(a) Assembly of Collateral. Assemble and make available to Secured Party the Collateral and all records relating thereto at any place or places specified by Secured Party.

(b) Secured Party Access. Permit Secured Party and its representatives and agents, to enter, occupy and use any premises where all or any part of the Collateral, or the books and records relating thereto, or both, are located, to take possession of all or any part of the Collateral, or the books and records relating thereto, or both, to remove all or any part of the Collateral, or the books and records relating thereto, or both, and to conduct sales of the Collateral, without any obligation to pay such Grantor for such use and occupancy.

5 . 4 **Proceeds.** The proceeds of the Collateral shall be applied by Secured Party to payment of the Secured Obligations with any proceeds remaining after such application returned to the relevant Grantor.

## ARTICLE VI

### WAIVERS, AMENDMENTS AND REMEDIES

No delay or omission of Secured Party to exercise any right or remedy granted under this Security Agreement shall impair such right or remedy or be construed to be a waiver of any Event of Default or an acquiescence therein, and any single or partial exercise of any such right or remedy shall not preclude any other or further exercise thereof or the exercise of any other right or remedy. No waiver of any term, condition or provision of this Security Agreement shall be valid unless evidenced in a writing signed by Secured Party. This Security Agreement, including any attachments or exhibits hereto, may be amended, modified, or supplemented only by a written amendment or agreement signed by Secured Party and each Grantor. All rights and remedies contained in this Security Agreement or by law afforded shall be cumulative and all shall be available to Secured Party until the Termination Date.

## ARTICLE VII

### GENERAL PROVISIONS

7.1 **Notice of Disposition of Collateral; Condition of Collateral.** Each Grantor hereby waives notice of the time and place of any public sale or the time after which any private sale or other disposition of all or any part of the Collateral may be made. To the extent such notice may not be waived under Applicable Law, any notice made shall be deemed commercially reasonable if sent to Brickell, addressed as set forth in Article VIII, at least ten (10) days prior to (i) the date of any such public sale or (ii) the time after which any such private sale or other disposition may be made. Any such public sale shall be held at such time or times within ordinary business hours and at such place or places as Secured Party may fix and state in the notice (if any) of such sale, and each Grantor agrees that the internet shall constitute a “place” for purposes of Section 9-610(b) of the UCC. Secured Party may adjourn any public or private sale from time to time by announcement at the time and place fixed therefor, and such sale may, without further notice, be made at the time and place to which it was so adjourned. To the maximum extent permitted by Applicable Law, each Grantor waives all claims, damages, and demands against Secured Party arising out of the repossession, retention or sale of the Collateral, except such as arise solely out of the gross negligence or willful misconduct of Secured Party as determined by a court of competent jurisdiction in a final and non-appealable judgment. To the extent it may lawfully do so, each Grantor absolutely and irrevocably waives and relinquishes the benefit and advantage of, and covenants not to assert against Secured Party, any valuation, stay, appraisal, extension, moratorium, redemption or similar laws and any and all rights or defenses it may have as a surety now or hereafter existing which, but for this provision, might be applicable to the sale of any Collateral made under the judgment, order or decree of any court, or privately under the power of sale conferred by this Security Agreement, or otherwise. Except as otherwise specifically provided herein, each Grantor hereby waives presentment, demand, protest or any notice (to the maximum extent permitted by Applicable Law) of any kind in connection with this Security Agreement or any Collateral. Each Grantor shall permit Secured Party and its representatives and agents, to inspect any of its Collateral or its books and financial records related thereto, to examine and make copies of its books of accounts and other financial records related to Collateral and to discuss matters pertaining to the Collateral with, and to be advised as to the same by, its officers at such reasonable times and intervals as Secured Party may designate. The Grantors shall pay the expenses of Secured Party for all visits, inspections and examinations that are made while any Event of Default is continuing and otherwise with respect to one such annual visit, inspection and examination.

7.2 **Limitation on Secured Party’s Duty with Respect to the Collateral.** Secured Party shall have no obligation to clean-up or otherwise prepare the Collateral for sale. Secured Party shall use reasonable care with respect to the Collateral in its possession or under its control; provided that Secured Party shall be deemed to have exercised reasonable care in the custody and preservation of any Collateral in its possession or under its control if such Collateral is accorded treatment substantially equal to that which Secured Party accords its own property. Secured Party

shall not have any other duty as to any Collateral in its possession or control or in the possession or control of any agent or nominee of Secured Party, or any income thereon or as to the preservation of rights against prior parties or any other rights pertaining thereto. To the extent that Applicable Law imposes duties on Secured Party to exercise remedies in a commercially reasonable manner, each Grantor acknowledges and agrees that it is commercially reasonable for Secured Party (i) to fail to incur expenses deemed significant by Secured Party to prepare Collateral for disposition or otherwise to transform raw material or work in process into finished goods or other finished products for disposition, (ii) to fail to obtain third party consents for access to Collateral to be disposed of, or to obtain or, if not required by other law, to fail to obtain governmental or third party consents for the collection or disposition of Collateral to be collected or disposed of, (iii) to fail to exercise collection remedies against account debtors or other Persons obligated on Collateral or to remove Liens on or any adverse claims against Collateral, (iv) to exercise collection remedies against account debtors and other Persons obligated on Collateral directly or through the use of collection agencies and other collection specialists, (v) to advertise dispositions of Collateral through publications or media of general circulation, whether or not the Collateral is of a specialized nature, (vi) to contact other Persons, whether or not in the same business as such Grantor, for expressions of interest in acquiring all or any portion of such Collateral, (vii) to hire one or more professional auctioneers to assist in the disposition of Collateral, whether or not the Collateral is of a specialized nature, (viii) to dispose of Collateral by utilizing internet sites that provide for the auction of assets of the types included in the Collateral or that have the reasonable capacity of doing so, or that match buyers and sellers of assets, (ix) to dispose of assets in wholesale rather than retail markets, (x) to disclaim disposition warranties, such as title, possession or quiet enjoyment, (xi) to purchase insurance or credit enhancements to insure Secured Party against risks of loss, collection or disposition of Collateral or to provide to Secured Party a guaranteed return from the collection or disposition of Collateral, or (xii) to the extent deemed appropriate by Secured Party, to obtain the services of other brokers, investment bankers, consultants and other professionals to assist Secured Party in the collection or disposition of any of the Collateral. Each Grantor acknowledges that the purpose of this Section 7.2 is to provide non-exhaustive indications of what actions or omissions by Secured Party would be commercially reasonable in Secured Party's exercise of remedies against the Collateral and that other actions or omissions by Secured Party shall not be deemed commercially unreasonable solely on account of not being indicated in this Section 7.2. Without limitation upon the foregoing, nothing contained in this Section 7.2 shall be construed to grant any rights to any Grantor or to impose any duties on Secured Party that would not have been granted or imposed by this Security Agreement or by Applicable Law in the absence of this Section 7.2.

**7.3 Secured Party's Performance of Grantor's Obligations.** Without having any obligation to do so, Secured Party may perform or pay any obligation which any Grantor has agreed to perform or pay in this Security Agreement and such Grantor shall promptly reimburse Secured Party on demand for any reasonable amounts paid by Secured Party pursuant to this Section 7.3. Each Grantor's obligation to reimburse Secured Party pursuant to the preceding sentence shall be a Secured Obligation payable on demand. Nothing in this Section 7.3 shall be interpreted as excusing any Grantor from the performance of, or imposing any obligation on Secured Party to cure or

perform, any covenants or other promises of any Grantor with respect to any of its obligations under this Security Agreement.

**7.4 Authorization for Secured Party to Take Certain Action.** Each Grantor irrevocably authorizes Secured Party at any time and from time to time in the sole discretion of Secured Party and appoints Secured Party as its attorney in fact (i) to execute on behalf of such Grantor as debtor and to file financing statements, including amendments thereto and/or continuations thereof, necessary or desirable in Secured Party's sole discretion to perfect and to maintain the perfection and priority of Secured Party's security interest in the Collateral, (ii) after the occurrence and during the continuance of an Event of Default, to indorse and collect any cash proceeds of the Collateral, (iii) to file a carbon, photographic or other reproduction of this Security Agreement or any financing statement with respect to the Collateral as a financing statement and to file any other financing statement or amendment and/or continuation of a financing statement (which does not add new collateral or add a debtor) in such offices as Secured Party in its sole discretion deems necessary or desirable to perfect and to maintain the perfection and priority of Secured Party's security interest in the Collateral, (iv) after the occurrence and during the continuance of an Event of Default, to apply the proceeds of any Collateral received by Secured Party to the Secured Obligations, (v) to discharge past due taxes, assessments, charges, fees or Liens on the Collateral (except for such Liens as are specifically permitted hereunder or under the Funding Agreement) and (vi) after the occurrence and during the continuance of an Event of Default, to exercise all rights and remedies under Article V or otherwise under this Security Agreement and each Grantor agrees to promptly reimburse Secured Party on demand for any reasonable payment made or any reasonable expense incurred by Secured Party in connection therewith; provided that (x) this authorization shall not relieve any Grantor of any of its obligations under this Security Agreement or under the Funding Agreement and (y) nothing herein contained shall be construed as requiring or obligating Secured Party to make any commitment or to make any inquiry as to the nature or sufficiency of any payment received by Secured Party, or to present or file any claim or notice, or to take any action with respect to the Collateral or any part thereof or the moneys due or to become due in respect thereof or any property covered thereby. The power-of-attorney granted hereby is coupled with an interest and shall be irrevocable.

**7.5 Specific Performance of Certain Covenants.** Each Grantor acknowledges and agrees that a breach of the covenants contained in Sections 5.2 and 5.3 hereof will cause irreparable injury to Secured Party, that Secured Party has no adequate remedy at law in respect of such breaches and therefore agrees, without limiting the right of Secured Party to seek and obtain specific performance of other obligations of the Grantors contained in this Security Agreement, that the covenants of the Grantors contained in the Sections referred to in this Section 7.5 shall be specifically enforceable against the Grantors.

**7.6 Reinstatement.** This Security Agreement shall remain in full force and effect and continue to be effective should any petition be filed by or against any Grantor for liquidation or reorganization, should any Grantor become insolvent or make an assignment for the benefit of any creditor or creditors or should a receiver or trustee be appointed for all or any significant part of

any Grantor's assets, and shall continue to be effective or be reinstated, as the case may be, if at any time payment and performance of the Secured Obligations, or any part thereof, is, pursuant to Applicable Law, rescinded or reduced in amount, or must otherwise be restored or returned by any obligee of the Secured Obligations, whether as a "voidable preference," "fraudulent conveyance," or otherwise, all as though such payment or performance had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, restored or returned, the Secured Obligations shall be reinstated and deemed reduced only by such amount paid and not so rescinded, reduced, restored or returned.

**7.7 Indemnification.** The Grantors shall indemnify and hold Secured Party harmless from and against any and all claims, losses and liabilities (including reasonable attorneys' fees) actually incurred by Secured Party (a) related solely to this Security Agreement arising out of claims, suits, actions or demands, in each case brought by a Third Party, or any settlements or judgments arising therefrom, or (b) arising from the enforcement of this Security Agreement and the security interests hereby created, except claims, losses or liabilities resulting from Secured Party's gross negligence or willful misconduct as determined by a final judgment of a court of competent jurisdiction. With respect to any claim for indemnification under clause (a) of the preceding sentence, the provisions of Section 10.2 of the Funding Agreement shall be incorporated herein, mutatis mutandis. Any liability of the Grantors to indemnify and hold Secured Party harmless pursuant to the preceding sentence shall be part of the Secured Obligations. Each Grantor's obligations under this Section 7.7 shall survive termination of this Security Agreement.

**7.8 Benefit of Agreement.** The terms and provisions of this Security Agreement shall be binding upon and inure to the benefit of the Grantors, Secured Party and their respective successors and assigns (including all persons who become party to this Security Agreement as a Grantor), except that the Grantors shall not have the right to assign their rights or delegate their obligations under this Security Agreement or any interest herein, without the prior written consent of Secured Party. No sales of participations, assignments, transfers, or other dispositions of any agreement governing the Secured Obligations or any portion thereof or interest therein shall in any manner impair the Lien granted to Secured Party.

**7.9 Survival of Representations.** All representations and warranties of the Grantors contained in this Security Agreement shall survive the execution and delivery of this Security Agreement.

**7.10 Headings.** The title of and section headings in this Security Agreement are for convenience of reference only, and shall not govern the interpretation of any of the terms and provisions of this Security Agreement.

**7.11 Termination.** This Security Agreement shall continue in effect for the Term of the Funding Agreement.

**7.12 Entire Agreement.** This Security Agreement embodies the entire agreement and understanding between the Grantors and Secured Party relating to the Collateral and supersedes all

prior agreements and understandings among the Grantors and Secured Party relating to the Collateral.

**7.13 Governing Law; Jurisdiction; Waiver of Jury Trial.**

(a) Governing Law. This Security Agreement shall be governed by and construed, interpreted, and enforced in accordance with the laws of New York, as applied to agreements executed and performed entirely in New York, without giving effect to the principles of conflicts of law thereof, other than Section 5-1401 of the New York General Obligations Law.

(b) WAIVER OF JURY TRIAL. EACH PARTY HERETO IRREVOCABLY WAIVES ANY RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTION OR PROCEEDING IN CONNECTION WITH OR RELATING TO THIS SECURITY AGREEMENT OR ANY AGREEMENT ENTERED INTO PURSUANT HERETO AND AGREES THAT ANY SUCH SUIT, ACTION, OR PROCEEDING SHALL BE TRIED BEFORE A COURT AND NOT BEFORE A JURY.

(c) Dispute Resolution and Equitable Relief. Sections 11.3 and 11.4 of the Funding Agreement shall apply to this Security Agreement as if set out herein in full, mutatis mutandis.

7.14 **Severability**. Any provision in this Security Agreement that is held to be inoperative, unenforceable, or invalid in any jurisdiction shall, as to that jurisdiction, be inoperative, unenforceable, or invalid without affecting the remaining provisions in that jurisdiction or the operation, enforceability, or validity of that provision in any other jurisdiction, and to this end the provisions of this Security Agreement are declared to be severable.

7.15 **Counterparts**. This Security Agreement may be executed in counterparts (and by different parties hereto in different counterparts), each of which shall constitute an original, but all of which when taken together shall constitute a single contract. Delivery of an executed counterpart of a signature page of this Security Agreement by telecopy or other electronic transmission shall be effective as delivery of a manually executed counterpart of this Security Agreement.

7.16 **Security Interest Absolute**. All rights of Secured Party hereunder, the grant of a security interest in the Collateral and all obligations of each Grantor hereunder, shall be absolute and unconditional irrespective of (a) any lack of validity or enforceability of the Funding Agreement, any agreement with respect to any of the Secured Obligations or any other agreement or instrument relating to any of the foregoing, (b) any change in the time, manner or place of payment of, or in any other term of, all or any of the Secured Obligations, or any other amendment or waiver of or any consent to any departure from the Funding Agreement or any other agreement or instrument relating to any of the foregoing, (c) any exchange, release or nonperfection of any other collateral, or any release or amendment or waiver of or consent to or departure from any guaranty, for all or any of the Secured Obligations or (d) any other circumstance (other than payment in full of the Secured Obligations (other than inchoate obligations)) that might otherwise constitute a defense available to, or a discharge of, any Grantor in respect of the Secured Obligations or in respect of this Security Agreement.

7.17 **Additional Grantors.** Each Grantor agrees to provide prompt written notice to Secured Party of the formation or acquisition of any new subsidiary that has an interest in Product Assets and such subsidiary shall be required to enter in this Security Agreement as a Grantor. Upon execution and delivery by Secured Party and any such new subsidiary of a Supplement to U.S. Security Agreement in the form of Exhibit I hereto, such subsidiary shall become a Grantor hereunder with the same force and effect as if originally named as a Grantor herein. The execution and delivery of such instrument shall not require the consent of any Grantor hereunder. The rights and obligations of each Grantor hereunder shall remain in full force and effect notwithstanding the addition of any new Grantor as a party to this Security Agreement.

7.18 **Release of Liens.** Upon the termination of this Security Agreement in accordance with Section 7.11, each Grantor shall automatically be released from its obligations under this Security Agreement, and the security interests in the Collateral created by this Security Agreement and the Funding Agreement shall be automatically released. In addition, upon any sale or other disposition by any Grantor of any Collateral in a transaction permitted under the Funding Agreement (other than a disposition to another Grantor), the security interests in such Collateral created by this Security Agreement shall, upon written notice to Secured Party, be automatically released.

In connection with any termination or release pursuant to this Section 7.18, Secured Party shall execute and deliver to the applicable Grantor all documents that such Grantor shall reasonably request to evidence such termination or release.

## ARTICLE VIII

### NOTICES

8.1 **Sending Notices.** Any notice required or permitted to be given under this Security Agreement shall be sent (and deemed received) in the manner and to the addresses set forth in Section 11.7 of the Funding Agreement. Any notice delivered to Brickell shall be deemed to have been delivered to all of the Grantors.

[Signature Pages Follow]

IN WITNESS WHEREOF, each of the Grantor and Secured Party has executed this Security Agreement as of the date first above written.

**GRANTOR:**

**Brickell Subsidiary, Inc.**

By:           /s/ Robert Brown            
Name:           Robert Brown            
Title:           Chief Executive Officer          

*[Signature Page to Security Agreement]*

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**SECURED PARTY:**

**NovaQuest Co-Investment Fund X, L.P.**

By: **NQ POF V GP, LTD., its general partner**

By: /s/ John L. Bradley, Jr.

Name: John L. Bradley, Jr.

Title: Director

*[Signature Page to Security Agreement]*

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**Schedule A**

Prior names, jurisdiction of formation, place of business (if the Grantor has only one place of business), chief executive office (if the Grantor has more than one place of business), mergers and mailing address:

<b>Grantor</b>	<b>Prior Name</b>	<b>Jurisdiction of Formation</b>	<b>Principal Place of Business</b>	<b>Chief Executive Office / Mailing Address</b>	<b>Significant Mergers or Acquisitions</b>
Brickell Subsidiary, Inc.	Brickell Biotech, Inc.	DE, USA	5777 Central Ave. Suite 102, Boulder, CO, USA	5777 Central Ave. Suite 102, Boulder, CO, USA	On August 31, 2019, Brickell Biotech, Inc. merged with and into Victory Subsidiary, Inc., with Brickell Biotech, Inc. being the surviving corporation. Pursuant to the Certificate of Merger, the surviving corporation was renamed Brickell Subsidiary, Inc.

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**Schedule B**

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**Schedule C**

**Offices in Which UCC Financing Statements Shall Be Filed**

<b>Grantor</b>	<b>Jurisdictions</b>
Brickell Subsidiary, Inc.	Delaware, SOS

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**Schedule D**

**[Reserved]**

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**Schedule E**

**Federal Employer Identification Number;  
State Organization Number; Jurisdiction of Incorporation**

<b>Grantor</b>	<b>Federal Employer Identification Number</b>	<b>Type of Organization</b>	<b>State/ Jurisdiction of Organization or Incorporation</b>	<b>State/ Jurisdiction of Organization Number</b>
Brickell Subsidiary, Inc.	27-0943393	C-Corp	DE	

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**Exhibit I**  
**Supplement**  
**to**  
**U.S. Security Agreement**

Reference is hereby made to the U.S. Security Agreement (as amended, restated, supplemented or otherwise modified from time to time, the “**Agreement**”), dated as of [ ], 2019, made by the Grantors party thereto on the date thereof (together with any additional obligor, whether now existing or hereafter formed or acquired, which becomes party to the Agreement from time to time by executing a Supplement to U.S. Security Agreement in substantially the form hereof, the “**Grantors**”), in favor of Secured Party. Capitalized terms used herein and not defined herein shall have the meanings given to them in the Agreement.

By its execution below, the undersigned, [NAME OF NEW GRANTOR], a [ ] [corporation/limited liability company/limited partnership] (the “**New Grantor**”) agrees to become, and does hereby become, a Grantor under the Agreement and agrees to be bound by the Agreement as if originally a party thereto. The New Grantor hereby pledges and grants to Secured Party a security interest in all of the New Grantor’s right, title and interest, wherever located and whether now owned or hereafter acquired, in and to the Collateral to secure the prompt and complete payment and performance of the Secured Obligations. For the avoidance of doubt, the grant of a security interest herein shall not be deemed to be an outright assignment of intellectual property rights owned by the New Grantor.

By its execution below, the undersigned represents and warrants as to itself that all of the representations and warranties contained in the Agreement are true and correct in all material respects as of the date hereof (other than to the extent qualified by materiality or “Material Adverse Effect”, in which case, such representations and warranties shall be true and correct). The New Grantor represents and warrants that the supplements to the Schedules to the Agreement attached hereto are true and correct in all respects and that such supplements set forth all information required to be scheduled under the Agreement with respect to the New Grantor. The New Grantor shall take all steps necessary and required under the Agreement to perfect, in favor of Secured Party, a first-priority security interest in and lien against the New Grantor’s Collateral subject to any Permitted Liens.

New Grantor hereby authorizes Secured Party to file, and if requested will execute and deliver to Secured Party, all financing statements describing the Collateral owned by such New Grantor and other documents and take such other actions as may from time to time reasonably be requested by Secured Party (and in accordance with the terms of the Agreement) in order to maintain a perfected security interest in and, if applicable, Control of, the Collateral owned by such New Grantor. Such financing statements may describe the Collateral in the same manner as described in the Agreement or may contain an indication or description of collateral that describes such property in any other manner as Secured Party may determine, in its sole discretion, is necessary, advisable

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or prudent to ensure that the perfection of the security interest in the Collateral granted to Secured Party in the Agreement (as supplemented hereby), including, without limitation, describing such property as “all assets of the Debtor whether now owned or hereafter acquired and wheresoever located, including all accessions thereto and proceeds thereof” or using words of similar import.

**THIS SECURITY AGREEMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAW OF THE STATE OF NEW YORK.**

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IN WITNESS WHEREOF, the New Grantor has executed and delivered this Supplement to U.S. Security Agreement as of this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

**[NAME OF NEW GRANTOR]**

By: \_\_\_\_  
Name: \_\_\_\_  
Title: \_\_\_\_

**NovaQuest Co-Investment Fund X, L.P.**

By: **[NQ, its general partner]**

By: **[NQ, its sole member]**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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## Exhibit II

### [Form of] Patent Security Agreement

THIS PATENT SECURITY AGREEMENT (as the same may be amended, restated, supplemented or otherwise modified from time to time, the "**Patent Security Agreement**") is made effective as of [\_\_\_\_], 20[ ] by and from [\_\_\_\_] (the "**Grantor**"), to and in favor of NovaQuest Co-Investment Fund X, L.P., a Delaware limited partnership (the "**Grantee**").

WHEREAS, the Grantor has entered into a U.S. Security Agreement dated as of [ ], 2019 (as may be amended, restated, supplemented or otherwise modified from time to time, the "**U.S. Security Agreement**").

WHEREAS, the Grantor owns the patents listed on Schedule A attached hereto (the "**Patents**"), which Patents are pending or registered with the United States Patent and Trademark Office.

WHEREAS, this Patent Security Agreement has been executed in conjunction with the security interest granted under the U.S. Security Agreement to the Grantee. In the event that any provisions of this Patent Security Agreement are deemed to conflict with the U.S. Security Agreement, the provisions of the U.S. Security Agreement shall govern.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is hereby agreed that:

1) Definitions. All capitalized terms not defined herein shall have the respective meaning given to them in the Funding Agreement or the U.S. Security Agreement.

2) The Security Interest.

(a) This Patent Security Agreement is made to secure the prompt and complete payment and performance of all the Secured Obligations. Upon the occurrence of the Termination Date (as defined in the U.S. Security Agreement), the Grantee shall promptly, upon such satisfaction, execute, acknowledge, and deliver to the Grantor all reasonably requested instruments in writing releasing the security interest in the Patents acquired under the U.S. Security Agreement and this Patent Security Agreement.

(b) The Grantor hereby pledges and grants to the Grantee a security interest in all of the Grantor's right, title and interest, wherever located and whether now owned or hereafter acquired, in and to (i) any and all patents and patent applications, including those listed on Schedule A hereto; (ii) all inventions and improvements described and claimed therein; (iii) all reissues,

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divisions, continuations, renewals, extensions, and continuations-in-part thereof; (iv) all income, royalties, damages, claims, and payments now or hereafter due or payable under and with respect thereto, including, without limitation, damages and payments for past and future infringements thereof; (v) all rights to sue for past, present, and future infringements thereof; and (vi) all rights corresponding to any of the foregoing throughout the world.

3 ) Governing Law. **THIS PATENT SECURITY AGREEMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAW OF THE STATE OF NEW YORK.**

4 ) Recordation. The Grantor hereby authorizes and requests that the Commissioner of Patents and Trademarks record this Patent Security Agreement.

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IN WITNESS WHEREOF, the Grantor has executed this Patent Security Agreement effective as of the date first written above.

**[GRANTOR]**

By: \_\_\_  
Name: \_\_\_  
Title: \_\_\_

**NovaQuest Co-Investment Fund X, L.P.**

By: [NQ, its general partner]

By: [NQ, its sole member]

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**Schedule A**

Patents

Title	Patent No.	Date Issued	Application No.	Date Filed

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**Exhibit III**

**[Form of] Trademark Security Agreement**

THIS TRADEMARK SECURITY AGREEMENT (as the same may be amended, restated, supplemented or otherwise modified from time to time, the “*Trademark Security Agreement*”) is made effective as of [\_\_\_\_], 20[ ] by and from [ ] (the “*Grantor*”), to and in favor of NovaQuest Co-Investment Fund X, L.P., a Delaware limited partnership (the “*Grantee*”).

WHEREAS, the Grantor has entered into a U.S. Security Agreement dated as of [ ], 2019 (as may be amended, restated, supplemented or otherwise modified from time to time, the “*U.S. Security Agreement*”).

WHEREAS, the Grantor owns the trademarks listed on Schedule A attached hereto (the “*Trademarks*”), which Trademarks are pending or registered with the United States Patent and Trademark Office.

WHEREAS, this Trademark Security Agreement has been executed in conjunction with the security interest granted under the U.S. Security Agreement to the Grantee. In the event that any provisions of this Trademark Security Agreement are deemed to conflict with the U.S. Security Agreement, the provisions of the U.S. Security Agreement shall govern.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is hereby agreed that:

1) Definitions. All capitalized terms not defined herein shall have the respective meaning given to them in the Funding Agreement or the U.S. Security Agreement.

2) The Security Interest.

(a) This Trademark Security Agreement is made to secure the prompt and complete payment and performance of all the Secured Obligations. Upon the occurrence of the Termination Date (as defined in the U.S. Security Agreement), the Grantee shall promptly, upon such satisfaction, execute, acknowledge, and deliver to the Grantor all reasonably requested instruments in writing releasing the security interest in the Trademarks acquired under the U.S. Security Agreement and this Trademark Security Agreement.

(b) The Grantor hereby pledges and grants to the Grantee a security interest in (other than applications for trademarks or service marks filed in the United States Patent and Trademark Office or any successor office thereto pursuant to 15 U.S.C. §1051 Section 1(b) unless and until evidence of use of the mark in interstate commerce is submitted to the United States Patent

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and Trademark Office or any successor office thereto pursuant to 15 U.S.C. §1051 Section 1(c) or Section 1(d)) all of the Grantor's right, title and interest, wherever located and whether now owned or hereafter acquired, in and to (i) all trademarks (including service marks), trade names, trade styles, trade dress and the registrations and applications for registration thereof, including those listed on Schedule A hereto and the goodwill of the business symbolized by the foregoing; (ii) all renewals of the foregoing; (iii) all income, royalties, damages, claims and payments now or hereafter due or payable with respect thereto, including, without limitation, damages, claims, and payments for past and future infringements thereof; (iv) all rights to sue for past, present, and future infringements of the foregoing, including the right to settle suits involving claims and demands for royalties owing; and (v) all rights corresponding to any of the foregoing throughout the world.

3) Governing Law. **THIS TRADEMARK SECURITY AGREEMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAW OF THE STATE OF NEW YORK.**

4) Recordation. The Grantor hereby authorizes and requests that the Commissioner of Patents and Trademarks record this Trademark Security Agreement.

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IN WITNESS WHEREOF, the Grantor has executed this Trademark Security Agreement effective as of the date first written above.

[GRANTOR]

By: \_\_\_  
Name: \_\_\_  
Title: \_\_\_

**NovaQuest Co-Investment Fund X, L.P.**

By: [NQ, its general partner]

By: [NQ, its sole member]

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**Schedule A**

**Trademarks**

<b>Mark</b>	<b>App. No.</b>	<b>App. Date</b>	<b>Reg. No.</b>	<b>Reg. Date</b>

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**Exhibit IV**

**[Form of] Copyright Security Agreement**

THIS COPYRIGHT SECURITY AGREEMENT (as the same may be amended, restated, supplemented or otherwise modified from time to time, the “*Copyright Security Agreement*”) is made effective as of [\_\_\_\_], 20[ ] by and from [ ] (the “*Grantor*”), to and in favor of NovaQuest Co-Investment Fund X, L.P., a Delaware limited partnership (the “*Grantee*”).

WHEREAS, the Grantor has entered into a U.S. Security Agreement dated as of [ ], 2019 (as may be amended, restated, supplemented or otherwise modified from time to time, the “*U.S. Security Agreement*”).

WHEREAS, Grantor owns the copyrights listed on Schedule A attached hereto (the “*Copyrights*”), which Copyrights are pending or registered with the United States Copyright Office.

WHEREAS, this Copyright Security Agreement has been granted in conjunction with the security interest granted under the U.S. Security Agreement to the Grantee. In the event that any provisions of this Copyright Security Agreement are deemed to conflict with the U.S. Security Agreement, the provisions of the U.S. Security Agreement shall govern.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is hereby agreed that:

1) Definitions. All capitalized terms not defined herein shall have the respective meaning given to them in the Funding Agreement or the U.S. Security Agreement.

2) The Security Interest.

(a) This Copyright Security Agreement is made to secure the prompt and complete payment and performance of all the Secured Obligations. Upon the occurrence of the Termination Date (as defined in the U.S. Security Agreement), the Grantee shall promptly, upon such satisfaction, execute, acknowledge, and deliver to the Grantor all reasonably requested instruments in writing releasing the security interest in the Copyrights acquired under the U.S. Security Agreement and this Copyright Security Agreement.

(b) The Grantor hereby pledges and grants to the Grantee a security interest in all of the Grantor’s right, title and interest, wherever located and whether now owned or hereafter acquired, in and to (i) all copyrights, rights and interests in copyrights, works protectable by copyright, copyright registrations, and copyright applications, including those listed on Schedule A hereto; (ii) all extensions and renewals of any of the foregoing; (iii) all income, royalties, damages,

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claims and payments now or hereafter due and/or payable under any of the foregoing, including, without limitation, damages or payments for past or future infringements or violations for any of the foregoing; (iv) the right to sue for past, present, and future infringements of any of the foregoing; and (v) all rights corresponding to any of the foregoing throughout the world.

3 ) Governing Law. **THIS COPYRIGHT SECURITY AGREEMENT SHALL BE CONSTRUED IN ACCORDANCE WITH AND GOVERNED BY THE LAW OF THE STATE OF NEW YORK.**

4 ) Recordation. The Grantor hereby authorizes and requests that the Commissioner of Copyrights record this Copyright Security Agreement.

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IN WITNESS WHEREOF, the Grantor has executed this Copyright Security Agreement effective as of the date first written above.

**[GRANTOR]**

By: \_\_\_  
Name: \_\_\_  
Title: \_\_\_

**NovaQuest Co-Investment Fund X, L.P.**

By: [NQ, its general partner]

By: [NQ, its sole member]

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**Schedule B**

**Copyrights**

<b>Copyright Title</b>	<b>Reg. No.</b>	<b>Reg. Date</b>

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-30181) pertaining to the 1992 Stock Plan of Vical Incorporated,
- (2) Registration Statement (Form S-8 No. 333-80681) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (3) Registration Statement (Form S-8 No. 333-60293) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (4) Registration Statement (Form S-8 No. 333-66254) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (5) Registration Statement (Form S-8 No. 333-97019) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (6) Registration Statement (Form S-8 No. 333-107581) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (7) Registration Statement (Form S-8 No. 333-116951) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (8) Registration Statement (Form S-8 No. 333-135266) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (9) Registration Statement (Form S-8 No. 333-143885) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (10) Registration Statement (Form S-8 No. 333-169344) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (11) Registration Statement (Form S-8 No. 333-183215) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (12) Registration Statement (Form S-8 No. 333-190343) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (13) Registration Statement (Form S-8 No. 333-213034) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (14) Registration Statement (Form S-8 No. 333-219804) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated, and
- (15) Registration Statement (Form S-3 No. 333-225208) of Vical Incorporated

of our report dated July 2, 2019, with respect to the financial statements of Brickell Biotech, Inc. included in this Current Report (Form 8-K) of Brickell Biotech, Inc. (formerly Vical Incorporated).

/s/ Ernst & Young LLP

Denver, Colorado  
September 3, 2019

### **Brickell Biotech Completes Merger with Vical**

*Newly Nasdaq-listed BBI focused on developing differentiated therapeutics for treatment of dermatologic disorders*

*Merger brings \$60 Million in Combined Cash from Vical and R&D funding from NovaQuest*

*Pivotal Phase 3 Clinical Trials for Brickell's Lead Product Candidate, Sofpironium Bromide, in Patients with Axillary Hyperhidrosis to Begin Q4 2019*

BOULDER, CO — September 3, 2019 —Brickell Biotech, Inc. (“Brickell”) (Nasdaq: BBI), a clinical-stage pharmaceutical company, today announced the completion of its merger with Vical Incorporated (“Vical”), following approval by Vical’s stockholders. Brickell is expected to commence trading today on The Nasdaq Capital Market under the ticker symbol “BBI.”

“This merger is a significant milestone for Brickell. We are on track to initiate the Phase 3 program of our lead asset, sofpironium bromide, for patients with axillary hyperhidrosis this year,” said Robert Brown, Brickell’s Chief Executive Officer. “With over 10 million individuals in the United States suffering from this debilitating condition, we are excited to advance the development of sofpironium bromide as a potential best-in-class therapy.”

Vical contributes approximately \$35 million to the combined company in addition to an R&D financing arrangement with NovaQuest Capital Management (“NovaQuest”) that provides \$25 million in funding.

Following the completion of the merger, the combined company has approximately 7.8 million shares of common stock outstanding. Brickell’s stockholders received common stock, representing approximately 56% of the outstanding shares and Vical’s stockholders retained approximately 44% based on certain assumptions regarding the calculation of the fully diluted shares.

The combined company will continue to operate under the leadership of Robert Brown as Chief Executive Officer. Rob joined Brickell in January 2019 from Eli Lilly where, for the prior ten years, he was the Chief Marketing Officer overseeing global product launches and commercial operations of the company.

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## **About Sofpironium Bromide**

Sofpironium bromide is a new molecular entity and “soft” drug that belongs to a class of medications called anticholinergics. Anticholinergics block the action of acetylcholine, a chemical that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. Soft drugs, such as sofpiroonium bromide, are designed to exert their action topically and be rapidly metabolized once absorbed into the blood. This mechanism of action may allow for highly effective doses to be used while limiting systemic side effects associated with drugs in this class.

Based upon the positive Phase 2 clinical trial results and the recently completed pivotal Phase 3 clinical trial results from Brickell’s Japanese partner, Kaken, as well as Brickell’s ongoing Phase 3 long-term safety study, Brickell intends to initiate two pivotal Phase 3 clinical trials in patients with primary axillary hyperhidrosis in the United States in the fourth quarter of 2019.

## **About Hyperhidrosis**

Hyperhidrosis is a life-altering medical condition where a person sweats more than the body requires to regulate its temperature. More than 15 million people, or 4.8% of the population of the United States, are believed to suffer from hyperhidrosis. Axillary (underarm) hyperhidrosis is the targeted first indication for sofpiroonium bromide and is the most common occurrence of hyperhidrosis, affecting an estimated 65% of patients in the United States or 10 million individuals. Doolittle et al. Arch Dermatol Res (2016).

## **About Brickell**

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on developing innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. Brickell’s pipeline consists of potential novel therapeutics for hyperhidrosis, cutaneous T-cell lymphoma, psoriasis, and other prevalent dermatological conditions. Brickell’s executive management team and board of directors bring extensive experience in product development and global commercialization, having served in leadership roles at large global pharmaceutical companies and biotechs that have developed and/or launched successful products, including several that were first-in-class and/or achieved iconic status, such as Cialis<sup>®</sup>, Taltz<sup>®</sup>, Gemzar<sup>®</sup>, Prozac<sup>®</sup>, Cymbalta<sup>®</sup> and Juvederm<sup>®</sup>. Brickell’s strategy is to leverage this experience to in-license, acquire, develop and commercialize innovative products that Brickell believes can be successful in the currently underserved dermatology global marketplace. For more information, visit [www.brickellbio.com](http://www.brickellbio.com).

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## **Cautionary Note Regarding Forward-Looking Statements**

Any statements made in this press release relating to future financial, business and/or research and clinical performance, conditions, plans, prospects, trends, or strategies and other such matters, including without limitation, the anticipated timing, scope, design and/or results of future clinical trials and prospects for commercializing any of Brickell's product candidates are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Brickell, may identify forward-looking statements. Brickell cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time, often quickly and in unanticipated ways. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation whether or when Brickell will achieve any of the milestones in the funding agreement with NovaQuest, potential delays in product development, regulatory or law changes, unanticipated demands on cash resources, risks associated with developing, and obtaining regulatory approval for and commercializing novel therapeutics.

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained in Brickell's filings with the United States Securities and Exchange Commission (SEC), which are available at [www.sec.gov](http://www.sec.gov) (or at [www.brickellbio.com](http://www.brickellbio.com)). The forward-looking statements represent the estimates of Brickell as of the date hereof only, and Brickell specifically disclaims any duty or obligation to update forward-looking statements.

### **Brickell Investor Contact:**

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Chief Business Officer  
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**BRICKELL BIOTECH, INC.**

**INDEX TO FINANCIAL STATEMENTS**

**Audited Financial Statements for the Years Ended December 31, 2018 and 2017**

Report of Independent Registered Public Accounting Firm	<a href="#">F-2</a>
Balance Sheets as of December 31, 2018 and 2017	<a href="#">F-3</a>
Statements of Operations for the Years Ended December 31, 2018 and 2017	<a href="#">F-4</a>
Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit for the Years Ended December 31, 2018 and 2017	<a href="#">F-5</a>
Statements of Cash Flows for the Years Ended December 31, 2018 and 2017	<a href="#">F-6</a>
Notes to Audited Financial Statements for the Years Ended December 31, 2018 And 2017	<a href="#">F-7</a>

## Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Brickell Biotech, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Brickell Biotech, Inc. (the Company) as of December 31, 2018 and 2017, the related statements of operations, redeemable convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

### The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017  
Denver, Colorado  
July 2, 2019

**BRICKELL BIOTECH, INC.**  
**BALANCE SHEETS**

(In thousands, except share and per share data)

	<b>December 31, 2018</b>	<b>December 31, 2017</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,067	\$ 5,399
Prepaid expenses and other current assets	204	89
Deferred sublicensing costs, current portion	—	342
Total current assets	8,271	5,830
Property and equipment, net	37	74
Intangible assets	441	441
Deferred sublicensing costs, net of current portion	—	342
Total assets	\$ 8,749	\$ 6,687
<b>Liabilities, redeemable convertible preferred stock and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 4,067	\$ 1,222
Accrued liabilities	3,272	3,456
Deferred revenue, current portion	8,117	1,709
Notes payable, current portion	4,639	2,131
Total current liabilities	20,095	8,518
Contingent consideration	145	148
Redeemable convertible preferred stock warrant liability	242	486
Note payable, net of current portion	—	3,408
Deferred revenue, net of current portion	1,595	1,709
Total liabilities	22,077	14,269
Redeemable convertible preferred stock (Series A, B, C and C-1), \$0.0001 par value, 4,182,943 shares authorized at December 31, 2018 and 2017; 3,639,905 shares issued and outstanding at December 31, 2018 and 2017; aggregate liquidation preference of \$46,985 and \$43,493 at December 31, 2018 and 2017, respectively	58,290	52,354
Commitments and contingencies (Note 9)		
Stockholders' deficit:		
Common Stock, \$0.0001 par value, 8,000,000 shares authorized at December 31, 2018 and 2017; 1,706,251 and 1,695,418 issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Additional paid-in capital	—	—
Accumulated deficit	(71,618)	(59,936)
Total stockholders' deficit	(71,618)	(59,936)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 8,749	\$ 6,687

See accompanying notes to audited financial statements.

**BRICKELL BIOTECH, INC.**  
**STATEMENTS OF OPERATIONS**  
*(In thousands, except share and per share data)*

	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2017</u>
Collaboration revenue	\$ 10,888	\$ 7,567
Operating expenses:		
Research and development	12,960	11,885
General and administrative	6,379	5,648
Total operating expenses	<u>19,339</u>	<u>17,533</u>
Loss from operations	(8,451)	(9,966)
Interest income	61	25
Interest expense	(1,090)	(1,049)
Change in fair value of redeemable convertible preferred stock warrant liability	244	(126)
Net loss	<u>(9,236)</u>	<u>(11,116)</u>
Accretion of redeemable convertible preferred stock to redemption value	(5,936)	(11,925)
Net loss attributable to common stockholders	<u>\$ (15,172)</u>	<u>\$ (23,041)</u>
Basic and diluted net loss per common share attributable to common stockholders	<u>\$ (8.92)</u>	<u>\$ (13.60)</u>
Shares used in computing basic and diluted net loss per share attributable to common stockholders	<u>1,700,344</u>	<u>1,693,581</u>

See accompanying notes to audited financial statements.

**BRICKELL BIOTECH, INC.**  
**STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**  
*(In thousands, except share and per share data)*  
YEARS ENDED DECEMBER 31, 2018 AND 2017

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Par Value	Shares	Par Value			
Balance, December 31, 2016	3,053,064	\$ 32,685	1,692,918	\$ —	\$ —	\$ (37,786)	\$ (37,786)
Stock based compensation	—	—	—	—	881	—	881
Issuance of common stock through exercise of stock option	—	—	2,500	—	10	—	10
Issuance of Series C-1 convertible preferred stock, net of issuance costs of \$120	586,841	7,744	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	11,925	—	—	(891)	(11,034)	(11,925)
Net loss	—	\$ —	—	\$ —	\$ —	\$ (11,116)	\$ (11,116)
Balance, December 31, 2017	3,639,905	\$ 52,354	1,695,418	\$ —	\$ —	\$ (59,936)	\$ (59,936)
Effect of adoption of Topic 606	—	—	—	—	—	2,734	2,734
Stock based compensation	—	—	—	—	711	—	711
Issuance of common stock through exercise of stock option	—	—	10,833	—	45	—	45
Accretion of redeemable convertible preferred stock to redemption value	—	5,936	—	—	(756)	(5,180)	(5,936)
Net income	—	—	—	—	—	(9,236)	(9,236)
<b>Balance, December 31, 2018</b>	<b>3,639,905</b>	<b>\$ 58,290</b>	<b>1,706,251</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (71,618)</b>	<b>\$ (71,618)</b>

See accompanying notes to audited financial statements.

**BRICKELL BIOTECH, INC.**  
**STATEMENTS OF CASH FLOWS**  
*(In thousands)*

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (9,236)	\$ (11,116)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	49	48
Change in fair value of convertible preferred stock warrant liability	(244)	126
Change in fair value of contingent consideration	(3)	(45)
Amortization of debt discounts and financing costs	489	358
Stock-based compensation	711	881
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(115)	545
Deferred sublicensing fees	—	513
Accounts payable	2,845	262
Accrued liabilities	(241)	1,587
Deferred revenue	9,712	(2,567)
Net cash provided by (used in) operating activities	<u>3,967</u>	<u>(9,408)</u>
<b>Cash flows from investing activities:</b>		
Capital expenditures	(12)	(11)
Net cash used in investing activities	<u>(12)</u>	<u>(11)</u>
<b>Cash flows from financing activities:</b>		
Principal payments made on note payable	(1,282)	(1,410)
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	7,764
Note payable issuance costs	(50)	—
Proceeds from the exercise of stock options	45	10
Net cash provided by (used in) financing activities	<u>(1,287)</u>	<u>6,364</u>
<b>Net increase (decrease) in cash and cash equivalents</b>	<u>2,668</u>	<u>(3,055)</u>
<b>Cash and cash equivalents—Beginning</b>	<u>5,399</u>	<u>8,454</u>
<b>Cash and cash equivalents—Ending</b>	<u>\$ 8,067</u>	<u>\$ 5,399</u>
<b>Supplement disclosure of cash flow information:</b>		
Interest paid	<u>\$ 608</u>	<u>\$ 699</u>
<b>Supplement disclosure of non-cash financing and investing activities:</b>		
Accretion of redeemable convertible preferred stock to redemption value	<u>\$ 5,896</u>	<u>\$ 11,897</u>
Accretion of redeemable convertible preferred stock issuance costs	<u>\$ 40</u>	<u>\$ 28</u>

See accompanying notes to audited financial statements.

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**NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS**

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Brickell Biotech, Inc. (the “Company”) was incorporated in the state of Delaware and commenced activities on September 17, 2009. The Company is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated therapeutics for the treatment of skin diseases. Its current pipeline consists of new molecular entities targeting the treatment of the following indications: hyperhidrosis, allergic contact dermatitis, androgenic alopecia, cutaneous t-cell lymphoma and psoriasis. The Company’s lead product candidate, sofipironium bromide, for the topical treatment of axillary hyperhidrosis (underarm sweating beyond what is needed for normal body temperature regulation), demonstrated positive results in a confirmatory Phase 2b study in the fourth quarter of 2017. Based upon these results, along with the completion of the Company’s end-of-Phase 2 meeting with the U.S. Food and Drug Administration (“FDA”) in the first quarter of 2018, the Company expects to initiate its pivotal Phase 3 clinical trials in the U.S. and Canada in the first half of 2019. The Company is headquartered in Boulder, Colorado.

***Liquidity and Capital Resources***

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has incurred significant operating losses and has an accumulated deficit as a result of ongoing efforts to develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the year ended December 31, 2018, the Company had a net loss of \$9.2 million and net cash provided by operating activities of \$4.0 million. As of December 31, 2018, the Company had cash and cash equivalents of \$8.1 million and an accumulated deficit of \$71.6 million.

The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company’s research and development activities. The Company plans to finance operations through equity or debt financing arrangements, and/or third-party collaboration funding. Additional funding will be required in the future to maintain its present and proposed research activities. There can be no assurance that additional equity or debt financing will be available on acceptable terms, if at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations. These factors raise substantial doubt about the Company’s ability to continue as a going concern for a period of twelve months subsequent to the issuance of these financial statements.

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**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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***Basis of Presentation***

The accompanying financial statements are presented in U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”).

***Use of Estimates in the Preparation of Financial Statements***

The preparation of financial statements, in conformity with US GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the balance sheet dates and the reported amounts of revenues and expenses for the periods presented. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, accrued research and development expenses, intangible assets, other long-lived assets, redeemable convertible preferred stock, warrants, stock-based compensation, and the valuation of deferred tax assets. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

***Risks and Uncertainties***

The Company’s business is subject to significant risks common to early-stage companies in the pharmaceutical industry including, but not limited to, the ability to develop appropriate formulations, scale up and production of the compounds, dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents, clinical success, the lengthy and expensive regulatory approval process, compliance with regulatory requirements, competition from other products; uncertainty of broad adoption of its approved

products, if any, by physicians and patients; significant competition; ability to manage third-party manufacturers, suppliers and contract research organizations (“CROs”) and obtaining additional financing to fund the Company’s efforts.

The product candidates developed by the Company require approvals from the FDA and foreign regulatory agencies prior to commercial sales in the United States or foreign jurisdictions, respectively. There can be no assurance that the Company’s current and future product candidates will receive the necessary approvals. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company’s business and its financial condition.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

#### ***Cash and Cash Equivalents***

The Company considers all highly liquid debt instruments with an original maturity of three months or less from date of purchase to be cash equivalents. Cash equivalents, which are stated at cost, consist primarily of amounts held in short-term money market accounts with highly rated financial institutions.

#### ***Concentrations of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash balances in several accounts with one financial institution which, from time to time, are in excess of federally insured limits.

#### ***Property and Equipment***

Property and equipment is stated at cost, less accumulated depreciation. Expenditures for major betterments and additions are charged to the asset accounts, while replacements, maintenance and repairs, which do not improve or extend the lives of the respective assets, are charged to expense as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Depreciation expense amounted to approximately \$49,000 and \$48,000 for the years ended December 31, 2018 and 2017, respectively. Accumulated depreciation amounted to approximately \$146,000 and \$97,000 as of December 31, 2018 and 2017, respectively.

#### ***Impairment of Long-Lived Assets***

The Company assesses changes in the performance of its product candidates in relation to its expectations, and industry, economic and regulatory conditions and makes assumptions regarding estimated future cash flows in evaluating the value of its property and equipment, and in-process research and development (“IPR&D”).

The Company periodically evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, an impairment loss is recognized to the extent the carrying amount of the impaired asset exceeds its fair value.

IPR&D represents the fair value assigned to incomplete research projects that the Company acquires in business acquisitions, which, at the time of acquisition, have not reached technological feasibility. Amounts capitalized and accounted for as indefinite-lived intangible assets are subject to impairment testing until completion or abandonment of the project. The Company tests IPR&D for impairment at least annually, or more frequently, if impairment indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the IPR&D intangible asset is less than its carrying amount. If the Company concludes it is more likely than not that the fair value is less than the carrying amount, a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value is performed. If the Company discontinues or abandons a program related to IPR&D and determines that there are no other indicators of value, the Company will impair the entire amount of the related intangible asset. There were no impairments of IPR&D during the years ended December 31, 2018 and 2017.

#### ***Fair Value Measurements***

Fair value is the price that the Company would receive to sell an asset or pay to transfer a liability in a timely transaction with an independent counterparty in the principal market or in the absence of a principal market, the most advantageous market for the asset or liability. A three-tier hierarchy is established to distinguish between (1) inputs that reflect the assumptions market participants would use in pricing an asset or liability developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) inputs that reflect the reporting entity’s own assumptions about the assumptions market participants would

use in pricing an asset or liability developed based on the best information available in the circumstances (unobservable inputs), and establishes a classification of fair value measurements for disclosure purposes.

The hierarchy is summarized in the three broad levels listed below.

**Level 1**—quoted prices in active markets for identical assets and liabilities

**Level 2**—other significant observable inputs (including quoted prices for similar assets and liabilities, interest rates, credit risk, etc.)

**Level 3**—significant unobservable inputs (including the Company’s own assumptions in determining the fair value of assets and liabilities)

The following tables set forth the fair value of the Company’s financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	\$ 8,067	\$ —	\$ —
Total	\$ 8,067	\$ —	\$ —
Liabilities:			
Redeemable convertible preferred stock warrant liability	\$ —	\$ —	\$ 242
Contingent consideration	—	—	145
Total	\$ —	\$ —	\$ 387
	December 31, 2017		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	\$ 5,399	\$ —	\$ —
Total	\$ 5,399	\$ —	\$ —
Liabilities:			
Redeemable convertible preferred stock warrant liability	\$ —	\$ —	\$ 486
Contingent consideration	—	—	148
Total	\$ —	\$ —	\$ 634

#### **Fair Value of Financial Instruments**

The following methods and assumptions were used by the Company in estimating the fair values of each class of financial instrument disclosed herein:

*Money market funds*—The carrying amounts reported in the balance sheets approximate their fair values due to their short-term nature and/or market rates of interest (Level 1 of the fair value hierarchy).

*Contingent consideration*—These amounts represent future payments in conjunction with various business combinations. The ultimate amount of future payments is based on specified future criteria, such as the achievement of certain future development and regulatory milestones. The Company evaluates its estimates of the fair value of contingent consideration on a periodic basis. The fair value of the contingent consideration was determined by a third-party valuation firm applying the income approach. This approach estimates the fair value of the contingent consideration related to the achievement of future development and regulatory milestones by assigning an achievement probability and date of expected completion to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The probability of success of each milestone assumes that the prerequisite developmental milestones are successfully completed and is based on the asset’s current stage of development and anticipated regulatory requirements. The probability of success for each milestone is determined by multiplying the preceding probabilities of success. The unobservable inputs (Level 3 of the fair value hierarchy) to the valuation models that have the most significant effect on the fair value of the Company’s contingent consideration are the probabilities that certain in-process development projects will meet specified development milestones, including ultimate approval by the FDA, with individual cumulative probabilities ranging from

2.1% to 20.9%. Other unobservable inputs used in this approach include: risk-adjusted discount rates ranging from 15.5% to 27.1% and estimates of the timing of the achievement of the various product development, regulatory approval and sales milestones.

*Redeemable convertible preferred stock warrant liability*—These amounts represent potential future obligations to transfer assets to the holders at a future date. The Company remeasures these warrants to current fair value at each balance sheet date, and any change in fair value is recognized as a change in fair value of warrant liability in the statements of operations. The Company estimated the fair value of these warrants at the respective balance sheet dates using the Black-Scholes option-pricing model (Level 3 of the fair value hierarchy table) (see further discussion in Note 7).

Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The most significant unobservable inputs used in the fair value measurement of the convertible preferred stock warrant liability are the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The fair value of the outstanding convertible preferred stock warrants was remeasured as of December 31, 2018 using the Black-Scholes option-pricing model with the following assumptions: contractual term of 7.1 years, expected volatility of 30.0%, risk-free rate of 2.59%, and expected dividend yield of 0%.

*Fair Value of Redeemable Convertible Preferred Stock.* The fair value of the shares of the convertible preferred stock underlying the preferred stock warrants has historically been determined by a third-party valuation firm. Because there has been no public market for the Company's convertible preferred stock, the third-party valuation firm has determined fair value of the convertible preferred stock at each balance sheet date by considering a number of objective and subjective factors, including valuation of comparable companies, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors.

*Remaining Term.* The Company derived the expected term based on the time from the balance sheet date until the preferred stock warrant's expiration date.

*Expected Volatility.* Since the Company was a private entity with no historical data regarding the volatility of its preferred stock, the expected volatility used is based on volatility of a group of similar entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

*Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the warrants.

*Expected Dividend Rate.* The Company has never paid any dividends and does not plan to pay dividends in the foreseeable future and, therefore, used an expected dividend rate of zero in the valuation model.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

	<b>Redeemable Convertible Preferred Stock Warrant Liability</b>	<b>Contingent Consideration Liabilities</b>
Fair value as of December 31, 2016	\$ 360	\$ 193
Change in fair value	126	(45)
Fair value as of December 31, 2017	486	148
Change in fair value	(244)	(3)
Fair value as of December 31, 2018	<u>\$ 242</u>	<u>\$ 145</u>

#### ***Redeemable Convertible Preferred Stock***

Redeemable convertible preferred stock is classified as a mezzanine instrument outside of the Company's capital accounts. Accretion of redeemable convertible preferred stock includes the greater of an adjustment to fair market value or the accrual of dividends on and accretion of issuance costs of the Company's redeemable convertible preferred stock. The carrying values of the redeemable convertible preferred stock are increased by periodic accretion to their respective redemption values, using the effective interest

method, from the date of issuance to the earliest date the holders can demand redemption. These increases are recorded as charges against additional paid-in capital balance until the additional paid-in capital balance is reduced to zero. At that time, additional accretion adjustments are recorded as additions to accumulated deficit.

Preferred stock issuance costs represent costs related to the Company issuing redeemable convertible preferred stock. These amounts are included as a reduction of redeemable convertible preferred stock and are amortized over the estimated redemption period. Amortization of preferred stock issuance costs amounted to approximately \$40,000 and \$28,000 for the years ended December 31, 2018 and 2017, respectively.

#### ***Redeemable Convertible Preferred Stock Warrants***

The Company accounts for warrants to purchase shares of its redeemable convertible preferred stock as liabilities at their estimated fair value because the underlying shares are redeemable, which may obligate the Company to transfer assets to the holders at a future date. The warrants are subject to remeasurement to fair value at each balance sheet date, and any fair value adjustments are recognized as change in fair value of redeemable convertible preferred stock warrant liability in the statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the redeemable convertible preferred stock warrants, conversion of redeemable convertible preferred stock into common stock, or until holders of the redeemable convertible preferred stock can no longer trigger a deemed liquidation event. At that time, the redeemable convertible preferred stock warrant liability will be adjusted to fair value in the statements of operations with the final fair value reclassified to equity.

#### ***Revenue Recognition***

Effective January 1, 2018, the Company adopted Accounting Standards Update (“ASU”) 2018-18, Collaborative Arrangements: Clarifying the Interaction Between Topic 808 and Topic 606 (“Topic 808” or “ASU 2018-18”) using the retrospective method and ASU 2014-09, Revenue from Contracts with Customers (Topic 606) (“Topic 606” or “ASU 2014-09”) using the modified retrospective method which consisted of applying and recognizing the cumulative effect of Topic 606 at the date of initial application. Topic 606 supersedes the revenue recognition requirements in Accounting Standards Codification (“ASC”) Topic 605, Revenue Recognition (“Topic 605”), including most industry-specific revenue recognition guidance throughout the Industry Topics of the ASC. All periods prior to the adoption date of Topic 606 have not been restated to reflect the impact of the adoption of Topic 606, but continue to be accounted for and presented under Topic 605.

The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

To date, the Company’s drug candidates have not been approved for sale by the FDA and the Company has not generated or recognized any revenue from the sale of products.

In March 2015, the Company entered into a license and collaboration agreement with Kaken Pharmaceutical, Co., Ltd. (“Kaken”), which is referred to as the “Collaboration Agreement”. Under the Collaboration Agreement, the Company granted to Kaken an exclusive right to develop, manufacture and commercialize the Company’s sofipronium bromide compound (formerly BBI-4000), a topical anticholinergic, in Japan and certain other Asian countries (the “Territory”). In exchange, Kaken paid the Company an upfront, non-refundable payment of \$11.0 million (the “upfront fee”). In addition, the Company is entitled to receive aggregate payments of up to \$10.0 million upon the achievement of specified development milestones, and \$30.0 million upon the achievement of commercial milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. The Collaboration Agreement further provides that Kaken will be responsible for funding all development and commercial costs for the program in the Territory and, until such time, if any, as Kaken elects to establish its own source of supply of drug product, Kaken can purchase product supply from the Company to perform all non-clinical studies, and Phase I and Phase II clinical trials in Japan at cost. Kaken is also required to enter into negotiations with the Company, to supply the Company, at cost, with clinical supplies to perform Phase III clinical trials in the U.S.

#### ***Collaboration arrangement subsequent to adoption of Topic 606***

The Company evaluates collaboration arrangements to determine whether units of account within the collaboration arrangement exhibit the characteristics of a vendor and customer relationship. The Company determined that the licenses transferred to Kaken in exchange for the upfront fees were representative of this type of a relationship. If a license to our intellectual property is determined to

be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition on a prospective basis.

Under Topic 606, the Company evaluated the terms of the Collaboration Agreement and the transfer of intellectual property and manufacturing rights (the “license”) was identified as the only performance obligation as of the inception of the agreement. The Company concluded that the license for the intellectual property was distinct from its ongoing supply obligations. The Company further determined that the transaction price under the arrangement was comprised of the \$11.0 million upfront payment. The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained. As part of our evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals, each of which is uncertain at this time. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur. Future potential milestone amounts would be recognized as revenue from collaboration arrangements, if unconstrained. The remainder of the arrangement, which largely consisted of both parties incurring costs in their respective territories, provides for the reimbursement of the ongoing supply costs. These costs were representative of a collaboration arrangement outside of the scope of Topic 606 as it does not have the characteristics of a vendor and customer relationship. Reimbursable program costs are recognized proportionately with the delivery of drug substance and are accounted for as reductions to research and development expense and are excluded from the transaction price.

Under Topic 606, the entire transaction price of \$11.0 million was allocated to the license performance obligation. The license was deemed to be delivered in 2015 in connection with the execution of the Collaboration Agreement and upon transfer of the underlying intellectual property the performance obligation was fully satisfied. As a result, a cumulative adjustment to reduce deferred revenue and the corresponding sublicensing costs of \$2.7 million was recorded upon the adoption of Topic 606 on January 1, 2018. As of December 31, 2018, the Company does not have a deferred revenue or deferred sublicensing costs balance related to the upfront fee on the balance sheet.

In May 2018, the Company entered into an amendment to the Collaboration Agreement (as further amended, “Collaboration Agreement”), pursuant to which, the Company received an upfront non-refundable fee of \$15.6 million (the “Collaboration R&D Payment”), which was initially recorded as deferred revenue, to provide the Company with research and development funds to conduct certain clinical trials. These clinical trials have a benefit to Kaken and have the characteristics of a vendor and customer relationship. The Company has accounted for these under the provisions of Topic 606. This Collaboration R&D Payment will be initially recognized using an input method over the average estimated performance period of 1.45 years in proportion to the cost incurred. Upon receipt of the Collaboration R&D Payment, on May 31, 2018, a milestone payment originally due upon the first commercial sale in Japan was removed from the Collaboration Agreement and all future royalties to the Company under the Collaboration Agreement were reduced 150 basis points.

Consequently, during the year ended December 31, 2018, the Company recognized revenue of \$5.9 million related to the Collaboration R&D Payment. As of December 31, 2018, the Company has a deferred revenue balance related to the Collaboration R&D Payment of \$9.7 million, of which \$8.1 million, is recorded in deferred revenue, current portion on the accompanying balance sheets.

#### *Milestones*

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or our collaboration partner’s control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjust the Company’s estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

In October 2017, the Company entered into an amendment to the Collaboration Agreement, pursuant to which, the Company granted Kaken a prepayment option (the “Kaken Option”) on 50% of the Initiation of Phase III milestone (the “Phase III milestone”). The

Kaken Option was exercisable by Kaken within 25 business days of receipt of the BBI-4000-CL-203 study topline results. In December 2017, Kaken exercised the Kaken Option and paid the Company \$5.0 million (the “Kaken Option Payment”). Upon receipt of the non-refundable Kaken Option Payment, the Company provided Kaken the right to negotiate an exclusive license to develop, manufacture and commercialize each of the Company’s other product candidates in Japan (“ROFN Agreement”). Under the ROFN Agreement, following the completion of any Initial Proof of Concept Clinical Trial (“Initial POC”) for the Company’s other product candidates, the Company must provide Kaken with certain information relating to the results of the clinical trial (“Initial POC Package”). The ROFN Agreement is exercisable by Kaken within 30 days of receipt of the Initial POC Package. In December 2017, the Company recognized collaboration revenue related to the Collaboration Agreement of \$5.0 million, in connection with the Kaken Option. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

The Collaboration Agreement was further amended in March 2018 to accelerate payment of the Phase III milestone. The Phase III milestone was modified to be due upon the successful completion of the End of Phase 2 Meeting with the PMDA by Kaken on March 8, 2018, as determined by Kaken in its reasonable discretion (the “Third Milestone”). In March 2018, Kaken triggered the Third Milestone and paid the Company \$5.0 million (the “Third Milestone Payment”). Upon receipt of the non-refundable Third Milestone Payment, the ROFN Agreement was amended (the “Amended ROFN Agreement”) to grant an additional option to exercise upon completion of a Subsequent Clinical Trial (first clinical trial after the Initial POC) for the Company’s other product candidates. The Company has determined that the ROFN Agreement is not a material right and has not allocated transaction price to this provision. As of December 31, 2018, Kaken has not exercised the Amended ROFN Agreement. In March 2018, the Company recognized collaboration revenue related to the Collaboration Agreement of \$5.0 million in connection with the Third Milestone. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

#### *Royalties*

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognized revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from any collaborative arrangement.

Under collaborative arrangements, the Company has been reimbursed for a portion of the Company’s research and development expenses, including costs of drug supplies. When the research and development services are performed under a reimbursement or cost sharing model with a collaboration partner, the Company records these reimbursements as a reduction of research and development expense in the Company’s statements of operations.

#### *Revenue recognition prior to adoption of Topic 606*

Prior to the adoption of Topic 606, the Company was initially recorded the \$11.0 million upfront fee as deferred revenue. This upfront fee, along with the corresponding sublicensing fees, was initially recognized over the estimated period during which the research and development plan would be conducted. Consequently, during the years ended December 31, 2017 and 2016, the Company recognized revenue of \$2.6 million and \$2.9 million, respectively. As of December 31, 2017 and 2016, the Company has a deferred revenue balance related to the upfront fee of \$3.4 million and \$6.0 million, respectively, of which \$1.7 million and \$2.9 million, respectively, is recorded in deferred revenue, current portion on the accompanying balance sheets.

Additionally, during the years ended December 31, 2017 and 2016, the Company recognized sublicensing costs of \$0.5 million and \$0.6 million, respectively, which are included in general and administrative expenses in the accompanying statements of operations. As of December 31, 2017 and 2016, the Company has \$0.7 million and \$1.2 million, respectively, in deferred sublicensing costs related to the upfront fee, of which \$0.3 million and \$0.6 million, respectively, is recorded in deferred sublicensing costs, current portion on the accompanying balance sheets.

#### *Contingent Consideration*

Contingent consideration represents future amounts the Company may be required to pay in conjunction with business combinations. The ultimate amount of future payments is based on specified future criteria, such as the achievement of certain future development and regulatory milestones. The Company estimates the fair value of the contingent consideration related to the achievement of future development and regulatory milestones by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The Company evaluates its estimates of the fair value of contingent consideration on a periodic basis. Any changes in the fair value of contingent consideration are recorded in the accompanying statements of operations as general and administrative expenses. The total estimated fair value of contingent consideration was approximately \$145,000 and \$148,000 at December 31, 2018 and 2017, respectively.

### ***Research and Development***

Research and development costs are charged to expense when incurred and consist of costs incurred for independent and collaborative research and development activities. The major components of research and development costs include formulation development, clinical studies, clinical manufacturing costs, salaries and employee benefits, toxicology studies, allocations of various overhead and occupancy costs, and licensing fees and milestone payments incurred under license agreements. Research costs typically consist of applied research, preclinical, and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis, and the transfer and scale-up of manufacturing at contract manufacturers.

### ***Accrued Research and Development Expenses***

The Company records accruals for estimated costs of research, preclinical and clinical studies, and manufacturing development, which are a significant component of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, including CROs. The Company's contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on actual work completed in accordance with the respective agreements. In the event the Company makes advance payments, the payments are recorded as a prepaid asset and recognized as the services are performed. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fees to be paid for such services.

The Company makes significant judgments and estimates in determining the accrual balance in each reporting period. As actual costs become known, the Company adjusts its accruals. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company understands the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in the Company reporting amounts that are too high or too low in any particular period. The Company's accrual is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. To date, there have been no material differences from the Company's accrued estimated expenses to the actual clinical trial expenses. However, variations in the assumptions used to estimate accruals including, but not limited to the number of patients enrolled, the rate of patient enrollment, and the actual services performed may vary from the Company's estimates, resulting in adjustments to, clinical trial expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect its financial condition and results of operations.

Prepaid expenses and other current assets includes prepaid research and development costs of \$95,000 and \$12,000 as of December 31, 2018 and 2017, respectively.

### ***Stock-Based Compensation***

Stock options granted to employees and non-employees under the Company's stock option plan are accounted for by using a fair value based method. Stock-based payments to employees, including grants of employee stock options, are measured based on their fair values at the date of grant, net of forfeitures, and are recorded on a straight-line basis over the requisite employee service period. The fair value of stock-based payments to non-employees is estimated at each reporting period, net of forfeitures, until a measurement date is reached, and recorded over the service period on a straight-line basis.

### ***Net Loss per Common Share***

Basic and diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing the Company's net earnings by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares.

Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method, and redeemable convertible preferred stock, using the if-converted method. In computing diluted earnings per share, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted earnings per share computation in net loss periods, since their effect would be anti-dilutive.

The following table sets forth the potential common shares excluded from the calculation of net loss per common share, because their inclusion would be anti-dilutive:

	<u>2018</u>	<u>2017</u>
Redeemable convertible preferred stock (as converted into common stock)	3,639,905	3,639,905
Options to purchase common stock	1,090,045	826,225
Warrants to purchase common stock	160,365	160,365
Warrants to purchase redeemable convertible preferred stock (as converted into common stock)	26,087	26,087
	<u>4,916,402</u>	<u>4,652,582</u>

### ***Income Taxes***

The Company accounts for income taxes under the liability method, whereby deferred tax assets and liabilities are provided for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

Deferred tax assets, net of a valuation allowance, are recorded when management believes it is more likely than not that the tax benefits will be realized. Realization of the deferred tax assets is dependent upon generating sufficient taxable income in the future. The amount of deferred tax asset considered realizable could change in the near term if estimates of future taxable income are modified. The Company assesses its tax positions and determines whether it has any material unrecognized liabilities for uncertain tax positions expected to be taken in a tax return for open tax years (generally a period of three years from the later of each return's due date or the date filed) that remain subject to examination by the Company's major tax jurisdictions. Generally, the Company is no longer subject to income tax examinations by major taxing authorities for years before 2014.

The Company assesses its tax positions and determines whether it has any material unrecognized liabilities for uncertain tax positions. The Company records these liabilities to the extent it deems them more likely than not to be incurred. Interest and penalties related to uncertain tax positions, if any, would be classified as a component of income tax expense. The Company believes that it does not have any significant uncertain tax positions requiring recognition or measurement in the accompanying financial statements.

### ***Segment Data***

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is identifying, developing and commercializing innovative and differentiated therapeutics for the treatment of skin diseases. No revenue from sales of product has been generated since inception, and all tangible assets are held in the United States.

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### **NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS**

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In November 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-18. ASU 2018-18 clarifies when certain transactions between collaborative arrangement participants should be accounted for under ASC 606 and incorporates unit-of-account guidance consistent with ASC 606 to aid in this determination. ASU 2018-18 is effective for public companies for annual and interim periods beginning after December 15, 2019, with early adoption permitted. ASU 2018-18 should generally be applied retrospectively to the date of initial application of Topic 606. The Company adopted this standard as of January 1, 2018 in connection with its adoption of Topic 606.

As noted above, effective January 1, 2018, the Company adopted Topic 606. Since ASU 2014-09 was issued, several additional ASUs have been issued and incorporated within Topic 606 to clarify various elements of the guidance. As part of its adoption efforts, the Company completed the assessment of its collaboration and license agreements under Topic 606. The Company adopted Topic 606 in the first quarter of 2018 using the modified retrospective method which consists of applying and recognizing the cumulative effect of Topic 606 at the date of initial application and providing certain additional disclosures as defined per Topic 606. On January 1, 2018, the Company recorded a cumulative adjustment to decrease deferred revenue, deferred sublicensing costs and accumulated deficit by approximately \$2.7 million, to reflect the impact of the adoption of Topic 606.

Below is a summary of the affected line items on the balance sheets upon adoption of Topic 606 (in thousands):

Balance Sheet	Balance at December 31, 2017	Adjustments Due to Topic 606	Balance at January 1, 2018
Deferred sublicensing costs, current portion	\$ (342)	\$ 342	\$ —
Deferred sublicensing costs, net of current portion	(342)	342	—
Deferred revenue, current	1,709	(1,709)	—
Deferred revenue, net of current portion	1,709	(1,709)	—
Accumulated deficit	\$ (59,936)	\$ 2,734	\$ (57,202)

As a result of adopting Topic 606 on January 1, 2018 under the modified retrospective method, the Company did not revise the comparative financial statements for the prior years as if Topic 606 had been effective for those periods. Below is disclosure of what the affected line items on the statement of operations would have been in the year ended December 31, 2018 under Topic 605 (in thousands):

Statement of Operations	Year Ended December 31, 2018		
	As Reported	Balances Without Adoption Topic 606	Effect of Change
Collaboration revenue	\$ 10,888	13,186	(2,298 )
General and administrative	(6,379 )	(6,724 )	345

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”), which amends certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-13, but does not anticipate it will have a material impact on its disclosures.

In January 2017, the FASB issued ASU 2017-01, “Business Combinations (Topic 805): Clarifying the Definition of a Business” (“ASU 2017-01”), which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The amendments of ASU 2017-01 are effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years for public companies and for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019 for private companies. The Company adopted this standard as of January 1, 2018, and there was no material impact to the Company’s financial statements as a result of the adoption.

In August 2016, the FASB issued ASU 2016-15, “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments” (“ASU 2016-15”), which will make eight targeted changes to how cash receipts and cash payments are presented and classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017 for public companies and for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019 for private companies. ASU 2016-15 will require adoption on a retrospective basis. Early adoption is permitted. The Company adopted this standard as of January 1, 2018, and there was no material impact to the Company’s financial statements as a result of the adoption.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018 for public companies and for annual periods beginning after December 15, 2018, and interim periods within annual periods beginning after December 15, 2019 for private companies. Early adoption is permitted. The Company will adopt ASU 2016-02 on January 1, 2019. The Company expects to recognize a right-of-use asset and a lease liability on its balance sheet for the discounted value of future lease payments from the adoption of this ASU. As of December 31, 2018, the Company had aggregate future minimum lease payments of approximately \$0.3 million. The Company is currently evaluating the full impact that the adoption of this ASU will have on its financial statements and related disclosures.

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**NOTE 4. ACCRUED LIABILITIES**

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Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2018	2017
Accrued sublicensing fees	\$ —	\$ 1,000
Accrued compensation	569	206
Accrued note issuance costs	587	537
Accrued professional fees	1,269	968
Accrued contracted research and development services	847	745
	<u>\$ 3,272</u>	<u>\$ 3,456</u>

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**NOTE 5. INTANGIBLE ASSETS**

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In January 2015, the Company acquired certain assets and assumed certain liabilities associated with the rights to an IPR&D molecular compound in the Phase I stage of development, BBI-5000, for \$100,000 plus up to an aggregate of \$13.5 million in payments contingent upon achieving certain future development milestones. The Company intends to develop BBI-5000 as a potential once-daily oral treatment for patients with moderate to severe atopic dermatitis.

In November 23, 2015, the Company secured the exclusive worldwide rights to a series of novel retinoic acid-related orphan nuclear receptor gamma (“RORγ”) inhibitors from Orca Pharmaceuticals (“Orca”) and New York University (“NYU”), for an upfront payment of \$105,000 plus up to an aggregate of \$3.4 million in payments contingent upon achieving certain future development and sales milestones. The Company intends to develop BBI-6000 as a potential topical treatment for patients with psoriasis.

The Company accounted for both transactions as business combinations. The asset purchase agreements meet the definition of a business pursuant to the guidance prescribed in ASC Topic 805, “Business Combinations”. Accordingly, for BBI-5000 and BBI-6000, the Company capitalized the \$321,000 and \$120,000 acquisition-date fair values of these intangible assets, respectively. As of all periods presented, these assets are considered to be indefinite-lived and will not be amortized, but will be tested for impairment on an annual basis, as well as between annual tests if changes in circumstances indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives.

For BBI-5000 and BBI-6000 the Company has estimated the fair value of the contingent consideration to be \$221,000 and \$15,000, respectively, as of the acquisition date by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The Company evaluates its estimates of the fair value of contingent consideration on a periodic basis. Any changes in the fair value of contingent consideration are recorded as general and administrative expense.

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**NOTE 6. INCOME TAXES**

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During the years ended December 31, 2018 and 2017, the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	<u>2018</u>	<u>2017</u>
Federal statutory income tax rate	21.00 %	34.00 %
State taxes, net of federal benefit	3.71	1.07
Research and development tax credits	8.77	6.15
Permanent differences and other	2.36	(2.14)
Change in tax rate	1.80	(46.04)
Change in deferred tax asset valuation allowance	(37.64)	6.96
Effective income tax rate	<u>— %</u>	<u>— %</u>

At December 31, approximate deferred tax assets (liabilities) resulting from timing differences between financial and tax bases related to the following items:

	<u>2018</u>	<u>2017</u>
Net operating loss carryforwards	\$ 8,918,000	\$ 7,967,000
Stock-based compensation	520,000	393,000
Research and development credit	3,207,000	2,398,000
Net book value of intangible assets	75,000	70,000
Deferred revenue	2,040,000	718,000
Other	514,000	251,000
Net deferred tax asset	<u>15,274,000</u>	<u>11,797,000</u>
Less: valuation allowance	<u>(15,274,000)</u>	<u>(11,797,000)</u>
	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2018, the Company had net operating loss carryforwards for federal income tax reporting purposes of approximately \$36.5 million, which begin to expire in 2030, and state net operating loss carryforwards of \$30.9 million, which begin to expire in 2030. As of December 31, 2018, the Company also had research and development tax credit carryforwards for federal income tax reporting purposes available of \$3.2 million, which begin to expire in 2035.

On December 22, 2017, the U.S. Tax Cuts and Jobs Acts ("Tax Act") was signed into law. The Tax Act significantly revised the U.S. corporate income tax regime by, among other changes, lowering the federal corporate tax rate from 34% to 21% effective January 1, 2018. Based on provisions of the Tax Act, the Company remeasured its deferred tax assets and liabilities to reflect the lower statutory tax rate. The Company has recorded a decrease related to deferred tax assets of \$5.1 million. However, since the Company established a valuation allowance to offset its deferred tax assets, there is no impact to its effective tax rate, as any changes to deferred taxes would be offset by the valuation allowance.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2018 and 2017. Management reevaluates the positive and negative evidence at each reporting period. The Company's valuation allowance increased by approximately \$3.5 million and decreased by approximately \$0.8 million for the years ended December 31, 2018 and 2017, respectively.

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## NOTE 7. NOTE PAYABLE

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### *Note Payable*

On February 18, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. (the "Lender") under which the Company borrowed \$7.5 million upon the execution of the Loan Agreement. The interest rate applicable to each tranche is variable based upon the greater of either (i) 9.2% and (ii) the sum of (a) the Prime Rate as reported in The

Wall Street Journal minus 3.5%, plus (b) 9.2%; notwithstanding the above, such rate shall not exceed the permissible rates of interest on commercial loans under the laws of the State of California. Payments under the Loan Agreement were interest only until June 1, 2017, followed by equal monthly payments of principal and interest through the scheduled maturity date on September 1, 2019.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of the Company's assets, other than its intellectual property. The Company also has agreed not to pledge or otherwise encumber its intellectual property assets, except that the Company may grant non-exclusive licenses of intellectual property entered into in the ordinary course of business, and licenses approved by the Company's Board of Directors that may be exclusive in respects other than territory and may be exclusive as to territory as to discrete geographical areas outside of the United States.

The Company has paid the Lender a facility fee of \$150,000 in connection with the Loan Agreement. In addition, if the Company repays all or a portion of the loan prior to maturity, it will pay the Lender a prepayment penalty fee, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs prior to February 19, 2017, 2% if the prepayment occurs prior to February 19, 2018, or 1% if the prepayment occurs thereafter. In addition, the Company is required to make an end of term payment of 4.5% of the sum of (i) term loan advances, plus (ii) 50% of the aggregate unfunded term loan commitments.

The Loan Agreement was amended in December 2017 (as further amended, "Loan Agreement") to provide for an additional three-month interest only period ending on March 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, the end of term payment was increased by \$30,500.

The Loan Agreement was further amended in March 2018 to provide for an additional two-month interest only period ending on June 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, a facility fee of \$25,000 was paid upon execution and the end of term payment was increased by \$25,000.

The Loan Agreement was again amended in July 2018 to provide for an additional three-month interest only period ending on October 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, a facility fee of \$25,000 was paid upon execution and the end of term payment was increased by \$25,000.

The Loan Agreement includes customary affirmative and restrictive covenants, and also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 4% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

Under the Loan Agreement, the Company grants the Lender the right to participate in and/or designate one or more of its affiliates to participate in any subsequent financing in an amount up to \$1.0 million on the same terms, conditions and pricing afforded to other participating in such subsequent financing.

Note payable at December 31, 2018 consisted of the following (in thousands):

Face value of note payable	\$ 7,500
Accrued interest	46
Discounts on note payable related to warrants	(329)
Note payable issuance costs	(1,061)
	6,156
Principal payments through December 31, 2018	(2,692)
Accumulated accretion	1,175
Note payable	<u>\$ 4,639</u>

The following is a schedule of aggregate note payable maturities, excluding the unamortized amount related to the end of term payment, for each of the years subsequent to December 31, 2018 (in thousands):

<u>Year Ending December 31,</u>	
2019	\$ 4,808
	<u>\$ 4,808</u>

In connection with the Loan Agreement, the Company issued warrants to the Lender, which are exercisable for 26,087 shares of Series C redeemable convertible preferred stock at a per share exercise price of \$11.50 (the "Warrants"). The Warrants will terminate, if not earlier exercised, on February 18, 2026. The fair value of the warrants was recorded as a redeemable convertible preferred stock warrant liability upon issuance. The fair value of the warrants on the date of issuance of \$0.3 million was determined using the Black-Scholes option-pricing model. The fair value of the warrants was recorded as a debt discount upon issuance and will be amortized to interest expense over the term of the loan based on the effective interest method.

As of December 31, 2018, there were unaccreted debt discounts and issuance costs of \$0.2 million, which were recorded as a direct deduction from note payable on the accompanying balance sheets.

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#### **NOTE 8. LICENSEE AGREEMENTS**

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The Company enters into licensing agreements with universities and other research related entities for the exclusive right to commercially develop, produce, manufacture, use, and sell certain products and methods of use thereof (the "Inventions"). Typically, the license agreements are effective through the later of (i) the end of the term of the last-to-expire of licensor's patent rights licensed under the license agreements, or (ii) ten years after the first sale of the first licensed product if no patent has issued from the patent rights.

In April 2011, the Company executed a license agreement with the University of Manchester ("UM") for a worldwide, exclusive license to manufacture, market, sell and sublicense BBI-2000 based upon certain patents, with a field of use, limited to all dermatological indications.

In June 2012, the Company executed a license agreement with the UAB Research Foundation ("UABRF") for a worldwide, exclusive license to manufacture, market, sell and sublicense BBI-3000 based upon certain patents, with a field of use limited to all dermatological indications.

In December 2012, the Company entered into a license agreement with Bodor Laboratories, Inc. ("Bodor") for a worldwide, exclusive license to manufacture, market, sell and sublicense sofipironium bromide based upon certain patents, with a field of use, limited to the treatment of hyperhidrosis and excessive sweating.

In November 2015, the Company entered into a license agreement with NYU for a worldwide, exclusive world-wide license to manufacture, market, sell and sublicense BBI-6000, a series of novel RORy inhibitors, initially targeting the topical treatment of psoriasis.

Under the license agreements, the Company is required to make royalty payments based upon a percentage of net sales of any product developed from the Inventions.

The Company is required to make milestone payments under the license agreements upon the occurrence of certain events related to the licensed products:

<u>Milestone</u>	<u>Range</u>
Initiation of Phase I, II and/or III clinical trials in Dermatology Field	\$25,000 - \$500,000
Filings of NDA or European equivalents in Dermatology Field	\$150,000 - \$1,000,000
Receipt of NDA approval or European equivalent in Dermatology Field	\$250,000 - \$2,000,000
Receipt of NDA approval or European or Japanese equivalent Non-Dermatology Field	\$1,000,000 - \$5,000,000

As of December 31, 2018, contractual milestone payments set forth in the license agreements to which the Company was party aggregated to \$10.8 million.

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**NOTE 9. COMMITMENTS AND CONTINGENCIES**

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***Operating Leases***

In August 2016, the Company entered into a five-year lease for office space in Boulder, Colorado that expires on October 31, 2021 (the “Boulder Lease”) subject to the Company’s option to renew the Boulder Lease for two additional terms of three years each. Pursuant to the Boulder Lease, the Company leased 3,038 square feet of space in a multi-suite building. Rent payments under the Boulder Lease included base rent of \$4,430 per month during the first year of the Boulder Lease with an annual increase of 3.5%, and additional monthly fees to cover the Company’s share of certain facility expenses, including utilities, property taxes, insurance and maintenance, which were \$2,160 per month during the first year of the Boulder Lease.

The terms of the Boulder Lease provide for rental payments on a monthly basis on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not paid. Rent expense for the years ended December 31, 2018 and 2017 was \$0.1 million.

The following is a schedule of approximate future minimum rental commitments required under operating leases for years subsequent to December 31, 2018 (in thousands):

<u>Year Ending December 31,</u>	
2019	\$ 57
2020	59
2021	51
Total future minimum rental commitments	<u>\$ 167</u>

The table above excludes approximately \$0.1 million of additional rent due over the period of the operating lease to cover the Company’s share of facility expenses, including utilities, property taxes, insurance and maintenance.

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**NOTE 10. REDEEMABLE CONVERTIBLE PREFERRED STOCK**

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As of December 31, 2018 and 2017, the Company had authorized 4,182,943 shares of redeemable convertible preferred stock, par value of \$0.0001, of which 1,162,505 are designated Series A redeemable convertible preferred stock (“Preferred Stock A”), 882,216 are designated Series B redeemable convertible preferred stock (“Preferred Stock B”), 869,565 are designated Series C redeemable convertible preferred stock (“Preferred Stock C”) and 1,268,657 are designated Series C-1 redeemable convertible preferred stock (“Preferred Stock C-1”).

From October 2016 through October 2017, the Company issued 905,076 shares of Preferred Stock C-1 to investors at a price of \$13.40 per share for net proceeds of \$12.0 million.

In connection with the issuance of the Preferred Stock A, B, C and C-1 (the “Preferred Stock”), the Company incurred approximately \$0.5 million of issuance costs. The unaccreted discount as of December 31, 2018 and 2017 amounted to approximately \$0.1 million.

Redeemable convertible preferred stock consisted of the following (in thousands, except share data):

December 31, 2018						
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Fair Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A	1,162,505	1,162,505	\$ 1,163	\$ 16,098	\$ 11,898	1,162,505
Series B	882,216	828,998	829	13,011	9,803	828,998
Series C	869,565	743,326	743	13,018	11,418	743,326
Series C-1	1,268,657	905,076	905	16,163	13,866	905,076
	<u>4,182,943</u>	<u>3,639,905</u>	<u>\$ 3,640</u>	<u>\$ 58,290</u>	<u>\$ 46,985</u>	<u>3,639,905</u>

  

December 31, 2017						
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Fair Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A	1,162,505	1,162,505	\$ 1,163	\$ 14,689	\$ 11,017	1,162,505
Series B	882,216	828,998	829	11,305	9,077	828,998
Series C	869,565	743,326	743	11,938	10,571	743,326
Series C-1	1,268,657	905,076	905	14,422	12,828	905,076
	<u>4,182,943</u>	<u>3,639,905</u>	<u>\$ 3,640</u>	<u>\$ 52,354</u>	<u>\$ 43,493</u>	<u>3,639,905</u>

The rights, preferences and privileges of the Preferred Stock are as follows:

#### **Dividends**

The Company recognizes certain dividend rights for the holders of the Preferred Stock, in that these holders will receive preference to any declaration or payment of dividends at the rate of 8% of the original issue price of \$5.3333 of Preferred Stock A, \$8.14 of Preferred Stock B, \$11.50 of Preferred Stock C, and \$13.40 of Preferred Stock C-1 per share per annum, compounded annually, on each outstanding share. Holders of Preferred Stock A, B, C and C-1 rank pari passu with respect to the payment of accrued dividends. Accrued dividends at December 31, 2018 amounted to \$5.7 million (\$4.90 per share), \$3.1 million (\$3.68 per share), \$2.9 million (\$3.86 per share), and \$1.7 million (\$1.92 per share) on Preferred Stock A, B, C and C-1, respectively. Accrued dividends at December 31, 2017 amounted to \$4.8 million (\$4.14 per share), \$2.3 million (\$2.81 per share), \$2.0 million (\$2.72 per share), and \$0.7 million (\$0.77 per share) on Preferred Stock A, B, C and C-1, respectively. Accrued dividends are included as a component of redeemable convertible preferred stock in the accompanying balance sheets.

#### **Liquidation Preference**

Preferred Stock carries certain liquidation rights upon the liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary (including a change in control), whereas before any distribution or payment shall be made to the holders of any common stock, the holders of the Preferred Stock shall be entitled to be paid an amount equal to the original purchase price plus any accrued but unpaid dividends out of the assets of the Company legally available for distribution for each share. If the assets of the Company available for distribution upon liquidation are not sufficient to pay the preferred stock preference amount, the assets will be distributed ratably among the holders of the Preferred Stock in proportion to the full amount of the preference amount such holder is otherwise entitled to receive.

Any proceeds remaining after the distribution of the preference amount shall be distributed pro rata to the holders of the Preferred Stock (on as-if-converted to Common Stock basis) and the holders of Common Stock.

#### **Conversion**

Preferred Stock may be converted into common stock at the initial conversion ratio of 1:1, which ratio shall be altered in accordance with stock dividends, splits, combinations and other similar events, including the sale of additional shares of common or preferred stock at an effective price per common share lower than the conversion price then in effect. Each share of the Preferred Stock will automatically convert into shares of common stock, at the applicable conversion ratio of each series of redeemable convertible preferred stock then in effect, upon (i) a qualified public offering with net proceeds of not less than \$30 million and a price of not less

than \$57.50 per share, subject to appropriate adjustment for any stock dividend, stock split, combination or other similar recapitalization, or (ii) the date specified by written consent or agreement of the holders of at least two-thirds of the then outstanding shares of Preferred Stock voting together as a single class on an as-if-converted to Common Stock basis.

#### **Redemption**

At any time after July 16, 2021, the holders of the Company's Preferred Stock will have the right to require the Company to redeem all or a portion of their shares for cash at a redemption price equal to the greater of: (i) the purchase price of such shares plus all accrued and unpaid dividends thereon, or the (ii) fair market value of the shares.

#### **Voting Rights**

The holders of Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Holders of Preferred Stock have the right to vote the number of shares equal to the number of shares of common stock into which such Preferred Stock could convert on the record date for determination of stockholders entitled to vote. The holders of the majority of Preferred Stock, voting separately as a single class, are entitled to elect two directors of the Company.

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#### **NOTE 11. STOCK-BASED COMPENSATION**

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The Company's 2009 Equity Incentive Plan, as amended and restated (the "2009 Plan"), provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Board of Directors and consultants of the Company. At December 31, 2018, the total shares authorized under the 2009 Plan were 2,872,986 shares. The Board of Directors or a designated Committee of the Board is responsible for the administration of the 2009 Plan and determines the term, exercise price, and vesting terms of each option. Under the terms of existing awards, all stock option grants expire ten years from grant date.

A summary of all stock option activity under the 2009 Plan is presented below:

<b>Outstanding Options</b>	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Total Intrinsic Value</b>	<b>Weighted Average Remaining Contractual Life (In Years)</b>
Outstanding at December 31, 2017	1,354,166	\$ 3.91	\$ 2,511,589	7.74
Granted	775,967	5.68		
Exercised	(10,833)	4.20		
Forfeited	(100,625)	4.39		
Outstanding at December 31, 2018	2,018,675	\$ 4.56	\$ 2,265,118	7.96
Options vested and exercisable at December 31, 2018	1,090,045	\$ 3.75	\$ 2,103,832	6.51
Options vested at December 31, 2018 and expected to vest	1,953,675	\$ 4.53	\$ 2,253,829	7.91

At December 31, 2018 and 2017, a total of 538,060 shares and 416 shares, respectively, were available for grant under the 2009 Plan. The total estimated grant date fair value of stock options vested during the years ended December 31, 2018 and 2017 was \$0.8 million and \$0.9 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2018 and 2017 amounted to \$0.1 million.

Total stock-based compensation expense related to stock options granted under the 2009 Plan was allocated as follows:

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Research and development	\$ 340	\$ 343
General and administrative	371	538
Total stock-based compensation expense	\$ 711	\$ 881

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock-based awards. The determination of the fair value of stock-based awards on the date of grant using an option-pricing model is affected by the value of the Company's stock price, as well as assumptions regarding subjective variables. These variables include expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate and expected dividends.

The Company estimates the "simplified method" in accordance with Staff Accounting Bulletin ("SAB") No. 107, "Share-Based Payment", and SAB No. 110, "Simplified Method for Plain Vanilla Share Options", to develop the expected term of stock option awards that qualify as "plain-vanilla" options. Under this approach, the expected term of the option grant is presumed to be the midpoint between the vesting date and the contractual end of the option grant. The expected term of all other stock options granted is based on the Company's historical share option exercise experience, which approximates the midpoint between the vesting date and the contractual end of the option grant. The Company estimates volatility of the common stock by using the average share fluctuations of companies similar in size, operations, and life cycle. The risk-free interest rates used in the valuation model are based on U.S. Treasury issues with remaining terms similar to the expected term on the options. The Company does not anticipate paying any dividends in the foreseeable future and therefore used an expected dividend yield of zero.

Management has estimated the forfeiture rate at 7% based on past experience, forfeiture rates and the individuals receiving the options. The Company will monitor actual forfeiture experience and will periodically update forfeiture estimates based on actual experience. As of December 31, 2018, there was total unrecognized compensation expense of approximately \$3.7 million, which is expected to be recognized over a period of approximately 3.96 years.

#### Stock Options Granted to Employees

During the years ended December 31, 2018 and 2017, the Company granted 731,967 stock options and 108,500 stock options, respectively, to employees and non-employee directors to purchase shares of common stock with a weighted-average grant date fair value of \$4.16 and \$4.02 per share, respectively, and a weighted-average exercise price of \$5.68 and \$5.45 per share, respectively.

The assumptions used to calculate the fair value of stock options granted to employees and non-employee directors under the 2009 Plan are as follows, presented on a weighted average basis:

	<u>2018</u>	<u>2017</u>
Expected term (in years)	6.1	6.1
Expected volatility	85.43 %	88.19 %
Risk free interest rate	2.77 %	2.16 %
Expected dividend yield	— %	— %

The stock-based compensation expense related to employee stock options was approximately \$0.6 million for the years ended December 31, 2018 and 2017.

#### Stock Options Granted to Non-employees

During the years ended December 31, 2018 and 2017, the Company granted 44,000 stock options and 25,000 stock options, respectively, to persons other than employees and non-employee members of the Company's Board of Directors with a weighted-average exercise price of \$5.68 and \$5.34 per share, respectively.

The assumptions used to calculate the fair value of stock options granted to non-employees under the 2009 Plan are as follows, presented on a weighted average basis:

	<u>2018</u>	<u>2017</u>
Expected term (in years)	9.96	9.85
Expected volatility	86.17 %	84.39 %
Risk free interest rate	2.69 %	2.35 %
Expected dividend yield	— %	— %

The stock-based compensation expense related to non-employee stock options was approximately \$0.1 million and \$0.2 million for the years ended December 31, 2018 and 2017, respectively.

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**NOTE 12. STOCKHOLDERS' DEFICIT**

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**Common Stock**

As of December 31, 2018, the Company had authorized 8,000,000 shares of common stock, par value \$0.0001 per share.

The Company has reserved authorized shares of common stock, on an as-converted basis, for future issuance at December 31, 2018 as follows:

	<u>2018</u>
Conversion of Preferred Stock A	1,162,505
Conversion of Preferred Stock B	828,998
Conversion of Preferred Stock C	743,326
Conversion of Preferred Stock C-1	905,076
Preferred Stock C warrants issued with note payable	26,087
Common stock warrants	160,365
Common stock options outstanding	2,018,675
Options available for grant under the 2009 Plan	538,060
	<u>6,383,092</u>

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**NOTE 13. SUBSEQUENT EVENTS**

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**Bridge Financing—Convertible Promissory Notes with Warrants**

In March 2019, the Company initiated a convertible promissory notes offering pursuant to which the Company issued unsecured convertible promissory notes (the "Prom Notes"), bearing interest at 12.00% and maturing in one year and can be converted into shares of Series C-1 redeemable convertible preferred stock or the most senior preferred equity outstanding at the time of conversion at the option of the holder at a conversion price of \$10.72 per share. In addition, the Prom Notes will automatically convert at maturity or if a qualified financing of at least \$15.0 million occurs before maturity, such mandatory conversion price will equal 80% of the effective price per share paid in the qualified financing, but not to exceed \$13.40 per share.

The Prom Notes also provide for the issuance of warrants at 50% coverage, which are exercisable into common stock for a term of five years at an exercise price of \$14.74 or, upon the occurrence of a qualified financing, 10% premium to the effective price per share paid in the qualified financing.

From March to April 2019, the Company issued Prom Notes and warrants for gross proceeds of \$3.6 million.

**Evaluation Date**

The Company has evaluated events that have occurred after the balance sheet date through April 30, 2019, which is when these financial statements were issued.

**BRICKELL BIOTECH, INC.**

**INDEX TO FINANCIAL STATEMENTS**

**Unaudited Financial Statements for the Three and Six Months Ended June 30, 2019**

Balance Sheet as of June 30, 2019	<a href="#">F-2</a>
Statements of Operations for the Three and Six Months Ended June 30, 2019 and 2018	<a href="#">F-3</a>
Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit for the Three and Six Months Ended June 30, 2019 and 2018	<a href="#">F-4</a>
Statements of Cash Flows for the Six Months Ended June 30, 2019 and 2018	<a href="#">F-5</a>
Notes to Financial Statements for the Six Months Ended June 30, 2019 and 2018	<a href="#">F-6</a>

**BRICKELL BIOTECH, INC.**  
**CONDENSED BALANCE SHEETS**  
*(In thousands, except share and per share data)*

	June 30, 2019	December 31, 2018
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,079	\$ 8,067
Prepaid expenses and other current assets	362	204
Total current assets	2,441	8,271
Property and equipment, net	20	37
Operating lease right-of-use asset	186	—
Intangible assets	441	441
Total assets	\$ 3,088	\$ 8,749
<b>Liabilities, redeemable convertible preferred stock and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 7,120	\$ 4,067
Accrued liabilities	4,039	3,272
Lease liability, current portion	67	—
Deferred revenue, current portion	3,040	8,117
Convertible promissory notes	3,598	—
Derivative liability	1,007	—
Notes payable	3,184	4,639
Total current liabilities	22,055	20,095
Contingent consideration	145	145
Lease liability, net of current portion	111	—
Warrant liability	1,048	242
Deferred revenue, net of current portion	608	1,595
Total liabilities	23,967	22,077
Redeemable convertible preferred stock (Series A, B, C and C-1), \$0.0001 par value, 4,446,228 and 4,182,943 shares authorized at June 30, 2019 and December 31, 2018, respectively; 3,639,905 shares issued and outstanding at June 30, 2019 and December 31, 2018; aggregate liquidation preference of \$48,017 and \$46,985 at June 30, 2019 and December 31, 2018, respectively	47,934	58,290
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Common Stock, \$0.0001 par value, 10,000,000 and 8,000,000 shares authorized at June 30, 2019 and December 31, 2018, respectively; 1,706,251 issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Additional paid-in capital	520	—
Accumulated deficit	(69,333)	(71,618)
Total stockholders' deficit	(68,813)	(71,618)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 3,088	\$ 8,749

See accompanying notes to unaudited financial statements.

**BRICKELL BIOTECH, INC.**  
**UNAUDITED CONDENSED STATEMENTS OF OPERATIONS**  
*(In thousands, except share and per share data)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	\$ 2,573	\$ 373	\$ 6,065	\$ 5,373
Operating expenses:				
Research and development	4,229	2,254	10,248	4,436
General and administrative	1,323	1,434	3,389	3,488
Total operating expenses	5,552	3,688	13,637	7,924
Loss from operations	(2,979)	(3,315)	(7,572)	(2,551)
Interest income	4	16	10	22
Interest expense	(660)	(255)	(884)	(502)
Change in fair value of derivative liability	(11)	—	(11)	—
Change in fair value of warrant liability	(8)	2	223	6
Net loss	(3,654)	(3,552)	(8,234)	(3,025)
(Accretion) reduction of redeemable convertible preferred stock to redemption value	(163)	(865)	10,356	(4,105)
Net income (loss) attributable to common stockholders	\$ (3,817)	\$ (4,417)	\$ 2,122	\$ (7,130)
Basic net income (loss) per common share attributable to common stockholders	\$ (2.24)	\$ (2.60)	\$ 1.24	\$ (4.20)
Diluted net income (loss) per common share attributable to common stockholders	\$ (2.24)	\$ (2.60)	\$ (1.54)	\$ (4.20)
Weighted-average shares used to compute basic net loss per share attributable to common stockholders	1,706,251	1,699,584	1,706,251	1,699,478
Weighted-average shares used to compute diluted net loss per share attributable to common stockholders	1,706,251	1,699,584	5,346,156	1,699,478

See accompanying notes to unaudited financial statements.

**BRICKELL BIOTECH, INC.****UNAUDITED CONDENSED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT***(In thousands, except share and per share data)*

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In-Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Carrying Value	Shares	Par Value			
Balance, December 31, 2017	3,639,905	\$ 52,354	1,695,418	\$ —	\$ —	\$ (59,936)	\$ (59,936)
Effect of adoption of Topic 606	—	—	—	—	—	2,734	2,734
Stock based compensation	—	—	—	—	190	—	190
Issuance of common stock through exercise of stock option	—	—	4,166	—	17	—	17
Accretion of redeemable convertible preferred stock to redemption value	—	3,240	—	—	(207)	(3,033)	(3,240)
Net income	—	—	—	—	—	527	527
Balance, March 31, 2018 (unaudited)	3,639,905	55,594	1,699,584	—	—	(59,708)	(59,708)
Stock based compensation	—	—	—	—	175	—	175
Accretion of redeemable convertible preferred stock to redemption value	—	865	—	—	(175)	(690)	(865)
Net loss	—	—	—	—	—	(3,552)	(3,552)
<b>Balance, June 30, 2018 (unaudited)</b>	<b>3,639,905</b>	<b>\$ 56,459</b>	<b>1,699,584</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (63,950)</b>	<b>\$ (63,950)</b>
Balance, December 31, 2018	3,639,905	\$ 58,290	1,706,251	\$ —	\$ —	\$ (71,618)	\$ (71,618)
Stock based compensation	—	—	—	—	384	—	384
Reduction of redeemable convertible preferred stock to redemption value	—	(10,519)	—	—	—	10,519	10,519
Net loss	—	—	—	—	—	(4,580)	(4,580)
Balance, March 31, 2019 (unaudited)	3,639,905	47,771	1,706,251	—	384	(65,679)	(65,295)
Stock based compensation	—	—	—	—	299	—	299
Accretion of redeemable convertible preferred stock to redemption value	—	163	—	—	(163)	—	(163)
Net loss	—	—	—	—	—	(3,654)	(3,654)
<b>Balance, June 30, 2019 (unaudited)</b>	<b>3,639,905</b>	<b>\$ 47,934</b>	<b>1,706,251</b>	<b>\$ —</b>	<b>\$ 520</b>	<b>\$ (69,333)</b>	<b>\$ (68,813)</b>

See accompanying notes to unaudited financial statements.

**BRICKELL BIOTECH, INC.**  
**UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS**  
*(In thousands)*

	Six Months Ended June 30,	
	2019	2018
	(unaudited)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (8,234)	\$ (3,025)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	21	25
Change in fair value of derivative liability	11	—
Change in fair value of warrant liability	(224)	(6)
Amortization of convertible promissory notes discount	381	—
Amortization of debt discounts and financing costs	170	196
Stock-based compensation	683	365
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(165)	(74)
Accounts payable	3,053	1,225
Accrued liabilities	866	(907)
Deferred revenue	(6,064)	15,230
Total adjustments	(1,268)	16,054
Net cash provided by (used in) operating activities	(9,502)	13,029
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Capital expenditures	(4)	(8)
Net cash used in investing activities	(4)	(8)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Principal payments made on note payable	(1,609)	(509)
Proceeds from issuance of convertible promissory notes	5,127	—
Proceeds from the exercise of stock options	—	17
Net cash provided by (used in) financing activities	3,518	(492)
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(5,988)	12,529
<b>CASH AND CASH EQUIVALENTS—BEGINNING</b>	8,067	5,399
<b>CASH AND CASH EQUIVALENTS—ENDING</b>	\$ 2,079	\$ 17,928
<b>Supplement Disclosure of Cash Flow Information:</b>		
Interest paid	\$ 234	\$ 310
<b>Supplement Disclosure of Non-Cash Financing and Investing Activities:</b>		
Accretion (reduction) of redeemable convertible preferred stock to redemption value	\$ (10,376)	\$ 4,085
Accretion of redeemable convertible preferred stock issuance costs	\$ 20	\$ 20
Deferred financing costs included in accrued liabilities	\$ 154	\$ —
Derivative liability issued with convertible promissory notes	\$ 996	\$ —
Warrants issued with convertible promissory notes to purchase common stock	\$ 1,029	\$ —

See accompanying notes to unaudited financial statements.

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**NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS**

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Brickell Biotech, Inc. (the “Company”) was incorporated in the state of Delaware and commenced activities on September 17, 2009. The Company is a clinical-stage pharmaceutical company focused on developing of innovative and differentiated therapeutics for the treatment of debilitating skin diseases. The Company’s pipeline consists of potential novel therapeutics for hyperhidrosis, cutaneous T-cell lymphoma, psoriasis, and other prevalent dermatological conditions. The Company’s pivotal Phase 3-ready clinical-stage product candidate, sofpironium bromide, is a new molecular entity and “soft” drug that belongs to a class of medications called anticholinergics. The Company is developing sofpironium bromide as a potential best-in-class, self-administered, once daily, topical prescription hyperhidrosis therapy for the treatment of primary axillary hyperhidrosis. The Company’s operations to date have been limited to business planning, raising capital, developing its pipeline assets (in particular sofpironium bromide), identifying product candidates, and other research and development. The Company is headquartered in Boulder, Colorado.

***Agreement and Plan of Merger***

On June 2, 2018, the Company, Victory Subsidiary, Inc. (“Merger Sub”), and Vical Incorporated (“Vical”), entered into the Merger Agreement, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company, with the Company continuing as a wholly-owned subsidiary of Vical and the surviving corporation of the Merger.

Subject to the terms and conditions of the Merger Agreement, at the closing of the Merger, each outstanding share of the Company capital stock will be converted into the right to receive shares of Vical common stock (subject to the payment of cash in lieu of fractional shares and after giving effect to a reverse stock split of Vical common stock if determined necessary or appropriate by the Company, Vical and Merger Sub) such that, immediately following the Effective Time, preexisting Company stockholders, optionholders and warrant holders are expected to own, or hold rights to acquire, approximately 60% of the Fully-Diluted Common Stock of Vical, and preexisting Vical stockholders, optionholders and warrant holders are expected to own, or hold rights to acquire, approximately 40% of the Fully-Diluted Common Stock of Vical. Consummation of the Merger is subject to certain closing conditions, including, among other things, approval by the stockholders of Vical, and satisfaction of minimum net working capital thresholds by each of Vical and the Company. At the effective time of the Merger, the Board of Directors of Vical is expected to consist of seven members, five of whom will be designated by the Company and two of whom will be designated by Vical.

Contemporaneously with the execution and delivery of the Merger Agreement, and as a condition of the willingness of Vical to enter into the Merger Agreement, the Company entered into a funding agreement with NovaQuest Capital Management, LLC (“NovaQuest”) pursuant to which NovaQuest committed up to \$25 million in research and development funding to the Company following the closing of the Merger. Concurrently with the closing of the funding agreement, the surviving corporation of the Merger will issue a warrant to NovaQuest to purchase shares of Vical common stock in an amount based on 10% warrant coverage on the \$25.0 million funding commitment and the exchange ratio for the Merger.

***Liquidity and Capital Resources***

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has incurred significant operating losses and has an accumulated deficit as a result of ongoing efforts to develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the six months ended June 30, 2019, the Company had a net loss of \$8.2 million and net cash used in operating activities of \$9.5 million. As of June 30, 2019, the Company had cash and cash equivalents of \$2.1 million and an accumulated deficit of \$69.3 million.

The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company’s research and development activities. The Company believes that its cash and cash equivalents as of June 30, 2019 as well as cash received from the Merger and the transactions mentioned in Note 11 will be sufficient to fund its operations for at least the next twelve months from the issuance of the unaudited financial statements, however the Merger is subject to conditions such as a shareholder vote and while expected, this is not certain. Additional funding will be required in the future to maintain its present and proposed research activities. There can be no assurance that additional equity or debt financing will be available on acceptable terms, if at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its

research programs and/or limit or cease its operations. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of twelve months subsequent to the issuance of these financial statements.

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**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

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***Basis of Presentation***

The accompanying unaudited condensed financial statements are presented in U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with US GAAP have been condensed or omitted. These condensed financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of our management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of our financial information. The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the full year ending December 31, 2019 or any other future period. The condensed balance sheet as of June 30, 2019 has been derived from financial statements at that date but does not include all of the information required by US GAAP for complete financial statements.

***Risks and Uncertainties***

The Company's business is subject to significant risks common to early-stage companies in the pharmaceutical industry including, but not limited to, the ability to develop appropriate formulations, scale up and production of the compounds, dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents, clinical success, the lengthy and expensive regulatory approval process, compliance with regulatory requirements, competition from other products; uncertainty of broad adoption of its approved products, if any, by physicians and patients; significant competition; ability to manage third-party manufacturers, suppliers and contract research organizations ("CROs") and obtaining additional financing to fund the Company's efforts.

The product candidates developed by the Company require approvals from the FDA and foreign regulatory agencies prior to commercial sales in the United States or foreign jurisdictions, respectively. There can be no assurance that the Company's current and future product candidates will receive the necessary approvals. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company's business and its financial condition.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

***Fair Value Measurements***

Fair value is the price that the Company would receive to sell an asset or pay to transfer a liability in a timely transaction with an independent counterparty in the principal market or in the absence of a principal market, the most advantageous market for the asset or liability. A three-tier hierarchy is established to distinguish between (1) inputs that reflect the assumptions market participants would use in pricing an asset or liability developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing an asset or liability developed based on the best information available in the circumstances (unobservable inputs), and establishes a classification of fair value measurements for disclosure purposes.

The hierarchy is summarized in the three broad levels listed below.

**Level 1**—quoted prices in active markets for identical assets and liabilities

**Level 2**—other significant observable inputs (including quoted prices for similar assets and liabilities, interest rates, credit risk, etc.)

**Level 3**—significant unobservable inputs (including the Company's own assumptions in determining the fair value of assets and liabilities)

The following tables set forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019		
	Level 1	Level 2	Level 3
<b>Assets:</b>			
Money market funds	\$ 2,079	\$ —	\$ —
<b>Total</b>	<b>\$ 2,079</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Liabilities:</b>			
Contingent consideration	\$ —	\$ —	\$ 145
Redeemable convertible preferred stock warrant liability	—	—	2
Derivative liability	—	—	1,007
Common stock warrant liability	—	—	1,046
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 2,200</b>
<b>December 31, 2018</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Assets:</b>			
Money market funds	\$ 8,067	\$ —	\$ —
<b>Total</b>	<b>\$ 8,067</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Liabilities:</b>			
Contingent consideration	\$ —	\$ —	\$ 145
Redeemable convertible preferred stock warrant liability	—	—	242
<b>Total</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 387</b>

#### **Fair Value of Financial Instruments**

The following methods and assumptions were used by the Company in estimating the fair values of each class of financial instrument disclosed herein:

*Money market funds*—The carrying amounts reported in the balance sheets approximate their fair values due to their short-term nature and/or market rates of interest (Level 1 of the fair value hierarchy).

*Contingent consideration*—These amounts represent future payments in conjunction with various business combinations. The ultimate amount of future payments is based on specified future criteria, such as the achievement of certain future development and regulatory milestones. The Company evaluates its estimates of the fair value of contingent consideration on a periodic basis. The fair value of the contingent consideration was determined by a third-party valuation firm applying the income approach. This approach estimates the fair value of the contingent consideration related to the achievement of future development and regulatory milestones by assigning an achievement probability and date of expected completion to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The probability of success of each milestone assumes that the prerequisite developmental milestones are successfully completed and is based on the asset's current stage of development and anticipated regulatory requirements. The probability of success for each milestone is determined by multiplying the preceding probabilities of success. The unobservable inputs (Level 3 of the fair value hierarchy) to the valuation models that have the most significant effect on the fair value of the Company's contingent consideration are the probabilities that certain in-process development projects will meet specified development milestones, including ultimate approval by the FDA, with individual cumulative probabilities ranging from 2.1% to 20.9%. Other unobservable inputs used in this approach include: risk-adjusted discount rates ranging from 15.5% to 27.1% and estimates of the timing of the achievement of the various product development, regulatory approval and sales milestones.

*Redeemable convertible preferred stock warrant liability*—These amounts represent potential future obligations to transfer assets to the holders at a future date. The Company remeasures these warrants to current fair value at each balance sheet date, and any change in fair value is recognized as a change in fair value of warrant liability in the statements of operations. The Company estimated the fair

value of these warrants at the respective balance sheet dates using the Black-Scholes option-pricing model (Level 3 of the fair value hierarchy table) (see further discussion in Note 6).

Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The most significant unobservable inputs used in the fair value measurement of the convertible preferred stock warrant liability are the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The fair value of the outstanding convertible preferred stock warrants was remeasured as of each period end using the Black-Scholes option-pricing model with the following assumptions:

	<u>2019</u>	<u>2018</u>
Expected term (in years)	6.6	7.1
Expected volatility	30.00 %	30.00 %
Risk free interest rate	1.87 %	2.59 %
Expected dividend yield	— %	— %

*Fair Value of Redeemable Convertible Preferred Stock.* The fair value of the shares of the convertible preferred stock underlying the preferred stock warrants has historically been determined by a third-party valuation firm. Because there has been no public market for the Company's convertible preferred stock, the third-party valuation firm has determined fair value of the convertible preferred stock at each balance sheet date by considering a number of objective and subjective factors, including valuation of comparable companies, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors.

*Remaining Term.* The Company derived the expected term based on the time from the balance sheet date until the preferred stock warrant's expiration date.

*Expected Volatility.* Since the Company was a private entity with no historical data regarding the volatility of its preferred stock, the expected volatility used is based on volatility of a group of similar entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

*Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the warrants.

*Expected Dividend Rate.* The Company has never paid any dividends and does not plan to pay dividends in the foreseeable future and, therefore, used an expected dividend rate of zero in the valuation model.

*Derivative liability*—These amounts represent potential future obligations to transfer assets to the holders at a future date. The fair value of the derivative liability has historically been determined by a third-party valuation firm (Level 3 of the fair value hierarchy table) (see further discussion in Note 5). Because there has been no public market for the Company's common stock, the third-party valuation firm has determined fair value of the stock at each balance sheet date by considering a number of objective and subjective factors, including valuation of comparable companies, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors. The derivative liability is marked-to-market each measurement period and any change in fair value is recorded in the statements of operations.

The fair value of the derivative liability as of June 30, 2019 was determined using the following assumptions: contractual term of 0.2 years, expected volatility of 70.00%, risk-free rate of 1.75%, and expected dividend yield of 0%.

*Common stock warrant liability*—These amounts represent potential future obligations to transfer assets to the holders at a future date. The fair value of the warrants has historically been determined by a third-party valuation firm (Level 3 of the fair value hierarchy table) (see further discussion in Note 5). Because there has been no public market for the Company's common stock, the third-party valuation firm has determined fair value of the stock at each balance sheet date by considering a number of objective and subjective factors, including valuation of comparable companies, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors. These warrants are remeasured to fair value at each balance sheet date, and any change in fair value is recognized as a change in fair value of

warrant liability in the statements of operations. The Company estimated the fair value of these warrants at the respective balance sheet dates using the Black-Scholes option-pricing model.

Inputs used to determine estimated fair value of the warrant liabilities include the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the underlying stock. The most significant unobservable inputs used in the fair value measurement of the warrant liability are the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The fair value of the warrants as of June 30, 2019 was determined using the following assumptions: contractual term of 4.6 years, expected volatility of 70.00%, risk-free rate of 1.75%, and expected dividend yield of 0%.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

	Derivative Liability	Common Stock Warrant Liability	Redeemable Convertible Preferred Stock Warrant Liability	Contingent Consideration Liabilities
Fair value as of December 31, 2017	\$ —	\$ —	\$ 486	\$ 148
Change in fair value	—	—	(244)	(3)
Fair value as of December 31, 2018	—	—	242	145
Fair value of financial instruments issued (unaudited)	996	1,029	—	—
Change in fair value (unaudited)	11	17	(240)	—
Fair value as of June 30, 2019 (unaudited)	\$ 1,007	\$ 1,046	\$ 2	\$ 145

### Leases

On January 1, 2019, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, Leases ("ASC 842"), using the modified retrospective method for all lease arrangements at the beginning of the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under ASC 842, while prior period amounts were not adjusted and continue to be presented in accordance with the Company's historical accounting under ASC Topic 840, Leases. ASC 842 had an impact on the Company's Condensed Balance Sheet but did not have a significant impact on the Company's net loss.

Under ASC 842, the Company determines if an arrangement is a lease at inception. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected the practical expedient not to recognize on the balance sheet leases with terms of one-year or less and not to separate lease components and non-lease components for long-term real-estate leases. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company estimates the incremental borrowing rate based on industry peers in determining the present value of lease payments. The Company's facility operating lease has one single component. The lease component results in a right-of-use asset being recorded on the balance sheet and amortized as lease expense on a straight-line basis in the Company's statements of operations.

### Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock is classified as a mezzanine instrument outside of the Company's capital accounts. Accretion of redeemable convertible preferred stock includes the greater of an adjustment to fair market value or the accrual of dividends on and accretion of issuance costs of the Company's redeemable convertible preferred stock. The carrying values of the redeemable convertible preferred stock are increased or reduced by periodic accretion or reduction to their respective redemption values, using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption. These increases are recorded as charges against additional paid-in capital balance until the additional paid-in capital balance is reduced to zero. At that time, additional accretion adjustments are recorded as additions to accumulated deficit.

Preferred stock issuance costs represent costs related to the Company issuing redeemable convertible preferred stock. These amounts are included as a reduction of redeemable convertible preferred stock and are amortized over the estimated redemption period. Amortization of preferred stock issuance costs amounted to approximately \$20,000 for the six months ended June 30, 2019 and 2018.

### ***Redeemable Convertible Preferred Stock Warrants***

The Company accounts for warrants to purchase shares of its redeemable convertible preferred stock as liabilities at their estimated fair value because the underlying shares are redeemable, which may obligate the Company to transfer assets to the holders at a future date. The warrants are subject to remeasurement to fair value at each balance sheet date, and any fair value adjustments are recognized as change in fair value of redeemable convertible preferred stock warrant liability in the statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the redeemable convertible preferred stock warrants, conversion of redeemable convertible preferred stock into common stock, or until holders of the redeemable convertible preferred stock can no longer trigger a deemed liquidation event. At that time, the redeemable convertible preferred stock warrant liability will be adjusted to fair value in the statements of operations with the final fair value reclassified to equity.

### ***Revenue Recognition***

The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

To date, the Company's drug candidates have not been approved for sale by the FDA and the Company has not generated or recognized any revenue from the sale of products.

In March 2015, the Company entered into a license and collaboration agreement with Kaken Pharmaceutical, Co., Ltd. ("Kaken"), which is referred to as the "Collaboration Agreement". Under the Collaboration Agreement, the Company granted to Kaken an exclusive right to develop, manufacture and commercialize the Company's sofipronium bromide compound (formerly BBI-4000), a topical anticholinergic, in Japan and certain other Asian countries (the "Territory"). In exchange, Kaken paid the Company an upfront, non-refundable payment of \$11.0 million (the "upfront fee"). In addition, the Company is entitled to receive aggregate payments of up to \$10.0 million upon the achievement of specified development milestones, and \$30.0 million upon the achievement of commercial milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. The Collaboration Agreement further provides that Kaken will be responsible for funding all development and commercial costs for the program in the Territory and, until such time, if any, as Kaken elects to establish its own source of supply of drug product, Kaken can purchase product supply from the Company to perform all non-clinical studies, and Phase I and Phase II clinical trials in Japan at cost. Kaken is also required to enter into negotiations with the Company, to supply the Company, at cost, with clinical supplies to perform Phase III clinical trials in the U.S.

### ***Collaboration arrangement subsequent to adoption of Topic 606***

The Company evaluates collaboration arrangements to determine whether units of account within the collaboration arrangement exhibit the characteristics of a vendor and customer relationship. The Company determined that the licenses transferred to Kaken in exchange for the upfront fees were representative of this type of a relationship. If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition on a prospective basis.

Under Topic 606, the Company evaluated the terms of the Collaboration Agreement and the transfer of intellectual property and manufacturing rights (the "license") was identified as the only performance obligation as of the inception of the agreement. The Company concluded that the license for the intellectual property was distinct from its ongoing supply obligations. The Company further determined that the transaction price under the arrangement was comprised of the \$11.0 million upfront payment. The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained. As part of our evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals, each of which is uncertain at this time. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur. Future potential milestone amounts would be recognized as revenue from collaboration arrangements, if unconstrained. The

remainder of the arrangement, which largely consisted of both parties incurring costs in their respective territories, provides for the reimbursement of the ongoing supply costs. These costs were representative of a collaboration arrangement outside of the scope of Topic 606 as it does not have the characteristics of a vendor and customer relationship. Reimbursable program costs are recognized proportionately with the delivery of drug substance and are accounted for as reductions to research and development expense and are excluded from the transaction price.

Under Topic 606, the entire transaction price of \$11.0 million was allocated to the license performance obligation. The license was deemed to be delivered in 2015 in connection with the execution of the Collaboration Agreement and upon transfer of the underlying intellectual property the performance obligation was fully satisfied. As a result, a cumulative adjustment to reduce deferred revenue and the corresponding sublicensing costs of \$2.7 million was recorded upon the adoption of Topic 606 on January 1, 2018. As of June 30, 2019, the Company does not have a deferred revenue or deferred sublicensing costs balance related to the upfront fee on the balance sheet.

In May 2018, the Company entered into an amendment to the Collaboration Agreement (as further amended, "Collaboration Agreement"), pursuant to which, the Company received an upfront non-refundable fee of \$15.6 million (the "Collaboration R&D Payment"), which was initially recorded as deferred revenue, to provide the Company with research and development funds to conduct certain clinical trials related to sofipironium bromide. These clinical trials have a benefit to Kaken and have the characteristics of a vendor and customer relationship. The Company has accounted for these under the provisions of Topic 606. This Collaboration R&D Payment will be initially recognized using an input method over the average estimated performance period of 1.45 years in proportion to the cost incurred. Upon receipt of the Collaboration R&D Payment, on May 31, 2018, a milestone payment originally due upon the first commercial sale in Japan was removed from the Collaboration Agreement and all future royalties to the Company under the Collaboration Agreement were reduced 150 basis points.

Consequently, during the three and six months ended June 30, 2019, the Company recognized revenue of \$2.6 million and \$6.1 million, respectively related to the Collaboration R&D Payment. As of June 30, 2019, the Company has a deferred revenue balance related to the Collaboration R&D Payment of \$3.6 million, of which \$3.0 million, is recorded in deferred revenue, current portion on the accompanying balance sheets.

#### *Milestones*

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or our collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

In October 2017, the Company entered into an amendment to the Collaboration Agreement, pursuant to which, the Company granted Kaken a prepayment option (the "Kaken Option") on 50% of the Initiation of Phase III milestone (the "Phase III milestone"). The Kaken Option was exercisable by Kaken within 25 business days of receipt of the BBI-4000-CL-203 study topline results. In December 2017, Kaken exercised the Kaken Option and paid the Company \$5.0 million (the "Kaken Option Payment"). Upon receipt of the non-refundable Kaken Option Payment, the Company provided Kaken the right to negotiate an exclusive license to develop, manufacture and commercialize each of the Company's other product candidates in Japan ("ROFN Agreement"). Under the ROFN Agreement, following the completion of any Initial Proof of Concept Clinical Trial ("Initial POC") for the Company's other product candidates, the Company must provide Kaken with certain information relating to the results of the clinical trial ("Initial POC Package"). The ROFN Agreement is exercisable by Kaken within 30 days of receipt of the Initial POC Package. In December 2017, the Company recognized collaboration revenue related to the Collaboration Agreement of \$5.0 million, in connection with the Kaken Option. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

The Collaboration Agreement was further amended in March 2018 to accelerate payment of the Phase III milestone. The Phase III milestone was modified to be due upon the successful completion of the End of Phase 2 Meeting with the PMDA by Kaken on March 8, 2018, as determined by Kaken in its reasonable discretion (the "Third Milestone"). In March 2018, Kaken triggered the Third Milestone and paid the Company \$5.0 million (the "Third Milestone Payment"). Upon receipt of the non-refundable Third Milestone Payment, the ROFN Agreement was amended (the "Amended ROFN Agreement") to grant an additional option to exercise upon completion of a Subsequent Clinical Trial (first clinical trial after the Initial POC) for the Company's other product candidates.

The Company has determined that the ROFN Agreement is not a material right and has not allocated transaction price to this provision. As of June 30, 2019, Kaken has not exercised the Amended ROFN Agreement. In March 2018, the Company recognized collaboration revenue related to the Collaboration Agreement of \$5.0 million in connection with the Third Milestone. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

#### Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognized revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from any collaborative arrangement.

Under collaborative arrangements, the Company has been reimbursed for a portion of the Company's research and development expenses, including costs of drug supplies. When the research and development services are performed under a reimbursement or cost sharing model with a collaboration partner, the Company records these reimbursements as a reduction of research and development expense in the Company's statements of operations.

#### Net Income (Loss) per Common Share

Basic and diluted net income (loss) per common share is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing the Company's net earnings by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares.

Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method, and redeemable convertible preferred stock, using the if-converted method. In computing diluted earnings per share, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted earnings per share computation in net loss periods, since their effect would be anti-dilutive.

The following table sets forth the potential common shares excluded from the calculation of net loss per common share, because their inclusion would be anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(Unaudited)			
Redeemable convertible preferred stock (as converted into common stock)	3,639,905	3,639,905	—	3,639,905
Promissory notes convertible into Series C-1 Redeemable Convertible Preferred Stock (as converted into common stock)	489,065	—	489,065	—
Options to purchase common stock	1,811,800	1,350,000	1,811,800	1,350,000
Warrants to purchase common stock	399,496	160,365	399,496	160,365
Warrants to purchase redeemable convertible preferred stock (as converted into common stock)	26,087	26,087	26,087	26,087
	<u>6,366,353</u>	<u>5,176,357</u>	<u>2,726,448</u>	<u>5,176,357</u>

#### NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement (“ASU 2018-13”), which amends certain disclosure requirements over Level 1, Level 2 and Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-13, but does not anticipate it will have a material impact on its disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance

sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The Company adopted ASU 2016-02 on January 1, 2019 using the modified retrospective approach. The adoption did not have a material impact on the Company's statements of operations. The new standard has required the Company to establish liabilities and corresponding right-of-use assets on its condensed balance sheet for operating leases of \$0.2 million that existed as of the January 1, 2019 adoption date. The impact on the Condensed Balance Sheets as of January 1, 2019 was as follows:

Balance Sheet	Topic 840 January 1, 2019	Topic 842 January 1, 2019	Impact of Adoption
Operating lease right-of-use asset	\$ —	\$ 219	\$ 219
Lease liability, current portion	—	(68)	(68)
Lease liability, net of current portion	—	(151)	(151)

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#### NOTE 4. ACCRUED LIABILITIES

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Accrued liabilities consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
	(unaudited)	
Accrued compensation	\$ 428	\$ 569
Accrued note issuance costs	587	587
Accrued professional fees	1,458	1,269
Accrued contracted research and development services	1,566	847
	\$ 4,039	\$ 3,272

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#### NOTE 5. CONVERTIBLE PROMISSORY NOTES

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In March 2019, the Company initiated a convertible promissory notes offering pursuant to which the Company issued unsecured convertible promissory notes (the "Prom Notes"), bearing interest at 12.00% and maturing in one year and can be converted into shares of Series C-1 redeemable convertible preferred stock or the most senior preferred equity outstanding at the time of conversion at the option of the holder at a conversion price of \$10.72 per share. In addition, the Prom Notes will automatically convert if a qualified financing of at least \$15.0 million occurs before maturity and such mandatory conversion price will equal 80% of the effective price per share paid in the qualified financing, but not to exceed \$13.40 per share. As of June 30, 2019, the Company had raised an aggregate principal amount of \$5.1 million in Prom Notes.

The Prom Notes also provide for the issuance of warrants at 50% coverage, to acquire a minimum of 239,131 shares of common stock. The warrants are exercisable for a term of five years at an exercise price of \$14.74 or 10% premium to the effective price per share paid in the qualified financing. The Company evaluated the various financial instruments under ASC 480 and ASC 815 and determined the warrants required fair value accounting. The fair value of the warrants was recorded as a warrant liability upon issuance. The fair value of the warrants on the date of issuance of \$1.0 million was determined by a third-party valuation firm. The fair value of the warrants was recorded as a debt discount upon issuance and will be amortized to interest expense over the term of the Prom Notes based on the effective interest method.

The Company analyzed the conversion feature of the agreement for derivative accounting consideration under ASC 815 and determined that the embedded conversion features should be classified as a derivative because the exercise price of the Prom Notes are subject to a variable conversion rate. The Company has determined that the variable conversion feature is a redemption feature that is not clearly and closely related to the Prom Notes and is therefore required to be bifurcated. In accordance with AC 815, the Company has bifurcated the conversion feature of the Prom Notes and recorded a derivative liability.

The embedded derivative for the Prom Notes is carried on the Company's balance sheet at fair value. The derivative liability is marked-to-market each measurement period and any change in fair value is recorded as a component of the statements of operations. The fair value of the derivative liability on the date of issuance of \$1.0 million was determined by a third-party valuation firm. The fair

value of the conversion feature was recorded as a debt discount upon issuance and will be amortized to interest expense over the term of the Prom Notes based on the effective interest method.

The Company then evaluated the conversion option to discern whether a beneficial conversion feature existed based upon comparing the effective exercise price of the convertible notes to the fair value of the shares they are convertible into. The Company concluded no beneficial conversion feature existed. During the three and six months ended June 30, 2019 recognized \$0.5 million of interest expense, including \$0.4 million of accretion of discounts using an effective interest rate of 12.00%.

As of June 30, 2019, there were unaccreted debt discounts of \$1.6 million, which were recorded as a direct deduction from convertible promissory notes on the accompanying balance sheets.

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## **NOTE 6. NOTE PAYABLE**

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### *Note Payable*

On February 18, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. (the "Lender") under which the Company borrowed \$7.5 million upon the execution of the Loan Agreement on February 18, 2016. The interest rate applicable to each tranche is variable based upon the greater of either (i) 9.2% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal minus 3.5%, plus (b) 9.2%; notwithstanding the above, such rate shall not exceed the permissible rates of interest on commercial loans under the laws of the State of California. Payments under the Loan Agreement were interest only until June 1, 2017, followed by equal monthly payments of principal and interest through the scheduled maturity date on September 1, 2019.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of the Company's assets, other than its intellectual property. The Company also has agreed not to pledge or otherwise encumber its intellectual property assets, except that the Company may grant non-exclusive licenses of intellectual property entered into in the ordinary course of business, and licenses approved by the Company's Board of Directors that may be exclusive in respects other than territory and may be exclusive as to territory as to discrete geographical areas outside of the United States.

The Company has paid the Lender a facility fee of \$150,000 in connection with the Loan Agreement. In addition, if the Company repays all or a portion of the loan prior to maturity, it will pay the Lender a prepayment penalty fee, based on a percentage of the then outstanding principal balance, equal to 3% if the prepayment occurs prior to February 19, 2017, 2% if the prepayment occurs prior to February 19, 2018, or 1% if the prepayment occurs thereafter. In addition, the Company is required to make an end of term payment of 4.5% of the sum of (i) term loan advances, plus (ii) 50% of the aggregate unfunded term loan commitments.

The Loan Agreement was amended in December 2017 (as further amended, "Loan Agreement") to provide for an additional three-month interest only period ending on March 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, the end of term payment was increased by \$30,500.

The Loan Agreement was further amended in March 2018 to provide for an additional two-month interest only period ending on June 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, a facility fee of \$25,000 was paid upon execution and the end of term payment was increased by \$25,000.

The Loan Agreement was again amended in July 2018 to provide for an additional three-month interest only period ending on October 1, 2018, at which time the outstanding loan balance would continue to be paid in equal monthly installments of principal and interest. Pursuant to the Loan Agreement, a facility fee of \$25,000 was paid upon execution and the end of term payment was increased by \$25,000.

The Loan Agreement includes customary affirmative and restrictive covenants, and also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default and following any applicable cure periods, a default interest rate of an additional 4% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

Under the Loan Agreement, the Company grants the Lender the right to participate in and/or designate one or more of its affiliates to participate in any subsequent financing in an amount up to \$1.0 million on the same terms, conditions and pricing afforded to other participating in such subsequent financing.

Note payable at June 30, 2019 consisted of the following (in thousands):

Face value of note payable	\$ 7,500
Accrued interest	30
Discounts on note payable related to warrants	(329)
Note payable issuance costs	(1,061)
	6,140
Principal payments through June 30, 2019	(4,300)
Accumulated accretion	1,344
Note payable	<u>\$ 3,184</u>

The following is a schedule of aggregate note payable maturities, excluding the unamortized amount related to the end of term payment, for each of the years subsequent to June 30, 2019 (in thousands):

<b>Year Ending December 31,</b>	
2019	<u>\$ 3,199</u>
	<u>\$ 3,199</u>

In connection with the Loan Agreement, the Company issued warrants to the Lender, which are exercisable for 26,087 shares of Series C redeemable convertible preferred stock at a per share exercise price of \$11.50 (the "Warrants"). The Warrants will terminate, if not earlier exercised, on February 18, 2026. The fair value of the warrants was recorded as a redeemable convertible preferred stock warrant liability upon issuance. The fair value of the warrants on the date of issuance of \$0.3 million was determined using the Black-Scholes option-pricing model. The fair value of the warrants was recorded as a debt discount upon issuance and will be amortized to interest expense over the term of the loan based on the effective interest method.

As of June 30, 2019, there were unaccrued debt discounts and issuance costs of \$0.1 million, which were recorded as a direct deduction from note payable on the accompanying balance sheets.

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## **NOTE 7. COMMITMENTS AND CONTINGENCIES**

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### ***Operating Leases***

In August 2016, the Company entered into a five-year lease for office space in Boulder, Colorado that expires on October 31, 2021 (the "Boulder Lease") subject to the Company's option to renew the Boulder Lease for two additional terms of three years each. Pursuant to the Boulder Lease, the Company leased 3,038 square feet of space in a multi-suite building. Rent payments under the Boulder Lease included base rent of \$4,430 per month during the first year of the Boulder Lease with an annual increase of 3.5%, and additional monthly fees to cover the Company's share of certain facility expenses, including utilities, property taxes, insurance and maintenance, which were \$2,160 per month during the first year of the Boulder Lease.

The Company recognized a right-of-use asset and corresponding lease liability on January 1, 2019, by calculating the present value of lease payments, discounted at 12.0%, the Company's estimated incremental borrowing rate, over the 2.8 years expected remaining term. As the Company's lease does not provide an implicit rate, the Company estimated the incremental borrowing rate based on industry peers. Industry peers consist of several public companies in the biotechnology industry with comparable characteristics, including clinical trials progress and therapeutic indications. Amortization of the operating lease right-of-use asset for the Boulder Lease amounted to \$17,000 and \$33,000 for the three and six months ended June 30, 2019, respectively, and was included in operating expense. As of June 30, 2019, the remaining lease term was 2.3 years.

The terms of the Boulder Lease provide for rental payments on a monthly basis on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period. Lease expense for the three and six months ended June 30, 2019 and 2018 was \$0.1 million.

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**NOTE 8. REDEEMABLE CONVERTIBLE PREFERRED STOCK**

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As of June 30, 2019 and December 31, 2018, the Company had authorized 4,446,228 and 4,182,943 shares of redeemable convertible preferred stock, par value of \$0.0001, of which 1,162,505 are designated Series A redeemable convertible preferred stock ("Preferred Stock A"), 882,216 are designated Series B redeemable convertible preferred stock ("Preferred Stock B"), 869,565 are designated Series C redeemable convertible preferred stock ("Preferred Stock C") and 1,531,942 are designated Series C-1 redeemable convertible preferred stock ("Preferred Stock C-1")

In connection with the issuance of the Preferred Stock A, B, C and C-1 (the "Preferred Stock"), the Company incurred approximately \$0.5 million of issuance costs. The unaccrued discount as of June 30, 2019 and December 31, 2018 amounted to approximately \$0.1 million.

Redeemable convertible preferred stock consisted of the following (in thousands, except share data):

June 30, 2019							
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion	
Series A	1,162,505	1,162,505	\$ 1,163	\$ 12,160	\$ 12,164	1,162,505	
Series B	882,216	828,998	829	10,080	10,084	828,998	
Series C	869,565	743,326	743	11,616	11,630	743,326	
Series C-1	1,531,942	905,076	905	14,078	14,139	905,076	
	<u>4,446,228</u>	<u>3,639,905</u>	<u>\$ 3,640</u>	<u>\$ 47,934</u>	<u>\$ 48,017</u>	<u>3,639,905</u>	

  

December 31, 2018							
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion	
Series A	1,162,505	1,162,505	\$ 1,163	\$ 16,098	\$ 11,898	1,162,505	
Series B	882,216	828,998	829	13,011	9,803	828,998	
Series C	869,565	743,326	743	13,018	11,418	743,326	
Series C-1	1,268,657	905,076	905	16,163	13,866	905,076	
	<u>4,182,943</u>	<u>3,639,905</u>	<u>\$ 3,640</u>	<u>\$ 58,290</u>	<u>\$ 46,985</u>	<u>3,639,905</u>	

The rights, preferences and privileges of the Preferred Stock are as follows:

**Dividends**

The Company recognizes certain dividend rights for the holders of the Preferred Stock, in that these holders will receive preference to any declaration or payment of dividends at the rate of 8% of the original issue price of \$5.3333 of Preferred Stock A, \$8.14 of Preferred Stock B, \$11.50 of Preferred Stock C, and \$13.40 of Preferred Stock C-1 per share per annum, compounded annually, on each outstanding share. Holders of Preferred Stock A, B, C and C-1 rank pari passu with respect to the payment of accrued dividends.

In May 2019, the Company amended dividend rights that have accrued through May 31, 2019 whereby the accrued dividends payable to the holders of the Company's outstanding preferred stock will settle with shares of the Company's common stock in lieu of cash. Dividends will not continue to accrue after May 31, 2019.

Accrued dividends at June 30, 2019 amounted to \$6.0 million (\$5.13 per share), \$3.3 million (\$4.02 per share), \$3.1 million (\$4.15 per share), and \$2.0 million (\$2.22 per share) on Preferred Stock A, B, C and C-1, respectively. Accrued dividends at December 31, 2018 amounted to \$5.7 million (\$4.90 per share), \$3.1 million (\$3.68 per share), \$2.9 million (\$3.86 per share), and \$1.7 million (\$1.92 per share) on Preferred Stock A, B, C and C-1, respectively. Accrued dividends are included as a component of redeemable convertible preferred stock in the accompanying balance sheets.

### **Liquidation Preference**

Preferred Stock carries certain liquidation rights upon the liquidation, dissolution, or winding up of the Company, whether voluntary or involuntary (including a change in control), whereas before any distribution or payment shall be made to the holders of any common stock, the holders of the Preferred Stock shall be entitled to be paid an amount equal to the original purchase price plus any accrued but unpaid dividends out of the assets of the Company legally available for distribution for each share. If the assets of the Company available for distribution upon liquidation are not sufficient to pay the preferred stock preference amount, the assets will be distributed ratably among the holders of the Preferred Stock in proportion to the full amount of the preference amount such holder is otherwise entitled to receive.

Any proceeds remaining after the distribution of the preference amount shall be distributed pro rata to the holders of the Preferred Stock (on as-if-converted to Common Stock basis) and the holders of Common Stock.

### **Conversion**

Preferred Stock may be converted into common stock at the initial conversion ratio of 1:1, which ratio shall be altered in accordance with stock dividends, splits, combinations and other similar events, including the sale of additional shares of common or preferred stock at an effective price per common share lower than the conversion price then in effect. Each share of the Preferred Stock will automatically convert into shares of common stock, at the applicable conversion ratio of each series of redeemable convertible preferred stock then in effect, upon (i) a qualified public offering with net proceeds of not less than \$30 million and a price of not less than \$57.50 per share, subject to appropriate adjustment for any stock dividend, stock split, combination or other similar recapitalization, or (ii) the date specified by written consent or agreement of the holders of at least two-thirds of the then outstanding shares of Preferred Stock voting together as a single class on an as-if-converted to Common Stock basis.

### **Redemption**

At any time after July 16, 2021, the holders of the Company's Preferred Stock will have the right to require the Company to redeem all or a portion of their shares for cash at a redemption price equal to the greater of: (i) the purchase price of such shares plus all accrued and unpaid dividends thereon, or the (ii) fair market value of the shares.

### **Voting Rights**

The holders of Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Holders of Preferred Stock have the right to vote the number of shares equal to the number of shares of common stock into which such Preferred Stock could convert on the record date for determination of stockholders entitled to vote. The holders of the majority of Preferred Stock, voting separately as a single class, are entitled to elect two directors of the Company.

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## **NOTE 9. STOCK-BASED COMPENSATION**

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Total stock-based compensation expense related to stock options granted under the 2009 Plan was allocated as follows:

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Research and development	\$ 78	\$ 93	\$ 156	\$ 187
General and administrative	221	82	527	178
Total stock-based compensation expense	<u>\$ 299</u>	<u>\$ 175</u>	<u>\$ 683</u>	<u>\$ 365</u>

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## **NOTE 10. STOCKHOLDERS' DEFICIT**

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### **Common Stock**

As of June 30, 2019, the Company had authorized 10,000,000 shares of common stock, par value \$0.0001 per share.

The Company has reserved authorized shares of common stock, on an as-converted basis, for future issuance at June 30, 2019 as follows:

	<u>2019</u>
Conversion of Preferred Stock A	1,162,505
Conversion of Preferred Stock B	828,998
Conversion of Preferred Stock C	743,326
Conversion of Preferred Stock C-1	905,076
Preferred Stock C warrants issued with note payable	26,087
Conversion of convertible promissory notes	489,065
Common stock warrants	399,496
Common stock options outstanding	1,811,800
Options available for grant under the 2009 Plan	2,607,274
	<u>8,973,627</u>

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**NOTE 11. SUBSEQUENT EVENTS**

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***Bridge Financing—Convertible Promissory Notes with Warrants***

In July 2019, the Company issued additional Prom Notes under substantially similar terms and related common warrants for gross proceeds of \$775,000.

***Evaluation Date***

The Company has evaluated events that have occurred after the balance sheet date through July 12, 2019, which is when these financial statements were issued.

**UNAUDITED PRO FORMA COMBINED FINANCIAL STATEMENTS**

On August 31, 2019, the Delaware corporation formerly known as “Vical Incorporated” completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of June 2, 2019, as amended by Amendment No. 1 to Agreement and Plan of Merger and Reorganization, dated August 20, 2019, and as further amended on August 30, 2019 (the “Merger Agreement”), by and among Vical Incorporated (“Vical”), Brickell Biotech, Inc. (“Brickell”) and Victory Subsidiary, Inc., a wholly-owned subsidiary of Vical (“Merger Sub”), pursuant to which Merger Sub merged with and into Brickell, with Brickell surviving the merger as a wholly-owned subsidiary of Vical (the “Merger”).

The unaudited pro forma combined financial statements were prepared in accordance with the regulations of the Securities and Exchange Commission (“SEC”). The following unaudited pro forma combined financial statements give effect to the Merger. The transaction is accounted for as a reverse recapitalization under existing U.S. generally accepted accounting principles, which is subject to change and interpretation. Accordingly, for accounting purposes, the Merger is treated as the equivalent of Brickell issuing shares of common stock for the net assets, primarily cash and investments, accompanied by a recapitalization. The net assets of Vical are recognized at fair value (which is consistent with carrying value), with no goodwill or intangible assets recorded. The unaudited pro forma combined financial statements presented below are based upon the historical financial statements of Brickell and Vical, adjusted to give effect to the reverse recapitalization, for accounting purposes. The pro forma adjustments are described in the accompanying notes presented on the following pages.

The unaudited pro forma combined balance sheet as of June 30, 2019, and the unaudited pro forma combined statement of operations and comprehensive loss for the six months June 30, 2019 and the year ended December 31, 2018 presented herein are based on the historical financial statements of Brickell and Vical, adjusted to give effect to the reverse recapitalization. The pro forma assumptions and adjustments are described in the accompanying notes presented in the following pages.

Brickell has been determined to be the accounting acquirer based on an evaluation of the facts of the Merger. Brickell securityholders and NovaQuest Co-Investment Fund X, L.P. (“NovaQuest”), collectively, hold a majority of the outstanding shares of Vical common stock and the Brickell directors and management hold a majority of board seats and all key positions in the management of the combined company. Other factors were considered, including the purpose and intent of the Merger, composition of the post-merger stockholders and the location of the Company’s headquarters noting that the preponderance of the evidence is indicative that Brickell is the accounting acquirer.

The stockholders’ equity of Brickell has been restated to give effect to the exchange of shares in the Merger and the historical results of operations of Brickell are reflected as the results of operations of the combined company.

The Brickell balance sheet as of June 30, 2019 and statement of operations for the six months ended June 30, 2019 were derived from its unaudited financial statements. The statement of operations and comprehensive loss for year ended December 31, 2018 were derived from its audited financial statements.

The Vical balance sheet as of June 30, 2019 and statement of operations for the six months ended June 30, 2019 were derived from its unaudited financial statements. The statement of operations and comprehensive loss for year ended December 31, 2018 were derived from its audited consolidated financial statements.

The historical financial statements have been adjusted to give pro forma effect to events that are (i) directly attributable to the Merger, (ii) factually supportable, and (iii) with respect to the statement of operations, expected to have a continuing impact on the combined results. These adjustments include the issuance of shares of common stock in the Merger resulting from the issuance of securities by Brickell prior to the closing of the Merger. Differences between these preliminary estimates and the final accounting will occur and could have a material impact on the accompanying unaudited pro forma combined financial statements and the combined company’s future results of operations and financial position. The actual amounts recorded as of the completion of the Merger may differ materially from the information presented in these unaudited pro forma combined financial statements as a result of the timing of completion of the Merger, changes to the final exchange ratio used as part of the Merger, issuances of common stock, convertible notes,

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warrants or options to purchase common stock and other changes in the Vical or Brickell net assets that occur prior to the completion of the Merger, which could cause material differences in the information presented below.

The unaudited pro forma combined financial statements do not give effect to the potential impact of current financial conditions, regulatory matters, operating efficiencies or other savings or expenses that may be associated with the Merger. The unaudited pro forma combined financial data also do not include any integration costs. The unaudited pro forma combined financial statements have been prepared for illustrative purposes only and are not necessarily indicative of the financial position or results of operations in future periods or the results that actually would have been realized had Brickell and Vical been a combined company during the specified period. The unaudited pro forma combined financial statements, including the notes thereto, should be read in conjunction with the Brickell historical audited financial statements for the year ended December 31, 2018 and in conjunction with the Vical historical audited consolidated financial statements.

The unaudited pro forma combined financial statements also do not give effect to the commitment by NovaQuest to provide up to \$25.0 million in near-term research and development funding to the combined company.

**Unaudited Pro Forma Combined Balance Sheet**  
**As of June 30, 2019**

	Historical Vical, Inc.	Historical Brickell Biotech, Inc.	Pro forma Merger Adjustments	Note	Pro Forma Combined
<b>Assets</b>					
<b>Current assets</b>					
Cash, cash equivalents and marketable securities	\$ 41,720,000	\$ 2,079,000	\$ (2,605,000)	A1	\$ 41,194,000
Receivables and other current assets	979,000	362,000	—		1,341,000
Total current assets	42,699,000	2,441,000	(2,605,000)		42,535,000
Property and equipment, net	2,000	20,000	—		22,000
Operating lease right of use asset	—	186,000	—		186,000
Other assets	—	441,000	—		441,000
Total assets	<u>\$ 42,701,000</u>	<u>\$ 3,088,000</u>	<u>\$ (2,605,000)</u>		<u>\$ 43,184,000</u>
<b>Liabilities and stockholders' equity (deficit)</b>					
<b>Current liabilities:</b>					
Accounts payable and accrued liabilities	\$ 1,159,000	\$ 11,159,000	\$ 2,610,000	A3	\$ 14,928,000
Lease liability	—	67,000	—		67,000
Deferred revenue	—	3,040,000	—		3,040,000
Convertible promissory notes	—	3,598,000	(3,598,000)	A4	—
Derivative liability	—	1,007,000	(1,007,000)	A4	—
Current portion of notes payable	—	3,184,000	—		3,184,000
Total current liabilities	1,159,000	22,055,000	(1,995,000)		21,219,000
Contingent consideration	—	145,000	—		145,000
Warrant liability	—	1,048,000	(1,048,000)	A6	—
Lease liability, net of current portion	—	111,000	—		111,000
Deferred revenue, net of current portion	—	608,000	—		608,000
Total liabilities	1,159,000	23,967,000	(3,043,000)		22,083,000
Preferred Stock	—	47,934,000	(47,934,000)	A5	—
Stockholders equity (deficit)					
Common Stock	229,000	—	317,000	A5	547,000
			1,000	A4	
Additional paid-in capital	490,343,000	520,000	(453,156,000)	A2	90,747,000
			1,048,000	A6	
			4,604,000	A4	
			47,388,000	A5	
Accumulated deficit	(449,072,000)	(69,333,000)	453,427,000	A2	(70,193,000)
			(2,605,000)	A1	
			(2,610,000)	A3	
Accumulated other comprehensive income				A2	
	42,000	—	(42,000)		—
Total stockholders' equity (deficit)	41,542,000	(68,813,000)	438,000		21,101,000
Total liabilities and stockholders' equity (deficit)	<u>\$ 42,701,000</u>	<u>\$ 3,088,000</u>	<u>\$ (2,605,000)</u>		<u>\$ 43,184,000</u>

**Unaudited Pro Forma Combined Statement of Operations and Comprehensive Loss  
For the Year Ended December 31, 2018**

	Historical Vical, Inc.	Historical Brickell Biotech, Inc.	Pro forma Merger Adjustments	Note	Pro Forma Combined
<b>Revenues:</b>					
Collaboration Revenue	\$ —	\$ 10,888,000	\$ —		\$ 10,888,000
Contract revenue	1,582,000	—	—		1,582,000
License and royalty revenue	40,000	—	—		40,000
Total Revenues	<u>1,622,000</u>	<u>10,888,000</u>	<u>—</u>		<u>12,510,000</u>
<b>Operating expenses:</b>					
Research and development	12,327,000	12,960,000	—		25,287,000
Manufacturing and production	1,436,000	—	—		1,436,000
General and Administrative	7,505,000	6,379,000	—		13,884,000
Total operating expenses	<u>21,268,000</u>	<u>19,339,000</u>	<u>—</u>		<u>40,607,000</u>
Loss from operations	(19,646,000)	(8,451,000)	—		(28,097,000)
Net investment and other income	3,392,000	61,000	—		3,453,000
Interest expense	—	(1,090,000)	—		(1,090,000)
Change in fair value of warrant liability	—	244,000	(244,000)	A6	—
Net loss	<u>\$ (16,254,000)</u>	<u>\$ (9,236,000)</u>	<u>\$ (244,000)</u>		<u>\$ (25,734,000)</u>
(Accretion)reduction of redeemable convertible preferred stock to redemption value	—	(5,936,000)	5,936,000	A5	—
Net loss attributable to common shareholders	<u>\$ (16,254,000)</u>	<u>\$ (15,172,000)</u>	<u>\$ 5,692,000</u>		<u>\$ (25,734,000)</u>
Net income(loss) per share, basic	<u>\$ (0.74)</u>	<u>\$ (8.92)</u>			<u>\$ (0.47)</u>
Net income(loss) per share, diluted	<u>\$ (0.74)</u>	<u>\$ (8.92)</u>			<u>\$ (0.47)</u>
Weighted average shares used to compute basic net income(loss) per share	21,842,000	1,700,000	31,135,000		54,677,000
Weighted average shares used to compute diluted net income(loss) per share	21,842,000	1,700,000	31,135,000		54,677,000

**Unaudited Pro Forma Combined Statement of Operations and Comprehensive Loss**  
**For the Six Months Ended June 30, 2019**

	Historical Vical, Inc.	Historical Brickell Biotech, Inc.	Pro forma Merger Adjustments	Note	Pro Forma Combined
<b>Revenues:</b>					
Collaboration Revenue	\$ —	\$ 6,065,000	\$ —		\$ 6,065,000
Contract revenue	—	—	—		—
License and royalty revenue	—	—	—		—
Total Revenues	—	6,065,000	—		6,065,000
<b>Operating expenses:</b>					
Research and development	4,641,000	10,248,000	—		14,889,000
General and Administrative	3,618,000	3,389,000	(955,000)	A7	6,052,000
Total operating expenses	8,259,000	13,637,000	(955,000)		20,941,000
Loss from operations	(8,259,000)	(7,572,000)	955,000		(14,876,000)
Net investment and other income	1,251,000	10,000	—		1,261,000
Interest expense	—	(884,000)	497,000	A4	(387,000)
Change in fair value of derivative liability	—	(11,000)	11,000	A4	—
Change in fair value of warrant liability	—	223,000	(223,000)	A6	—
Net loss	\$ (7,008,000)	\$ (8,234,000)	\$ 1,240,000		\$ (14,002,000)
Reduction of redeemable convertible preferred stock to redemption value	—	10,356,000	(10,356,000)	A5	—
Net income (loss) to common shareholders	\$ (7,008,000)	\$ 2,122,000	\$ (9,116,000)		\$ (14,002,000)
Net income(loss) per share, basic	\$ (0.31)	\$ 1.24			\$ (0.26)
Net loss per share, diluted	\$ (0.31)	\$ (1.54)			\$ (0.26)
Weighted average shares used to compute basic net income(loss) per share	22,404,000	1,706,000	30,567,000		54,677,000
Weighted average shares used to compute basic net loss per share	22,404,000	5,346,000	26,927,000		54,677,000

## NOTES TO UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

### 1. Description of Transaction and Basis of Presentation

#### *Description of Transaction*

On June 2, 2019, Brickell entered into the Merger Agreement with Vical and Merger Sub and on August 20, 2019 the parties entered into the Merger Agreement Amendment. Pursuant to the terms and subject to the conditions set forth in the Merger Agreement, Merger Sub merged with and into Brickell, with Brickell surviving as a wholly owned subsidiary of Vical.

At the effective time of the Merger, each outstanding share of the capital stock of Brickell was converted into the right to receive a number of shares of Vical common stock as determined pursuant to the Exchange Ratio described in the Merger Agreement, and all outstanding options, warrants or other rights to purchase shares of capital stock of Brickell, were exchanged for rights to acquire Vical common stock based on the Exchange Ratio described in the Merger Agreement. No fractional shares of Vical common stock were issued in connection with the Merger, and holders of Brickell capital stock were entitled to receive cash for any fractional share ownership in lieu of stock thereof.

Upon completion of the Merger, Brickell securityholders and NovaQuest, collectively, hold a majority of the outstanding shares of Vical common stock.

#### *Basis of Presentation*

Based on the terms of the Merger, the transaction is treated as a reverse recapitalization of Brickell in accordance with accounting principles generally accepted in the United States.

The unaudited pro forma combined balance sheet as of June 30, 2019 combines the historical balance sheets of Brickell and Vical as of June 30, 2019 as if the Merger had been completed on that date.

The unaudited pro forma combined statement of operations and comprehensive loss for the year ended December 31, 2018 combine the historical statements of operations and comprehensive loss of Brickell and Vical for their respective periods and give pro forma effect to the Merger as if it had been completed on January 1, 2018.

The unaudited pro forma combined statement of operations and comprehensive loss for the six months ended June 30, 2019 combine the historical statements of operations and comprehensive loss of Brickell and Vical for their respective periods and give pro forma effect to the Merger as if it had been completed on January 1, 2018.

The unaudited pro forma combined financial statements give effect to an exchange ratio of 2.4165 of Vical common stock for each share of Brickell common stock. The exchange ratio does not give any effect to the Vical reverse common stock split. The Exchange Ratio, calculated pursuant to the formula set forth in the Merger Agreement, allocated to the former Brickell securityholders and NovaQuest, collectively, a majority of the outstanding shares of Vical common stock.

### 2. Pro Forma Combined Earnings Per Share

The pro forma combined weighted average share outstanding included in the calculation of basic and diluted pro forma combined earnings (loss) per share consists of the following:

	<b>Year ended December 31, 2018</b>
Historical Vical weighted average shares	21,842,000
Shares issued to Brickell	32,835,000
Pro forma weighted common shares, basic and diluted	54,677,000

  

	<b>Six months ended June 30, 2019</b>
Historical Vical weighted average shares	22,404,000
Shares issued to Brickell	32,273,000
Pro forma weighted common shares, basic and diluted	54,677,000

### 3. Pro Forma Adjustments

The unaudited pro forma combined financial statements include pro forma adjustments to give effect to certain significant transactions as a direct result of the proposed Merger and reverse recapitalization for accounting purposes.

The pro forma adjustments reflecting the completion of the Merger are based upon the preliminary accounting analysis conclusion that the Merger should be accounted for as a reverse recapitalization and upon the assumptions set forth below.

The unaudited pro forma combined financial statements do not give effect to a Reverse Split.

The pro forma adjustments are as follows:

- A1: To reflect vendor payments for strategic advisor, legal, accounting and other direct costs of Vical and Brickell related to the Merger, which are not recognized in the respective balance sheets as of June 30, 2019.
- A2: To reflect the elimination of Vical's historical stockholders' equity balances, including accumulated deficit.
- A3: To reflect accrual for Vical's executive severance costs directly related to the Merger, which are not recognized in Vical's balance sheets as of June 30, 2019.
- A4: To reflect the conversion of the Brickell convertible notes into common stock prior to the close of Merger and prior to the exchange of shares.
- A5: To reflect the exchange of shares of Brickell common and convertible preferred stock outstanding, immediately prior to the closing of the Merger for shares of Vical common stock upon closing of the Merger.
- A6: To reclassify Brickell's warrant liability to equity upon the conversion of preferred stock to common stock upon the close of the Merger as the warrants are no longer expected to be required to be reflected as a liability upon becoming warrants to purchase common stock at a fixed exercise price.
- A7: To eliminate Merger cost incurred in the statement of operations, which are non-recurring.