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

FORM S-1
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

BRICKELL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

2836
(Primary Standard Industrial
Classification Code Number)

93-0948554
(I.R.S. Employer
Identification No.)

**5777 Central Avenue
Suite 102
Boulder, CO 80301
(720) 505-4755**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Robert B. Brown
Chief Executive Officer
5777 Central Avenue
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Boulder, CO 80301
(720) 505-4755**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Please send copies of all communications to:

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**Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering:

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer
 Non-accelerated filer

Accelerated filer
 Smaller reporting company
 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 7(a)(2)(B) of the Securities Act.

CALCULATION OF REGISTRATION FEE

Title of each class of Securities to be Registered	Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee
Common stock, par value \$0.01 per share ⁽²⁾⁽³⁾⁽⁴⁾	\$ 17,500,000	
Pre-funded warrants to purchase shares of common stock and common stock issuable upon exercise thereof ⁽²⁾⁽³⁾⁽⁴⁾	17,500,000	
Warrants to purchase common stock and shares of common stock issuance upon exercise thereof ⁽²⁾⁽³⁾		
Total	\$ 17,500,000	\$ 2,272

- (1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended (the “**Securities Act**”).
- (2) Includes the offering price of the shares of common stock (or, if applicable, pre-funded warrants).
- (3) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional securities as may be issuable to prevent dilution resulting from stock splits, dividends or similar transactions.
- (4) The proposed maximum aggregate offering price of the common stock proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the aggregate offering price of the pre-funded warrants offered and sold in the offering (plus the aggregate exercise price of the common stock issuable upon exercise of the pre-funded warrants), and as such the proposed aggregate maximum offering price of the common stock and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is \$17,500,000.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 15, 2020

PROSPECTUS



Shares of Common Stock
Pre-Funded Warrants to Purchase Shares of Common Stock
Warrants to Purchase up to Shares of Common Stock

We are offering shares of our common stock and common warrants to purchase an aggregate of _____ shares of our common stock (and the shares of common stock that are issuable from time to time upon exercise of the warrants). We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded warrants, in lieu of shares of common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant and accompanying common warrant will be equal to the price at which a share of common stock and accompanying common warrant are sold to the public in this offering, minus \$0.001, and the exercise price of each pre-funded warrant will be \$0.001 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. Each share of common stock and pre-funded warrant is being sold together with a common warrant to purchase share of our common stock, at an exercise price of \$ per share. The common warrants will be exercisable immediately and will expire five years from the date of issuance. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant for each share of our common stock and for each pre-funded warrant to purchase share of our common stock sold in this offering, the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold. The shares of common stock and pre-funded warrants, and the accompanying common warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance.

Our common stock is listed on The Nasdaq Capital Market under the symbol "BBI." On May , 2020, the last reported sale price of our common stock on The Nasdaq Capital Market was \$ per share.

The public offering price per share of common stock and accompanying common warrant and any pre-funded warrant and accompanying common warrant, as the case may be, will be determined by us at the time of pricing, may be at a discount to the current market price, and the recent market price used throughout this prospectus may

not be indicative of the final offering price. There is no established public trading market for the pre-funded warrants or common warrants, and we do not expect a market to develop. In addition, we do not intend to apply for a listing of the pre-funded warrants or common warrants on any national securities exchange.

You should read this prospectus, together with additional information described under the headings “Information Incorporated by Reference” and “Where You Can Find More Information,” carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See the section entitled “Risk Factors” beginning on page 8 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

	Per Share	Per Pre-Funded Warrant	Per Common Warrant	Total
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

(1) See “Underwriting” for additional information regarding underwriting compensation.

The delivery of the shares of common stock and any pre-funded warrants and common warrants to purchasers is expected to be made on or about , 2020.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Oppenheimer & Co.

The date of this prospectus is , 2020.

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ABOUT THIS PROSPECTUS

We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under “Where You Can Find More Information.” You should carefully read this prospectus as well as additional information described under “Information Incorporated by Reference,” before deciding to invest in our securities.

Neither we nor the underwriter have authorized anyone to provide you with additional information or information different from that contained or incorporated by reference in this prospectus filed with the Securities and Exchange Commission (the “SEC”). We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The underwriter is offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The information contained in this prospectus, or any document incorporated by reference in this prospectus, is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

The information incorporated by reference or provided in this prospectus contains statistical data and estimates, including those relating to market size and competitive position of the markets in which we participate, that we obtained from our own internal estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable. While we believe our internal company research is reliable and the definitions of our market and industry are appropriate, neither this research nor these definitions have been verified by any independent source.

For investors outside the United States: We and the underwriter have not done anything that would permit this offering or the possession or distribution of this prospectus in any jurisdiction where action for those purposes is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside of the United States.

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this prospectus other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, liquidity, future revenue, projected expenses, results of operations, expectations concerning the timing and our ability to commence and subsequently report data from planned non-clinical studies and clinical trials, prospects, plans and objectives of management are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “plan,” “expect,” “predict,” “potential,” “opportunity,” “goals,” or “should,” and similar expressions are intended to identify forward-looking statements. Such statements are based on management’s current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in “Risk Factors” in this prospectus, and under a similar heading in any other annual, periodic or current report incorporated by reference into this prospectus or that we may file with the SEC in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this prospectus, may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

You should also read carefully the factors described in the “Risk Factors” section of this prospectus, and under a similar heading in any other annual, periodic or current report incorporated by reference into this prospectus, to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised to consult any further disclosures we make on related subjects in our future public filings.

PROSPECTUS SUMMARY

This summary highlights information about our company, this offering and information contained in other parts of this prospectus or incorporated by reference into this prospectus from our filings with the SEC listed in the section entitled “Information Incorporated by Reference.” Because it is only a summary, it does not contain all of the information that you should consider before purchasing our securities in this offering and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere or incorporated by reference into this prospectus. You should read the entire prospectus, the registration statement of which this prospectus is a part, and the information incorporated by reference into this prospectus in their entirety, including the “Risk Factors” and our financial statements and the related notes incorporated by reference into this prospectus, before purchasing our securities in this offering.

Except as otherwise indicated herein or as the context otherwise requires, references in this prospectus to “Brickell,” “the Company,” “we,” “us” and “our” refer to Brickell Biotech, Inc. and our consolidated subsidiaries.

Company Overview

We are a clinical-stage pharmaceutical company focused on the development of innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. Our pipeline consists of potential novel therapeutics for hyperhidrosis and other prevalent dermatological conditions. Our 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 biotech companies that have developed and/or launched successful products, including several that were first-in-class and/or achieved iconic status, such as Cialis[®], Taltz[®], Gemzar[®], Prozac[®], Cymbalta[®] and Juvederm[®].

Our pivotal Phase 3-ready clinical-stage product candidate, sofpironium bromide, is a proprietary new molecular entity. It 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 activation of the sweat glands. Sofpironium bromide was retrometabolically designed. Retrometabolic drugs are designed to exert their action topically and are potentially rapidly metabolized once absorbed into the blood. This proposed mechanism of action may allow for highly effective doses to be used while limiting systemic side effects. We intend to develop sofpironium bromide as a potential best-in-class, self-administered, once-daily, topical therapy for the treatment of primary axillary hyperhidrosis.

Hyperhidrosis is a life-altering condition of sweating beyond what is physiologically required to maintain normal thermal regulation. It is believed to be caused by an overactive cholinergic response of the sweat glands and affects an estimated 15.3 million, or 4.8%, of the U.S. population. According to a 2016 update on the prevalence and severity of hyperhidrosis in the United States by Doolittle et al., axillary (underarm) hyperhidrosis, which is the targeted first potential indication for sofpironium bromide, is the most common occurrence of hyperhidrosis, affecting approximately 65% of patients in the United States or an estimated 10 million individuals.

Corporate Information

Vical Incorporated (“Vical”) was incorporated in Delaware in 1987. On August 31, 2019, Vical, completed a reverse merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated June 2, 2019, as further amended on August 20, 2019 and August 30, 2019, by and among Vical, Brickell Biotech, Inc., a then privately-held Delaware corporation that began activities in September 2009

(“Private Brickell”) and Victory Subsidiary, Inc., a wholly-owned subsidiary of Vical (“Merger Sub”), pursuant to which Merger Sub merged with and into Private Brickell, with Private 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.”

Our corporate headquarters are located in Boulder, Colorado, where we occupy facilities totaling approximately 3,038 square feet under lease agreements that expire in October 2021. We use our current facilities primarily for research and development and general and administrative personnel. Our telephone number is (720) 505-4755, and our website address is www.brickellbio.com. Information contained on our website is not a part of this prospectus, you should not consider information contained on our website in deciding whether to purchase our securities and the inclusion of our website address in this prospectus is an inactive textual reference only.

This prospectus and the information incorporated by reference into this prospectus contain references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus and the information incorporated by reference into this prospectus, including logos, artwork, and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

THE OFFERING

Common Stock to be Offered

shares, based on the sale of our common stock at an assumed combined public offering price of \$ per share of common stock and accompanying common warrant, which is the last reported sale price of our common stock on May , 2020, and no sale of any pre-funded warrants.

Pre-funded Warrants to be Offered

We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded warrants, in lieu of shares of common stock that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant and accompanying common warrant will equal the price at which the share of common stock and accompanying common warrant are being sold to the public in this offering, minus \$0.001, and the exercise price of each pre-funded warrant will be \$0.001 per share. The pre-funded warrants will be exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant for each share of our common stock and for each pre-funded warrant to purchase one share of our common stock sold in this offering, the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold.

Common Warrants to be Offered

Common warrants to purchase an aggregate of shares of our common stock. Each share of our common stock and each pre-funded warrant to purchase one share of our common stock is being sold together with a common warrant to purchase share of our common stock. Each common warrant will have an exercise price of \$ per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The shares of common stock and pre-funded warrants, and the accompanying common warrants, as the case may be, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.

Unless otherwise indicated, this prospectus reflects and assumes no issuances or exercises of any other outstanding options or warrants after March 31, 2020.

RISK FACTORS

Investing in our securities involves a high degree of risk. We urge you to carefully consider all of the information contained in this prospectus and other information which may be incorporated by reference in this prospectus as provided under "Information Incorporated by Reference." In particular, you should consider the risk factors below, together with those under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, which is incorporated by reference into this prospectus, as those risk factors are amended or supplemented by our subsequent filings with the SEC. These risks and uncertainties are not the only risks and uncertainties we face. Additional risks and uncertainties not currently known to us, or that we currently view as immaterial, may also impair our business. If any of the risks or uncertainties described below or in our SEC filings or any additional risks and uncertainties actually occur, our business, financial condition, results of operations and cash flow could be materially and adversely affected. As a result, you could lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS AND REGULATORY MATTERS

Major public health issues, and specifically the pandemic caused by the spread of COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.

The outbreak of the novel Coronavirus (COVID-19) has evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Should the coronavirus continue to spread, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, manufacturing and distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the coronavirus pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance. Infections and deaths related to the pandemic may disrupt the United States' and other countries' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay U.S. Food and Drug Administration (the "FDA") or other regulatory review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently rely on third parties, such as contract laboratories, contract research organizations, medical institutions and clinical investigators to conduct these studies and clinical trials. If these third-party parties themselves are adversely impacted by restrictions resulting from the coronavirus outbreak, we will likely experience delays and/or realize additional costs. As a result, our efforts to obtain regulatory approvals for, and to commercialize, our therapeutic candidates may be delayed or disrupted.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material adverse effect on our business, financial condition and results of operations and cash flows.

RISKS RELATED TO THIS OFFERING

If you purchase shares of common stock in this offering, you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity or equity-linked securities in the future.

Because the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer immediate and substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on an assumed combined public offering price of \$ per share of common stock and accompanying common warrant being sold in this offering, and our net tangible book value as of March 31, 2020, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$ per share with respect to the net tangible book value of the common stock. See the section entitled “Dilution” for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

If we issue additional shares of common stock, or securities convertible into or exchangeable or exercisable for shares of common stock, our stockholders, including investors who purchase shares of common stock and the accompanying warrants in this offering, will experience additional dilution, and any such issuances may result in downward pressure on the price of our common stock. We also cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

Future sales of substantial amounts of our common stock or securities convertible into or exchangeable or exercisable for shares of common stock, or the possibility that such sales could occur, could adversely affect the market price of our common stock.

Future sales in the public market of shares of our common stock or securities convertible into or exchangeable or exercisable for shares of common stock, including shares referred to in the foregoing risk factor or shares issued upon exercise of our outstanding stock options, or the perception by the market that these sales could occur, could lower the market price of our common stock or make it difficult for us to raise additional capital.

There is no public market for the pre-funded warrants or common warrants being offered in this offering.

There is no established public trading market for the pre-funded warrants or common warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or common warrants on any securities exchange or nationally recognized trading system, including The Nasdaq Capital Market. Without an active market, the liquidity of the pre-funded warrants or common warrants will be limited.

Holders of pre-funded warrants or common warrants purchased in this offering will have no rights as common stockholders until such holders exercise such warrants and acquire our common stock.

Until holders of pre-funded warrants or common warrants acquire shares of our common stock upon exercise of such warrants, holders of pre-funded warrants or common warrants will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the pre-funded warrants or common warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

We will have broad discretion in the use of our existing cash and cash equivalents, including the proceeds from this offering, and may invest or spend our cash in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of our cash and cash equivalents, including the proceeds from this offering. You may not agree with our decisions, and our use of cash may not yield any return on your investment. We intend to use the net proceeds from this offering for research and development, including clinical trials, working capital and general corporate purposes. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$ million from the sale of the securities offered by us in this offering, based on an assumed combined public offering price of \$ per share and accompanying common warrant, which was the last reported sales price of our common stock on The Nasdaq Capital Market on May , 2020, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, excluding the proceeds, if any, from the exercise of the common warrants issued in this offering.

A \$0.10 increase or decrease in the assumed combined public offering price of \$ per share and accompanying common warrant would increase or decrease the net proceeds to us from this offering by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Similarly, a 1.0 million share increase or decrease in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the net proceeds to us by approximately \$ million, based on the assumed combined public offering price of \$ per share and accompanying common warrant remaining the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The foregoing discussion assumes no sale of pre-funded warrants, which if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis.

We currently intend to use the net proceeds from this offering for research and development, including clinical trials, working capital and general corporate purposes. See “Risk Factors” for a discussion of certain risks that may affect our intended use of the net proceeds from this offering.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot currently allocate specific percentages of the net proceeds that we may use for the purposes specified above, and we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our preclinical and clinical development programs, and whether we are able to enter into future licensing or collaboration arrangements.

Pending the use of the net proceeds from this offering, we intend to invest the net proceeds in investment-grade, interest-bearing instruments, certificates of deposit or direct or guaranteed obligations of the United States.

DILUTION

If you invest in our securities, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the as adjusted net tangible book value per share of our common stock immediately after the closing of this offering.

Our historical net tangible book value as of March 31, 2020 was \$5.9 million, or \$0.61 per share of common stock. Our historical net tangible book value is the amount of our total tangible assets less our liabilities. Historical net tangible book value per common share is our historical net tangible book value divided by the number of shares of common stock outstanding as of March 31, 2020.

After giving effect to the sale of shares of common stock and the accompanying common warrants in this offering at an assumed combined public offering price of \$ per share and accompanying common warrant, which was the last reported sale price of our common stock on The Nasdaq Capital Market on May , 2020, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the common warrants issued in this offering, our as adjusted net tangible book value as of March 31, 2020 would be \$ million, or \$ per share of common stock. This amount represents an immediate increase in as adjusted net tangible book value of \$ per share to our existing stockholders and an immediate dilution of \$ per share to investors participating in this offering. We determine dilution per share to investors participating in this offering by subtracting as adjusted net tangible book value per share after this offering from the assumed public offering price per share paid by investors participating in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed combined public offering price per share and accompanying common warrant		\$
Historical net tangible book value per share as of March 31, 2020	\$	0.61
Increase in as adjusted net tangible book value per share attributable to this offering		
As adjusted net tangible book value per share after giving effect to this offering		
Dilution per share to new investors in this offering		

Each \$0.10 increase or decrease in the assumed public offering price of \$ per share and accompanying common warrant, which was the last reported sale price of our common stock on The Nasdaq Capital Market on May , 2020, would increase or decrease the as-adjusted net tangible book value per share by \$ per share and the dilution per share to investors participating in this offering by \$ per share, assuming that the number of shares and accompanying common warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the common warrants issued in this offering.

We may also increase or decrease the number of shares we are offering. A 1.0 million share increase in the number of shares and accompanying common warrants offered by us, as set forth on the cover page of this prospectus, would increase the as adjusted net tangible book value per share by approximately \$ and decrease the dilution per share to new investors participating in this offering by approximately \$, based on an assumed combined public offering price of \$ per share and accompanying common warrant, which was the last reported sale price of our common stock on The Nasdaq Capital Market on May , 2020, remaining the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the common warrants issued in this offering. A 1.0 million share decrease

in the number of shares and accompanying common warrants offered by us, as set forth on the cover page of this prospectus, would decrease the as adjusted net tangible book value per share after this offering by approximately \$ and increase the dilution per share to new investors participating in this offering by approximately \$, based on an assumed combined public offering price of \$ per share and accompanying common warrant, which was the last reported sale price of our common stock on The Nasdaq Capital Market on May , 2020, remaining the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the common warrants issued in this offering.

The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares and common warrants that we offer in this offering, and other terms of this offering determined at pricing. The discussion and table above assume (i) no sale of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis and (ii) no exercise of common warrants accompanying the shares of common stock sold in this offering.

DESCRIPTION OF CAPITAL STOCK

As of March 31, 2020, our restated certificate of incorporation authorized us to issue 50,000,000 shares of common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share. As of March 31, 2020, we had 9,671,904 shares of common stock and no shares of preferred stock outstanding and warrants outstanding to purchase (i) one share of our common stock at an exercise price of \$0.07 per share; (ii) 490,683 shares of our common stock at an exercise price of \$10.36 per share; (iii) 9,005 shares of our common stock at an exercise price of \$33.31 per share; (iv) 606,420 shares of our common stock at an exercise price of \$0.01 per share; and (v) 1,556,420 shares of our common stock at an exercise price of \$1.16 per share. As of March 31, 2020, we also had (i) 1,654,198 options issued and outstanding to purchase our common stock at a weighted average exercise price of \$12.95 per share and (ii) 201,488 shares of common stock underlying unvested restricted stock units outstanding. At our 2020 Annual Meeting of Stockholders on April 20, 2020, our stockholders approved the 2020 Omnibus Long-Term Incentive Plan, pursuant to which 679,389 shares of common stock are reserved for future issuance. If the holders of our outstanding stock options and warrants exercise their rights to acquire our common stock, the percentage ownership of our stockholders existing prior to the exercise of such rights will be diluted. No shares of preferred stock were outstanding.

Common Stock

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of our stockholders. The holders of our common stock are entitled to receive ratably the dividends, if any, that may be declared from time to time by our board of directors out of funds legally available for such dividends. In the event of a liquidation, dissolution or winding up of the Company, the holders of our common stock would be entitled to share ratably in all assets remaining after payment of liabilities and the satisfaction of any liquidation preferences granted to the holders of any outstanding shares of preferred stock.

Holders of our common stock have no preemptive rights and no conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. All the outstanding shares of common stock are, and all shares of common stock offered, when issued and paid for, will be validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any shares of our preferred stock.

Anti-Takeover Provisions

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law (“DGCL”). Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers of the corporation and (b) shares issued under

employee stock plans under which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person associated with, or controlling, controlled by, or under common control with, the entity or person.

Certificate of Incorporation and Bylaws

Some provisions of our restated certificate of incorporation and amended and restated bylaws could also have anti-takeover effects. These provisions:

- provide for a board comprised of three classes of directors with each class serving a staggered three-year term;
- authorize our board of directors to issue preferred stock from time to time, in one or more classes or series, without stockholder approval;
- require the approval of at least two-thirds of our outstanding voting stock to amend specified provisions of our restated certificate of incorporation;
- require the approval of at least two-thirds of our total number of authorized directors, or two-thirds of our outstanding voting stock, to amend our amended and restated bylaws;
- provide that special meetings of our stockholders may be called only by our Chief Executive Officer, or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;

- provide that vacancies on our board of directors and newly created directorships may be filled only by a majority of the directors then in office, though less than a quorum, or by a sole remaining director; and
- do not include a provision for cumulative voting for directors (under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors).

The Nasdaq Capital Market Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol “BBI.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC (AST). Its address is 6201 15th Avenue, Brooklyn, New York 11219 and its telephone number is (800) 937-5449.

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering (i) shares of our common stock or pre-funded warrants to purchase shares of our common stock and (ii) common warrants to purchase up to an aggregate of shares of our common stock. Each share of common stock or pre-funded warrant is being sold together with a common warrant to purchase share of common stock. The shares of common stock or pre-funded warrants and accompanying common warrants will be issued separately. We are also registering the shares of common stock issuable from time to time upon exercise of the pre-funded warrants and common warrants offered hereby.

Common Stock

The material terms and provisions of our common stock are described under the caption “Description of Capital Stock” in this prospectus.

Pre-Funded Warrants

The following summary of certain terms and provisions of pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration and Exercise Price. Each pre-funded warrant offered hereby will have an initial exercise price per share equal to \$0.001. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued separately from the accompanying common warrants and may be transferred separately immediately thereafter.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). Purchasers of the pre-funded warrants in this offering may elect to deliver their exercise notice following the pricing of the offering and prior to the issuance of the pre-funded warrants at closing to have their pre-funded warrants exercised immediately upon issuance and receive shares of common stock underlying the pre-funded warrants upon closing of this offering. A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder’s pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock. No fractional shares of common stock will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will round down to the next whole share.

Cashless Exercise. If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available, then in lieu of making the cash payment otherwise contemplated to be made to us upon such

exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Transferability. Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Exchange Listing. There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system.

Right as a Stockholder. Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Common Warrants

The following summary of certain terms and provisions of common warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of common warrants for a complete description of the terms and conditions of the common warrants.

Duration and Exercise Price. Each common warrant offered hereby will have an initial exercise price per share equal to \$. The common warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued separately from the common stock and may be transferred separately immediately thereafter. A common warrant to purchase share of our common stock will be issued for every one share of common stock purchased in this offering.

Exercisability. The common warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the common warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the

terms of the common warrants. No fractional shares of common stock will be issued in connection with the exercise of a common warrant. In lieu of fractional shares, we will round down to the next whole share.

Cashless Exercise. If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act is not then effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrants.

Transferability. Subject to applicable laws, a common warrant in book entry form may be transferred at the option of the holder through the facilities of the Depository Trust Company and common warrants in physical form may be transferred upon surrender of the common warrant to the warrant agent together with the appropriate instruments of transfer.

Exchange Listing. There is no established public trading market for the common warrants, and we do not expect a market to develop. In addition, we do not intend to list the common warrants on any securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the common warrants will be limited.

Right as a Stockholder. Except as otherwise provided in the common warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

Fundamental Transaction. In the event of a fundamental transaction, as described in the form of common warrant, and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction.

UNDERWRITING

We entered into an underwriting agreement with the underwriter named below on _____, 2020. Oppenheimer & Co. Inc. is acting as the sole underwriter. The underwriting agreement provides for the purchase of a specific number of shares of common stock and/or pre-funded warrants and accompanying common warrants to purchase shares of common stock by the underwriter. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase the number of shares, pre-funded warrants and warrants set forth opposite its name below:

	Number of Shares of Common Stock	Number of Pre-Funded Warrants	Number of Common Warrants
Oppenheimer & Co. Inc.			

The underwriter has agreed to purchase all of the shares of common stock and/or pre-funded warrants and accompanying common warrants offered by this prospectus, if any are purchased.

The underwriter is offering the shares of common stock and/or pre-funded warrants and accompanying common warrants subject to various conditions and may reject all or part of any order. The underwriter has advised us that it proposes initially to offer the shares of common stock and/or pre-funded warrants and accompanying common warrants to purchase shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to dealers at a price less a concession not in excess of \$ _____ per share and accompanying common warrant or \$ _____ per pre-funded warrant and accompanying common warrant, based on the combined public offering price per share and accompanying common warrant or pre-funded warrant and accompanying common warrant, to brokers and dealers. After the shares of common stock and/or pre-funded warrants and accompanying common warrants are released for sale to the public, the underwriter may change the offering price, the concession, and other selling terms at various times.

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriter by us, before expenses:

	Per Share	Per Pre-Funded Warrant	Per Common Warrant	Total Per Share and Accompanying Common Warrant	Total Per Pre-Funded Warrant and Accompanying Common Warrant
Public offering price	\$	\$	\$	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$	\$	\$

(1) We have agreed to pay the underwriters a commission of 6% of the gross proceeds of this offering.

We estimate that our total expenses of the offering, excluding the estimated underwriting discounts and commissions, will be approximately \$ _____, which includes the fees and expenses for which we have agreed to reimburse the underwriter, provided that any such fees and expenses in excess of an aggregate of \$50,000 will be subject to our prior written approval.

We have agreed to indemnify the underwriter against certain liabilities, including liabilities under the Securities Act.

We, our officers and directors have agreed to a 90-day “lock-up” with respect to shares of our common stock and other of our securities that they beneficially own, including securities that are convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus, we and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of Oppenheimer & Co. Inc. Notwithstanding the foregoing, the “lock-up” with respect to our sale of shares of our common stock to Lincoln Park Capital Fund, LLC (“Lincoln Park”) pursuant to the Purchase Agreement, dated February 17, 2020, between us and Lincoln Park, will be limited to a period of 45 days following the date of this prospectus.

Rules of the SEC may limit the ability of the underwriter to bid for or purchase shares before the distribution of the shares is completed. However, the underwriter may engage in the following activities in accordance with the rules:

- Stabilizing transactions - the underwriter may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.
- Penalty bids - if the underwriter purchases shares in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriter and selling group members who sold those shares as part of this offering.
- Passive market making - if the underwriter is a market maker, it may make bids for or purchases of shares, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

Neither we nor the underwriter makes any representation or prediction as to the effect that the transactions described above may have on the price of the shares. These transactions may occur on The Nasdaq Capital Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Electronic Delivery of Prospectus: A prospectus in electronic format may be delivered to potential investors by the underwriter participating in this offering. The prospectus in electronic format will be identical to the paper version of such prospectus. Other than the prospectus in electronic format, the information on any underwriter’s website and any information contained in any other website maintained by the underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part.

The underwriter and its affiliates have provided, or may in the future, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of our Company. The underwriter and its affiliates may also make investment recommendations and/or publish or express

independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Non-U.S. Investors

Belgium

The offering is exclusively conducted under applicable private placement exemptions and therefore it has not been and will not be notified to, and this document or any other offering material relating to the shares has not been and will not be approved by, the Belgian Banking, Finance and Insurance Commission (Commission bancaire, financière et des assurances/Commissie voor het Bank, Financier en Assurantiewezen). Any representation to the contrary is unlawful.

Each underwriter has undertaken not to offer sell, resell, transfer or deliver directly or indirectly, any shares, or to take any steps relating/ancillary thereto, and not to distribute or publish this document or any other material relating to the shares or to the offering in a manner which would be construed as: (a) a public offering under the Belgian Royal Decree of 7 July 1999 on the public character of financial transactions; or (b) an offering of securities to the public under Directive 2003/71/EC which triggers an obligation to publish a prospectus in Belgium. Any action contrary to these restrictions will cause the recipient and the Company to be in violation of the Belgian securities laws.

Canada

This document constitutes an “exempt offering document” as defined in and for the purposes of applicable Canadian securities laws. No prospectus has been filed with any securities commission or similar regulatory authority in Canada in connection with the offer and sale of the securities described herein (the “**Securities**”). No securities commission or similar regulatory authority in Canada has reviewed or in any way passed upon this document or on the merits of the Securities and any representation to the contrary is an offence.

Canadian investors are advised that this document has been prepared in reliance on section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (“NI 33-105”). Pursuant to section 3A.3 of NI 33-105, this document is exempt from the requirement to provide investors with certain conflicts of interest disclosure pertaining to “connected issuer” and/or “related issuer” relationships as would otherwise be required pursuant to subsection 2.1(1) of NI 33-105.

Resale Restrictions

The offer and sale of the securities in Canada is being made on a private placement basis only and is exempt from the requirement to prepare and file a prospectus under applicable Canadian securities laws. Any resale of Securities acquired by a Canadian investor in this offering must be made in accordance with applicable Canadian securities laws, which may vary depending on the relevant jurisdiction, and which may require resales to be made in accordance with Canadian prospectus requirements, a statutory exemption from the prospectus requirements, in a transaction exempt from the prospectus requirements or otherwise under a discretionary exemption from the prospectus requirements granted by the applicable local Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the Securities outside of Canada.

Representations of Purchasers

Each Canadian investor who purchases the securities will be deemed to have represented to the issuer and to each dealer from whom a purchase confirmation is received, as applicable, that the investor (i) is purchasing as principal, or is deemed to be purchasing as principal in accordance with applicable Canadian securities laws, for investment only and not with a view to resale or redistribution; (ii) is an “accredited investor” as such term is defined in section 1.1 of National Instrument 45-106 *Prospectus Exemptions* or, in Ontario, as such term is defined in section 73.3(1) of the *Securities Act* (Ontario); and (iii) is a “permitted client” as such term is defined in section 1.1 of National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*.

Taxation and Eligibility for Investment

Any discussion of taxation and related matters contained in this document does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a Canadian investor when deciding to purchase the securities and, in particular, does not address any Canadian tax considerations. No representation or warranty is hereby made as to the tax consequences to a resident, or deemed resident, of Canada of an investment in the securities or with respect to the eligibility of the securities for investment by such investor under relevant Canadian federal and provincial legislation and regulations.

Rights of Action for Damages or Rescission

Securities legislation in certain of the Canadian jurisdictions provides certain purchasers of securities pursuant to an offering memorandum, including where the distribution involves an “eligible foreign security” as such term is defined in Ontario Securities Commission Rule 45-501 *Ontario Prospectus and Registration Exemptions* and in Multilateral Instrument 45-107 *Listing Representation and Statutory Rights of Action Disclosure Exemptions*, as applicable, with a remedy for damages or rescission, or both, in addition to any other rights they may have at law, where the offering memorandum, or other offering document that constitutes an offering memorandum, and any amendment thereto, contains a “misrepresentation” as defined under applicable Canadian securities laws. These remedies, or notice with respect to these remedies, must be exercised or delivered, as the case may be, by the purchaser within the time limits prescribed under, and are subject to limitations and defences under, applicable Canadian securities legislation. In addition, these remedies are in addition to and without derogation from any other right or remedy available at law to the investor.

Language of Documents

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu'il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque manière que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d'achat ou tout avis) soient rédigés en anglais seulement.*

France

Neither this prospectus nor any other offering material relating to the shares has been submitted to the clearance procedures of the Autorité des marchés financiers in France. The shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering

material relating to the shares has been or will be: (a) released, issued, distributed or caused to be released, issued or distributed to the public in France; or (b) used in connection with any offer for subscription or sale of the shares to the public in France. Such offers, sales and distributions will be made in France only: (i) to qualified investors (investisseurs qualifiés) and/or to a restricted circle of investors (cercle restreint d'investisseurs), in each case investing for their own account, all as defined in and in accordance with Articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier; (ii) to investment services providers authorised to engage in portfolio management on behalf of third parties; or (iii) in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (Règlement Général) of the Autorité des marchés financiers, does not constitute a public offer (appel public à l'épargne). Such shares may be resold only in compliance with Articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French Code monétaire et financier.

United Kingdom/Germany/Norway/The Netherlands

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "**Relevant Member State**") an offer to the public of any shares which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State other than the offers contemplated in this prospectus in name(s) of Member State(s) where prospectus will be approved or passported for the purposes of a non-exempt offer once this prospectus has been approved by the competent authority in such Member State and published and passported in accordance with the Prospectus Directive as implemented in name(s) of relevant Member State(s) except that an offer to the public in that Relevant Member State of any shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to legal entities which are authorised or regulated to operate in the financial markets or, if not so authorised or regulated, whose corporate purpose is solely to invest in securities;
- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- (c) by the representative to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- (d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares shall result in a requirement for the publication by the Company or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented, warranted and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (the “FSMA”)) received by it in connection with the issue or sale of any shares in circumstances in which section 21(1) of the FSMA does not apply to the Company; and
- (b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Israel

In the State of Israel, the shares offered hereby may not be offered to any person or entity other than the following:

- (a) a fund for joint investments in trust (i.e., mutual fund), as such term is defined in the Law for Joint Investments in Trust, 5754-1994, or a management company of such a fund;
- (b) a provident fund as defined in Section 47(a)(2) of the Income Tax Ordinance of the State of Israel, or a management company of such a fund;
- (c) an insurer, as defined in the Law for Oversight of Insurance Transactions, 5741-1981, (d) a banking entity or satellite entity, as such terms are defined in the Banking Law (Licensing), 5741-1981, other than a joint services company, acting for their own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- (d) a company that is licensed as a portfolio manager, as such term is defined in Section 8(b) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- (e) a company that is licensed as an investment advisor, as such term is defined in Section 7(c) of the Law for the Regulation of Investment Advisors and Portfolio Managers, 5755-1995, acting on its own account;
- (f) a company that is a member of the Tel Aviv Stock Exchange, acting on its own account or for the account of investors of the type listed in Section 15A(b) of the Securities Law 1968;
- (g) an underwriter fulfilling the conditions of Section 56(c) of the Securities Law, 5728-1968;
- (h) a venture capital fund (defined as an entity primarily involved in investments in companies which, at the time of investment, (i) are primarily engaged in research and development or manufacture of new technological products or processes and (ii) involve above-average risk);
- (i) an entity primarily engaged in capital markets activities in which all of the equity owners meet one or more of the above criteria; and
- (j) an entity, other than an entity formed for the purpose of purchasing shares in this offering, in which the shareholders equity (including pursuant to foreign accounting rules, international accounting regulations

and U.S. generally accepted accounting rules, as defined in the Securities Law Regulations (Preparation of Annual Financial Statements), 1993) is in excess of NIS 50 million.

Any offeree of the shares offered hereby in the State of Israel shall be required to submit written confirmation that it falls within the scope of one of the above criteria. This prospectus will not be distributed or directed to investors in the State of Israel who do not fall within one of the above criteria.

Italy

The offering of the shares offered hereby in Italy has not been registered with the Commissione Nazionale per la Società e la Borsa (**CONSOB**) pursuant to Italian securities legislation and, accordingly, the shares offered hereby cannot be offered, sold or delivered in the Republic of Italy (“**Italy**”) nor may any copy of this prospectus or any other document relating to the shares offered hereby be distributed in Italy other than to professional investors (operatori qualificati) as defined in Article 31, second paragraph, of CONSOB Regulation No. 11522 of 1 July, 1998 as subsequently amended. Any offer, sale or delivery of the shares offered hereby or distribution of copies of this prospectus or any other document relating to the shares offered hereby in Italy must be made:

- (a) by an investment firm, bank or intermediary permitted to conduct such activities in Italy in accordance with Legislative Decree No. 58 of 24 February 1998 and Legislative Decree No. 385 of 1 September 1993 (the “**Banking Act**”);
- (b) in compliance with Article 129 of the Banking Act and the implementing guidelines of the Bank of Italy; and
- (c) in compliance with any other applicable laws and regulations and other possible requirements or limitations which may be imposed by Italian authorities.

Sweden

This prospectus has not been nor will it be registered with or approved by Finansinspektionen (the Swedish Financial Supervisory Authority). Accordingly, this prospectus may not be made available, nor may the shares offered hereunder be marketed and offered for sale in Sweden, other than under circumstances which are deemed not to require a prospectus under the Financial Instruments Trading Act (1991: 980).

Switzerland

The shares offered pursuant to this prospectus will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to art. 652a or art. 1156 of the Swiss Federal Code of Obligations. The Company has not applied for a listing of the shares being offered pursuant to this prospectus on the SIX Swiss Exchange or on any other regulated securities market, and consequently, the information presented in this prospectus does not necessarily comply with the information standards set out in the relevant listing rules. The shares being offered pursuant to this prospectus have not been registered with the Swiss Federal Banking Commission as foreign investment funds, and the investor protection afforded to acquirers of investment fund certificates does not extend to acquirers of shares.

Investors are advised to contact their legal, financial or tax advisers to obtain an independent assessment of the financial and tax consequences of an investment in shares.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to “incorporate by reference” information into this document, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information.

We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”) made subsequent to the date of this prospectus until the termination of the offering of the securities described in this prospectus (other than information in such filings that was “furnished,” under applicable SEC rules, rather than “filed”). We incorporate by reference the following documents or information that we have filed with the SEC:

- our annual report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 18, 2020;
- our quarterly report on Form 10-Q for the quarter ended March 31, 2020 filed with the SEC on May 14, 2020;
- our current reports on Form 8-K filed with the SEC on February 10, 2020, February 10, 2020, February 10, 2020, February 18, 2020, March 18, 2020 (with respect to Item 8.01 only), April 3, 2020, April 14, 2020 and April 20, 2020 (in each case, except for information contained therein which is furnished rather than filed);
- our definitive proxy statement on Schedule 14A filed with the SEC on March 30, 2020, as amended April 3, 2020; and
- the description of our common stock contained in our registration statement on Form S-8 filed with the SEC on September 10, 2019, including any amendment or report filed for the purpose of updating such description.

Any statement contained in this prospectus or contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded to the extent that a statement contained in this prospectus or any subsequently filed supplement to this prospectus, or document deemed to be incorporated by reference into this prospectus, modifies or supersedes such statement. Any statements so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of these filings at no cost, by writing or telephoning us at the following address:

Brickell Biotech, Inc.
5777 Central Avenue
Suite 102
Boulder, CO 80301
(720) 505-4755
E-mail: IR@brickellbio.com

You may also access these filings on our website at www.brickellbio.com. You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide different or

additional information on our behalf. An offer of these securities is not being made in any jurisdiction where the offer or sale is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date of those respective documents.

WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You should rely only on the information contained in this prospectus or incorporated by reference into this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any jurisdiction where the offer is not permitted. You should assume that the information contained in this prospectus, or any document incorporated by reference in this prospectus, is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus or any sale of our securities.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public from commercial document retrieval services and over the Internet at the SEC's website at <http://www.sec.gov>.

We maintain a website at www.brickellbio.com. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not incorporated by reference into, and is not part of, this prospectus.

LEGAL MATTERS

The validity of the common stock and certain other legal matters will be passed upon for us by Faegre Drinker Biddle & Reath LLP, Indianapolis, Indiana. Lowenstein Sandler LLP, New York, New York, has acted as counsel to the underwriter in connection with this offering.

EXPERTS

The consolidated financial statements of Brickell Biotech, Inc. appearing in Brickell Biotech, Inc.'s Annual Report (Form 10-K) for the year ended December 31, 2019, have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon included therein, and incorporated herein by reference. Such financial statements are, and audited financial statements to be included in subsequently filed documents will be, incorporated herein in reliance upon the reports of Ernst & Young LLP pertaining to such financial statements (to the extent covered by consents filed with the SEC) given on the authority of such firm as experts in accounting and auditing.



Shares of Common Stock
Pre-Funded Warrants to Purchase Shares of Common Stock
Warrants to Purchase up to Shares of Common Stock

PROSPECTUS

Oppenheimer & Co.

The date of this prospectus is , 2020.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale and distribution of the securities being registered. All of the amounts shown are estimates, except for the SEC registration fee and the FINRA filing fee:

	Amount to be paid
SEC registration fee	\$ 2,272
FINRA filing fee	3,125
Printing and mailing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent fees and expenses	*
Miscellaneous	*
Total expenses	\$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

The Company is incorporated under the laws of the State of Delaware. Section 145 of the DGCL provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful. A Delaware corporation may indemnify any persons who were or are, or are threatened to be made, a party to any threatened, pending or completed action or suit 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 such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests, except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where a present or former director or officer is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses (including attorney's fees) which such director or officer has actually and reasonably incurred. Article XI(B) of the Company's restated certificate of incorporation authorizes the Company to provide indemnification of its directors, officers, agents and any other persons to which applicable law permits the Company to provide indemnification, and Article V of the Company's amended and

restated bylaws provides for indemnification of its directors, officers, employees and other agents to the maximum extent permitted by the DGCL. In addition, the Company maintains a policy providing directors' and officers' liability insurance.

Section 102 of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability:

- for any breach of the director's duty of loyalty to the corporation or its stockholders;
- for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;
- for acts related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- for any transaction from which the director derived an improper personal benefit.

Article XI(A) of the Company's restated certificate of incorporation includes such a provision. Moreover, Article V, Section 5 of the Company's amended and restated bylaws provides that expenses incurred by any director, officer, employee or other agent in defending any such action, suit or proceeding in advance of its final disposition shall be paid by the Company upon delivery of an undertaking, by or on behalf of such person, to repay all amounts so advanced if it shall ultimately be determined that such person is not entitled to be indemnified by the Company.

Item 15. Recent Sales of Unregistered Securities.

Sales to Lincoln Park

On February 17, 2020, we and Lincoln Park entered into the Securities Purchase Agreement pursuant to which, Lincoln Park purchased, and we sold, (i) an aggregate of 950,000 shares of our common stock (the "**Common Shares**") (ii) a warrant to initially purchase an aggregate of up to 606,420 shares of our common stock at an exercise price of \$0.01 per share (the "**Series A Warrant**") and (iii) a warrant to initially purchase an aggregate of up to 1,556,420 shares of our common stock at an exercise price of \$1.16 per share (the "**Series B Warrant**," and together with the Series A Warrant, the "**Warrants**"), in each case in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act, for an aggregate gross purchase price of \$2.0 million. The sale of our Common Shares and the Warrants closed on February 20, 2020.

Amended and Restated License Agreement with Bodor

On February 17, 2020, we together with Brickell Subsidiary, Inc. ("**Brickell Subsidiary**") and Bodor Laboratories, Inc. and Dr. Nicholas S. Bodor (collectively, "**Bodor**"), entered into an amended and restated license agreement (the "**Amended and Restated License Agreement**"). The Amended and Restated License Agreement supersedes the License Agreement, dated December 15, 2012, entered into between Brickell Subsidiary and Bodor, as amended by Amendment No. 1 to License Agreement, effective as of October 21, 2013, and Amendment No. 2 to License Agreement, effective as of March 31, 2015.

The Amended and Restated License Agreement retains with us a worldwide, exclusive license to develop, manufacture, market, sell and sublicense products containing the proprietary compound sofpironium bromide based

upon the patents referenced in the Amended and Restated License Agreement for a defined field of use. In exchange for entering into the Amended and Restated License Agreement, settling the previously disclosed dispute, and resolving the associated litigation between us and Bodor, we made an upfront payment of \$1.0 million in cash to Bodor following the execution of the Amended and Restated License Agreement and the settlement agreement by and among us, Brickell Subsidiary, Inc., and Bodor, dated February 17, 2020. We are required to further pay Bodor (i) a royalty on sales of product outside the territory of Kaken Pharmaceutical, Co., Ltd. (the “**Kaken**”), including a low single-digit royalty on sales of certain product not covered by the patent estate licensed from Bodor; (ii) a specified percentage of all royalties we receive from Kaken for sales of product within its territory; (iii) a percentage of non-royalty sublicensing income we receive from Kaken or other sublicensees; and (iv) a specified cash amount following the occurrence of certain new milestone events.

We also agreed to issue to Bodor (i) \$500,000 of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time we enroll our first patient in a Phase 3 pivotal clinical trial in the United States for subjects with hyperhidrosis and (ii) \$1.0 million of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time we submit a new drug application with the FDA for a product containing sofipronium bromide. If we enter into a change of control transaction prior to the occurrence of either of such triggering events, any amount not previously paid in shares of common stock will be accelerated and become payable in cash, in lieu of shares of common stock, upon the closing of the change of control transaction. Such issuances will be exempt from registration under Section 4(a)(2) of the Securities Act.

Funding Agreement with NovaQuest

On June 2, 2019, we 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 us (the “**Financing**”). The Financing was consummated immediately following the Merger, \$5.6 million of the commitment was paid to us on September 3, 2019 and the remaining portion of the commitment was expected to be paid to us in quarterly reimbursements of 67% of invoiced research and development expenses incurred during the succeeding four fiscal quarters.

In connection with the consummation of the Financing, and as required by the Funding Agreement, we issued warrants to NovaQuest providing it with the right to purchase 241,225 shares of common stock at an exercise price of \$10.36 per share (the “**NovaQuest Warrants**”) and entered into a Registration Rights Agreement with NovaQuest. The NovaQuest Warrants were issued in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act.

On November 25, 2019, we, Brickell Subsidiary and NovaQuest entered into a Settlement and Termination Agreement (the “**Settlement and Termination Agreement**”) as a result of the previously disclosed license agreement-related dispute with Bodor, which Settlement and Termination Agreement terminated the Funding Agreement. NovaQuest agreed to cancel and surrender the NovaQuest Warrants in connection with the Funding Agreement, and we repaid NovaQuest the \$5.6 million advance previously made by NovaQuest, including accrued interest. Subject to the mutual indemnity included in the Settlement and Termination Agreement, NovaQuest agreed to waive any and all of our further obligations (including any and all future milestone payments and royalties owed to NovaQuest), and each party agreed to release any and all claims against the other party in respect of the Funding Agreement.

Sales of Convertible Promissory Notes and Warrants

In March 2019, we initiated a convertible promissory notes offering pursuant to which we issued unsecured convertible promissory notes (the **Prom Notes**"), bearing interest at 12.00% with a maturity of one year and convertible into shares of Series C-1 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 \$31.05 per share. In addition, the Prom Notes were automatically convertible upon the closing of a qualified financing of at least \$15.0 million before maturity at a conversion price equal to 80% of the effective price per share paid in the qualified financing, but not to exceed \$38.82 per share. Through August 31, 2019, we had raised an aggregate principal amount of \$7.4 million in Prom Notes issued to accredited investors, including \$1.7 million from certain of our management and board of directors. On August 31, 2019, immediately prior to the Merger, the Prom Notes and related accrued interest converted into 1,069,740 shares of Private Brickell common stock at a conversion price of \$7.54 per share. The Prom Notes also provided for the issuance of warrants at 50% coverage to acquire 490,683 shares of common stock. The warrants are exercisable for a term of five years at an exercise price of \$10.36 per share. Prior to the Merger, the warrants were exercisable at an exercise price of \$42.70 per share or a 10% premium to the effective price per share paid in a qualified financing. The Prom Notes and related warrants were issued in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act.

Sales of Series C-1 Preferred Stock

From October 2016 through October 2017, the Company issued 905,076 shares of Series C-1 Preferred Stock to accredited investors at a price of \$13.40 per share for net proceeds of \$12.0 million. On August 31, 2019, in connection with the Merger, the Series C-1 Preferred Stock and related accrued dividends were exchanged for 525,800 shares of the Company's common stock. The Series C-1 Preferred Stock was issued in reliance upon the exemption from securities registration afforded by Section 4(a)(2) of the Securities Act.

Item 16. Exhibits.

The list of exhibits following the signature page of this registration statement is incorporated by reference herein.

Item 17. Undertakings.

(1) The undersigned registrant hereby undertakes:

- (a) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no

more than 20 percent change in the maximum aggregate offering price set forth in the “Calculation of Registration Fee” table in the effective registration statement; and

- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
 - (b) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof; and
 - (c) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
 - (d) That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant hereby undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
 - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (§ 230.424 of this chapter);
 - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
 - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
 - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (2) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant’s annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan’s annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) The undersigned registrant hereby undertakes that:
- (a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance on Rule 430A and contained in a form of prospectus filed by the undersigned registrant pursuant to Rule 424(b)(1) or (4) or 497(h)

under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective; and

- (b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (4) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
1.1*	Form of Underwriting Agreement.
<u>3.1</u>	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>3.2</u>	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020).
<u>4.1</u>	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed with the SEC on September 10, 2019).
4.2*	Form of Warrant to Purchase Common Stock
4.3*	Form of Pre-Funded Warrant
5.1*	Opinion of Faegre Drinker Biddle & Reath LLP.
<u>10.1†</u>	License, Development and Commercialization Agreement, dated March 31, 2015, including certain amendments, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.2†</u>	Amendment No. 2 to License, Development and Commercialization Agreement, dated October 6, 2017, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd., including Right of First Negotiation Agreement, as amended, dated October 6, 2017, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.3†</u>	Amended and Restated License Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc. and Dr. Nicholas S. Bodor (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).
<u>10.4†</u>	Settlement Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc. and Dr. Nicholas S. Bodor (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).
<u>10.5†</u>	License Agreement, as amended, dated June 26, 2012, by and between Brickell Biotech, Inc. and the UAB Research Foundation (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.6†</u>	Second Restated License Agreement, dated November 23, 2015, by and between Orca Pharmaceuticals LLC and New York University, as further assigned by Orca Pharmaceuticals LLC to Brickell Biotech, Inc. (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.7†</u>	Asset Purchase Agreement, dated November 23, 2015, by and between Brickell Biotech, Inc., Orca Pharmaceuticals LLC, and Orca Pharmaceuticals Limited (incorporated by reference to Exhibit 10.8 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.8†</u>	Asset Purchase Agreement, dated January 30, 2015, by and between Brickell Biotech, Inc. and Panmira Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.9</u>	Lease, as amended, dated August 4, 2016, by and between Brickell Biotech, Inc. and BMC Properties, LLC (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).

<u>10.10</u>	Employment Agreement, dated November 16, 2018, by and between Brickell Biotech, Inc. and Robert Brown (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.11</u>	Second Amended and Restated Employment Agreement, dated November 27, 2018, by and between Brickell Biotech, Inc. and Andrew Sklawer (incorporated by reference to Exhibit 10.12 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.12</u>	Amended and Restated Employment Agreement, dated August 1, 2016, by and between Brickell Biotech, Inc. and Deepak Chadha (incorporated by reference to Exhibit 10.13 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.13</u>	Brickell Biotech, Inc. Letter Agreement, dated July 10, 2018, by and between Brickell Biotech, Inc. and Jose Breton (incorporated by reference to Exhibit 10.14 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.14</u>	Employment Agreement, dated July 1, 2019, and Amendment to Employment Agreement, dated August 27, 2019, by and between Brickell Biotech, Inc. and David R. McAvoy (incorporated by reference to Exhibit 10.15 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.15</u>	Employment Agreement, dated August 1, 2019, by and between Brickell Biotech, Inc. and Adam Levy (incorporated by reference to Exhibit 10.16 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).
<u>10.16</u>	Settlement and Termination Agreement, dated November 25, 2019, by and between Brickell Subsidiary, Inc., Brickell Biotech, Inc. and NovaQuest Co-Investment Fund X, L.P. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 25, 2019).
<u>10.17</u>	Securities Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (schedules omitted) (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).
<u>10.18</u>	Series A Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-3 filed with the SEC on February 28, 2020).
<u>10.19</u>	Series B Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-3 filed with the SEC on February 28, 2020).
<u>10.20</u>	Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).
<u>10.21</u>	Registration Rights Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).
<u>10.22</u>	At Market Issuance Sales Agreement, dated April 14, 2020, by and between Brickell Biotech, Inc. and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on April 14, 2020).
<u>10.23</u>	Brickell Biotech, Inc. 2020 Omnibus Long-Term Incentive Plan (incorporated by reference to the Company's Definitive Proxy Statement on Schedule 14A filed with the SEC on March 30, 2020).
<u>10.24</u>	Amended and Restated Stock Incentive Plan of Vical Incorporated (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the SEC on June 1, 2017).
<u>10.25</u>	Amended and Restated 2009 Equity Incentive Plan of Brickell Biotech, Inc. (incorporated by reference to Exhibit 99.2 to the Company's Registration Statement on Form S-8 filed with the SEC on September 10, 2019).

<u>21.1</u>	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2019).
<u>23.1</u>	Consent of Ernst & Young LLP.
<u>23.2*</u>	Consent of Faegre Drinker Biddle & Reath LLP (included as part of Exhibit 5.1).
<u>24.1</u>	Power of Attorney (included in the signature page to this registration statement).

† Certain confidential information contained in this agreement has been omitted because it (i) is not material and (ii) would be competitively harmful if publicly disclosed.
* To be filed by amendment.

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption “Experts” in the Registration Statement (Form S-1) and related Prospectus of Brickell Biotech, Inc. for the registration of up to \$17,500,000 of its common stock and warrants to purchase shares of its common stock and to the incorporation by reference therein of our report dated March 18, 2020, with respect to the consolidated financial statements of Brickell Biotech, Inc., included in Brickell Biotech Inc.’s Annual Report (Form 10-K) for the year ended December 31, 2019, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Denver, Colorado
May 15, 2020