

PROSPECTUS



19,003,510 Shares of Common Stock

Pre-Funded Warrants to Purchase 1,829,812 Shares of Common Stock

Warrants to Purchase up to 20,833,322 Shares of Common Stock

We are offering 19,003,510 shares of our common stock and common warrants to purchase an equal number 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 pre-funded warrants to purchase 1,829,812 shares of common stock to each purchaser 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. Each pre-funded warrant will be exercisable for one share of our common stock and is accompanied by a common warrant to purchase 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 the 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 one share of our common stock at an exercise price of \$0.72 per share. The common warrants will be exercisable immediately and will expire five years from the date of issuance. 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. The common warrants will be issued in book-entry form pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company, LLC, as warrant agent.

Our common stock is listed on The Nasdaq Capital Market under the symbol "BBI." On October 22, 2020, the last reported sale price of our common stock on The Nasdaq Capital Market was \$0.72 per share.

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 ⁽¹⁾ |
|---|-----------|---------------------------|--------------------|----------------------|
| Public offering price | \$ 0.71 | \$ 0.709 | \$ 0.01 | \$ 14,998,162 |
| Underwriting discounts and commissions ⁽²⁾ | \$ 0.0426 | \$ 0.0426 | \$ 0.0006 | \$ 899,999 |
| Proceeds to us, before expenses | \$ 0.6674 | \$ 0.6664 | \$ 0.0094 | \$ 14,098,163 |

(1) Reflects the issuance of 19,003,510 shares of our common stock and pre-funded warrants to purchase 1,829,812 shares of our common stock.

(2) See "Underwriting" for additional information regarding underwriting compensation.

The delivery of the shares of common stock, the pre-funded warrants and common warrants to purchasers is expected to be made on or about October 27, 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.

Sole Book-Running Manager

Oppenheimer & Co.

Lead Manager

Lake Street

The date of this prospectus is October 22, 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 underwriters 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 underwriters are 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 (“U.S.”): We and the underwriters 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 U.S. Persons outside the U.S. 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 U.S.

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 biotechs 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 clinical-stage product candidate, sofpironium bromide, is a proprietary new chemical 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 population of the U.S. According to a 2016 update on the prevalence and severity of hyperhidrosis in the U.S. 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 U.S. or an estimated 10 million individuals.

Recent Developments

Initiation of U.S. Phase 3 Clinical Study

In October 2020, we initiated our first of two pivotal U.S. Phase 3 clinical studies evaluating sofpironium bromide gel, 15% as a potential treatment for primary axillary (underarm) hyperhidrosis (the “**Cardigan I Study**”).

The Cardigan I Study, which is expected to enroll up to 350 subjects aged 9 years and older with primary axillary hyperhidrosis, is a multicenter, randomized, double-blinded, vehicle (placebo)-controlled Phase 3 study to evaluate the safety and efficacy of topically applied sofpironium bromide gel, 15%. Subjects will apply the investigational product once daily at bedtime to their underarms for six consecutive weeks, with a 2-week post-treatment follow-up.

The co-primary efficacy endpoints include the proportion of subjects achieving at least a 2-point improvement on the Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) scale, a proprietary and validated patient-reported outcome measure, and change in gravimetric sweat production (GSP), each from baseline to end of treatment (EOT). In addition, safety and tolerability assessments will be performed throughout the study.

In connection with the enrollment of the first patient in the Cardigan I Study in the U.S., on October 9, 2020, we issued 480,769 shares of our common stock, and made a milestone payment in cash of \$500,000, to Bodor Laboratories, Inc. and Dr. Nicholas S. Bodor (collectively, “**Bodor**”), pursuant to the amended and restated license agreement, dated as of February 17, 2020, among us, Brickell Subsidiary, Inc. (“**Brickell Subsidiary**”) and Bodor (the “**Amended and Restated License Agreement**”).

Regulatory Approval by Development Partner in Japan

In September 2020, our Japanese development partner, Kaken Pharmaceutical Co., Ltd. (“**Kaken**”), received regulatory approval to manufacture and market sofpironium bromide gel, 5% under the brand name ECCLOCK® in Japan for the treatment of primary axillary (underarm) hyperhidrosis.

This regulatory approval is based on the results of the Japanese Phase 3 pivotal registration study of sofpironium bromide gel, 5% in 281 patients with primary axillary hyperhidrosis, in which all primary and secondary efficacy endpoints demonstrated statistically significant differences between sofpironium bromide gel and vehicle (placebo). In addition, sofpironium bromide gel was deemed to be safe and generally well tolerated in this study, as well as in the accompanying 52-week long-term safety extension study in Japan.

Under our sublicense agreement with Kaken, we are entitled to receive sales-based milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide gel in Japan. Further, Kaken has rights to develop and commercialize sofpironium bromide in Korea, China and certain other Asian countries.

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 Offered by Us

19,003,510 shares.

Pre-funded Warrants Offered by Us

We are also offering pre-funded warrants to purchase 1,829,812 shares of common stock to each purchaser 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, in lieu of shares of common stock that would otherwise result in each 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 the pre-funded warrants sold in this offering.

Common Warrants Offered by Us

Common warrants to purchase an aggregate of 20,833,322 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 one share of our common stock. Each common warrant will have an exercise price of \$0.72 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.

Common Stock to be Outstanding after this Offering

51,685,664 shares (assuming no exercise of the pre-funded warrants or the common warrants issued in this offering). Assuming all of the pre-funded warrants were immediately exercised, there would be 53,515,476 shares of our common stock outstanding after this offering.

Use of Proceeds

We estimate that the net proceeds from this offering will be approximately \$13.7 million, excluding any proceeds that may be received upon the exercise of the pre-funded warrants and the common warrants, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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 "Use of Proceeds" for additional information.

Risk Factors

An investment in our securities involves a high degree of risk. See “Risk Factors” and the other information included and incorporated by reference in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

National Securities Exchange Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol “BBI.” We do not intend to list the pre-funded warrants or common warrants on any securities exchange or nationally recognized trading system.

The number of shares of our common stock that will be outstanding after this offering is based on 32,682,154 shares of common stock outstanding as of October 20, 2020, and assumes the sale and issuance by us of 19,003,510 shares of common stock in this offering and excludes:

- 4,743,537 shares of common stock issuable upon the exercise of options outstanding as of October 20, 2020 at a weighted average exercise price of \$4.67 per share;
- 204,233 shares of common stock underlying unvested restricted stock units outstanding as of October 20, 2020;
- 1,997,623 shares of common stock reserved for future issuance under the 2020 Omnibus Long-Term Incentive Plan as of October 20, 2020;
- 19,556,109 shares of common stock issuable upon the exercise of warrants outstanding as of October 20, 2020, of which there were warrants 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) 1,556,420 shares of our common stock at an exercise price of \$1.16 per share; and (v) 17,500,000 shares of our common stock at an exercise price of \$1.25 per share; and
- 22,663,134 shares of common stock issuable upon the exercise of the pre-funded warrants and common warrants issued in this offering.

Unless otherwise indicated, this prospectus reflects and assumes no issuances or exercises of any other outstanding shares, options or warrants after October 20, 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 OPERATIONS

Our business depends on the successful financing, clinical development, regulatory approval, and commercialization of sofipironium bromide.

The successful development, regulatory approval, and commercialization of sofipironium bromide requires significant additional financing and depends on a number of factors, including but not limited to the following:

- timely and successful completion of Phase 3 clinical trials in the U.S., which may be significantly costlier than we currently anticipate and/or produce results that do not achieve the endpoints of the trials or which are ultimately deemed not to be clinically meaningful;
- whether we are required by the U.S. Food and Drug Administration (the "FDA") or similar foreign regulatory agencies to conduct additional clinical trials beyond those currently planned to support the approval and commercialization of sofipironium bromide;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our and their contractual obligations and with all regulatory and legal requirements applicable to sofipironium bromide;
- ability of third parties with which we contract to manufacture consistently adequate clinical trial and commercial supplies of sofipironium bromide, to remain in good standing with regulatory agencies and to develop, validate and maintain or supervise commercially viable manufacturing processes that are compliant with FDA-regulated Current Good Manufacturing Practices, ("cGMPs"), and the product's package insert;
- a continued acceptable safety profile during clinical development and following approval of sofipironium bromide;
- ability to obtain favorable labeling for sofipironium bromide through regulators that allows for successful commercialization, given the drug may be marketed only to the extent approved by these regulatory authorities (unlike with most other industries);

- ability to commercialize sofpironium bromide successfully in the U.S. and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with Kaken or others;
- acceptance by physicians, insurers and payors, and patients of the quality, benefits, safety, and efficacy of sofpironium bromide, if approved, including relative to alternative and competing treatments and the next best standard of care;
- existence of a regulatory and legal environment conducive to the success of sofpironium bromide;
- ability to price sofpironium bromide to recover our development costs and generate a satisfactory profit margin; and
- our ability and our partners' ability to establish and enforce intellectual property rights in and to sofpironium bromide, including but not limited to patents and licenses.

If we do not achieve one or more of these factors, many of which are beyond our reasonable control, in a timely manner or at all, and with adequate financing, we could experience significant delays or an inability to obtain regulatory approvals or commercialize sofpironium bromide. Even if regulatory approvals are obtained, we may never be able to successfully commercialize sofpironium bromide. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of sofpironium bromide, or any current primary asset, to continue our business.

We have never conducted a Phase 3 clinical trial ourselves and may be unable to successfully do so for sofpironium bromide.

The conduct of a Phase 3 clinical trial is a long, expensive, complicated, uncertain, and highly regulated process. Although our employees have conducted successful Phase 2 and Phase 3 clinical trials in the past across many therapeutic areas while employed at other companies, we as a company have not conducted a pivotal Phase 3 clinical trial, and as a result, we may require more time and incur greater costs than we anticipate. We commenced a Phase 3 long-term safety study for sofpironium bromide gel in the third quarter of 2018 and intend to conduct two pivotal Phase 3 clinical trials in subjects with primary axillary hyperhidrosis in the U.S. While we initiated the U.S. Phase 3 pivotal program for sofpironium bromide gel, 15% in the fourth quarter of 2020, we may not be able to complete that program in a reasonable timeframe, or at all. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from, or delay us in, obtaining regulatory approval of and commercializing sofpironium bromide and could prevent us from, or delay us in, receiving development- or regulatory-based milestone payments and commercializing sofpironium bromide gel for the treatment of primary axillary hyperhidrosis, which would adversely impact our financial performance, as well as put us in potential breach of material contracts for the licensing and development of sofpironium bromide, subjecting us to significant contract liabilities, including but not limited to potential loss of rights in and to sofpironium bromide.

Clinical drug development for sofpironium bromide is very expensive, time-consuming, and uncertain.

Clinical development for sofpironium bromide is very expensive, time-consuming, difficult to design and implement, and its outcome is inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved many do not cover their costs of development or ever generate a profit. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, a local or central institutional review board, or other regulatory authorities, including

state and local agencies and counterpart agencies in foreign countries, may suspend, delay, extend, require modifications or add additional requirements to or terminate our clinical trials at any time.

In the case of sofpironium bromide, we are seeking to deliver sufficient concentrations of the active pharmaceutical ingredient (“**API**”), absorbed from the skin surface through the skin barrier to the targeted dermal tissue to achieve the intended therapeutic effect, in this case treatment of primary axillary (underarm) hyperhidrosis. The topical route of administration may involve new dosage forms, which can be difficult to develop and manufacture and may raise novel regulatory issues and result in development or review delays or inability to get the investigational drug approved for use.

Use of patient-reported outcome assessments (“PROs”), and gravimetric assessments in sofpironium bromide clinical trials may delay or adversely impact the development of sofpironium bromide gel or clinical trial results or increase our development costs.

Due to the difficulty of objectively measuring the symptoms of hyperhidrosis in a clinical trial, which is the primary target of treatment for sofpironium bromide, PROs will have an important role in the development and regulatory approval of sofpironium bromide. PROs involve patients’ own subjective assessments of efficacy, and this subjectivity increases the uncertainty of determining and achieving clinical endpoints and obtaining regulatory approval. Such assessments can be influenced by factors outside of our reasonable control and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial, notwithstanding that regulators may or may not accept PROs as part of the drug approval process. Additionally, gravimetric assessments of sweat production, another key clinical endpoint, may vary significantly for a particular patient, and from patient to patient and site to site within a clinical trial or between separate clinical trials. The reduction, if any, in a patient’s gravimetric sweat production has the potential for significant variability and uncertain outcomes. This potential for variability and uncertain outcomes may adversely impact our ability to achieve statistical significance on our primary and secondary endpoints or may provide us with initial or subsequent results that are ultimately deemed not to be clinically meaningful or that do not result in regulatory approval.

Sofpironium bromide may cause undesirable side effects or have other unexpected properties that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.

Unforeseen side effects from sofpironium bromide could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects caused by sofpironium bromide could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay, or halt clinical trials, or even later commercialization, and could result in a more restrictive or narrower product label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities, or a product recall and/or cancellation.

Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of sofpironium bromide for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may expose us to liability or harm our business, financial condition, operating results, and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by sofpironium bromide after obtaining U.S. or foreign regulatory approval, a number of potentially negative

consequences could result, which could prevent us or our potential partners from achieving or maintaining regulatory approval and/or market acceptance of sofipironium bromide and could substantially increase the costs (and extent) of commercializing sofipironium bromide, potentially even leading to withdrawal of the drug.

Under our Clinical Supply Agreement with Kaken, we owe an outstanding sum for API for further development of sofipironium bromide, and our inability to obtain such API from Kaken on a timely basis, or Kaken's attempt to immediately collect the outstanding sum in full, could have a material adverse impact on our business.

On July 30, 2019, we entered into a Clinical Supply Agreement with Kaken (the "**Clinical Supply Agreement**") under which we made various purchase orders for certain amounts of drug substance and product components for use in non-clinical and clinical studies, as well as for scale-up validation activities. As of October 20, 2020, we owed Kaken approximately \$2.8 million. As a result of our non-payment, Kaken could assert a breach or default under the Clinical Supply Agreement and seek damages and/or termination of the Clinical Supply Agreement, among other available remedies. We have entered into a letter agreement with Kaken specifying the terms under which Kaken will ship to us, and we will pay for, a portion of the API, but that letter agreement does not include a waiver of Kaken's rights in respect of our non-payment. If Kaken were to seek the immediate payment of all amounts owed under the Clinical Supply Agreement, and we are unable to secure additional resources, our liquidity and cash position would be impaired, and our ability to meet our other financial obligations as they come due could be materially adversely affected.

Kaken substantially controls the development of sofipironium bromide in Japan and certain other Asian countries and may make decisions regarding product development, regulatory strategy and commercialization that may not be in our best interests. Kaken may be unable to obtain positive approval of the drug in certain Asian markets, excluding Japan.

Our license, development and commercialization agreement with Kaken (as amended, the "**Kaken Agreement**"), granted Kaken an exclusive Japan license and certain rights to additional Asian countries to develop and commercialize sofipironium bromide. Under the terms of the Kaken Agreement, as amended, we received an up-front payment, development milestones and research and development payments and are eligible to receive future milestones and a royalty on net sales.

Kaken has final decision-making authority for the overall regulatory, development and commercialization strategy for sofipironium bromide, market access activities, pricing and reimbursement activities, promotion, distribution, packaging, sales and safety and pharmacovigilance in Japan and certain other Asian countries. In exercising its final decision-making authority in such territories, Kaken may make decisions regarding product development or regulatory strategy based on its determination of how best to preserve and extend regulatory approvals in these territories for sofipironium bromide, which may delay or prevent achieving regulatory approval for sofipironium bromide in Kaken's territories, as well as by us in the U.S. and the other territories where we maintain exclusive rights. Additionally, Kaken is responsible for conducting certain nonclinical and API-related activities (chemistry, manufacturing, and controls) that will be required for FDA approval in the U.S., and as a result, we are reliant on Kaken to execute successfully, in a timely, compliant, and efficient manner, such activities on our behalf. To the extent Kaken experiences delays and/or difficulties in performing its development activities, this could prevent or cause substantial delays in our ability to seek approval for sofipironium bromide gel in the U.S. and other territories in which we maintain exclusive rights.

In September 2020, Kaken received approval of a new drug application in Japan for the manufacturing and marketing of sofipironium bromide gel for primary axillary hyperhidrosis. Despite receiving such approval in Japan,

we cannot provide any assurance that such new drug application in any other Asian markets will be approved or that regulatory approvals in other Asian countries will occur. We will not receive additional milestone or other payments from Kaken if Kaken is not successful in its development, regulatory or commercial activities.

If we or any partners with which we may collaborate to market and sell sofipironium bromide are unable to achieve and maintain insurance coverage and adequate levels of reimbursement for this compound following regulatory approval and usage by patients, our commercial success may be hindered severely.

If sofipironium bromide only becomes available by prescription, successful sales by us or by any partners with which we collaborate may depend on the availability of insurance coverage and adequate reimbursement from third-party payors as patients would then be forced to pay for the drug out-of-pocket if coverage and associated reimbursement is denied. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and private third-party payors is often critical to new product acceptance regardless of how well the product works. Coverage decisions may depend on clinical and economic standards that disfavor new drug products when more established or lower-cost therapeutic alternatives are already available or subsequently become available, even if these alternatives are not as safe and effective, or may be affected by the budgets and demands on the various entities responsible for providing health insurance to patients who will use sofipironium bromide. If insurers and payors decide that hyperhidrosis itself is not a disease they are willing to extend coverage to, which could happen if they only think the treatment improves quality of life, then coverage and reimbursement for sofipironium bromide may be denied, or at least severely restricted. In this case, patients would be forced to pay for sofipironium bromide out-of-pocket for cash, which they may not be willing or able to do. Even if we obtain coverage for sofipironium bromide, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use sofipironium bromide unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of sofipironium bromide.

In addition, the market for sofipironium bromide will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies and there may be time limitations on when a new drug may even be eligible for formulary inclusion. Also, third-party payors may refuse to include sofipironium bromide in their formularies or otherwise restrict patient access to sofipironium bromide when a less costly generic equivalent or other treatment alternative is available in the discretion of the formulary.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In the U.S., although private third-party payors tend to follow Medicare and Medicaid practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as state to state. Consequently, the coverage determination process is often uncertain and a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require us to provide scientific, clinical and health economics support for the use of sofipironium bromide compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what amount or time frame.

Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the U.S. and in international markets, potentially based on changes in law and/or payor practices. Third-party coverage

and reimbursement for sofipirionium bromide may not be available or adequate in either the U.S. or international markets, which could harm our business, financial condition, operating results, and prospects.

Even if sofipirionium bromide obtains regulatory approval, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of sofipirionium bromide, if approved, will depend significantly on the broad adoption and use of it by physicians and patients for approved indications, and may not be commercially successful even though the drug is shown to be safe and effective. The degree and rate of physician and patient adoption of sofipirionium bromide, if approved, especially in the U.S., will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat hyperhidrosis;
- our ability to market and sell the drug, including through direct-to-consumer advertising and non-traditional sales strategies;
- our ability to manage the novel Coronavirus pandemic (“COVID-19”) to complete necessary clinical trials, supply/manufacture sofipirionium bromide for such trials and commercially, and otherwise market and sell sofipirionium bromide while the pandemic continues in effect;
- the safety and effectiveness of sofipirionium bromide, and ease of use, compared to other available hyperhidrosis therapies, whether approved or used by physicians off-label;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for sofipirionium bromide;
- the cost of treatment with sofipirionium bromide in relation to alternative hyperhidrosis treatments and willingness to pay for sofipirionium bromide, if approved, on the part of patients;
- overcoming physician or patient biases toward particular therapies for the treatment of hyperhidrosis and achieving acceptance by physicians, major operators of clinics and patients of sofipirionium bromide as a safe, effective, and economical hyperhidrosis treatment;
- patients’ perception of hyperhidrosis as a disease and one for which medical treatment may be appropriate and a prescription therapy may be available;
- insurers’ and physicians’ willingness to see hyperhidrosis as a disease worth treating and for which reimbursement will be made available for treatment;
- proper administration of sofipirionium bromide;
- patient satisfaction with the results and administration of sofipirionium bromide and overall treatment experience;
- limitations or contraindications, warnings, precautions, or approved indications for use different than those sought by us that are contained in any final FDA-approved labeling for sofipirionium bromide;
- any FDA requirement to undertake a risk evaluation and mitigation strategy, or results from any post-marketing surveillance studies that FDA may require as a condition of product approval;

- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, legal, medical, public relations, compliance, and distribution efforts;
- adverse publicity about sofipironium bromide or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or public or private institutional limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals or restrictions on sales representatives to market pharmaceuticals; and
- potential product liability claims or other product-related litigation or litigation related to licensing and or other commercial matters associated with sofipironium bromide.

If sofipironium bromide is approved for use but fails to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent, or limit our ability to generate revenue and continue our business.

Sofipironium bromide, if approved, will face significant competition and its failure to compete effectively may prevent it from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, less effective patent terms, and a strong emphasis on developing newer, fast-to-market proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing, and marketing of healthcare products competitive with those that we are developing, including sofipironium bromide. We face competition from a number of sources, such as pharmaceutical companies, generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, regulatory expertise, clinical trial expertise, intellectual property portfolios, more international reach, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces, and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, sofipironium bromide, if approved, may compete with other dermatological products, including over-the-counter (“OTC”) treatments, for a share of some patients’, or payors’, discretionary budgets and for physicians’ attention within their clinical practices.

We anticipate that sofipironium bromide would compete with other therapies currently used for hyperhidrosis, including but not limited to:

- **Self-Administered Treatments.** Self-administered treatments, such as OTC and prescription topical antiperspirants, and Qbrexza[®] (glycopyrronium) 2.4% topical cloth. Oral and compounded topical anticholinergics also may be used off-label.
- **Non-Surgical Office-Based Procedures.** Office-based procedures have been approved by the FDA for certain uses and which may be used, on-or off-label, to treat hyperhidrosis, including intradermal injections of BOTOX[®], marketed by Allergan plc., and MiraDry[®], a microwave-based treatment marketed by Miramar Labs, Inc.
- **Surgical Treatments.** Surgical treatments include techniques for the removal of sweat glands, such as excision, curettage, and liposuction. Surgical procedures, such as endoscopic thoracic sympathectomy, are also used to destroy nerves that transmit activating signals to sweat glands.

To compete successfully in this market, we will have to provide an attractive and cost-effective alternative to these existing and other new therapies. Such competition could lead to reduced market share for sofipronium bromide and contribute to downward pressure on the pricing of sofipronium bromide, which could harm our business, financial condition, operating results, and prospects.

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the U.S. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the U.S.

We may in the future face generic competition for sofipronium bromide, which could expose us to litigation or adversely affect our business, financial condition, operating results, and prospects.

Upon expiration of patent protection (including applicable extensions) in the U.S. (and any other countries where patent coverage exists) for sofipronium bromide, we could lose a significant portion of then-existing sales of sofipronium bromide in a short period of time from generic competition, which would reduce existing sales and could expose us to litigation, adversely affecting our business, financial condition, operating results, and prospects.

We have in the past relied, and expect to continue to rely, on third-party Clinical Research Organizations (“CROs”), and other third parties to conduct and oversee our sofipronium bromide clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required or are unable to staff our trials, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, sofipronium bromide.

We have in the past relied, and expect to continue to rely, on third-party CROs to conduct and oversee our sofipronium bromide clinical trials and other aspects of product development. We also rely on various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA’s regulations and good clinical practice (“GCP”) requirements, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP and good laboratory practice (“GLP”) requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for sofipronium bromide. Regulatory authorities enforce these GCP and GLP requirements through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP and GLP requirements, or reveal noncompliance from an audit or inspection, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authorities may require us to perform additional clinical trials before approving our or our partners’ marketing applications. We cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials comply with applicable GCP and GLP requirements. In addition, our clinical trials generally must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to extend or repeat clinical trials, which would delay the regulatory approval process.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, including but not limited to impacts caused by the ongoing COVID-19 pandemic, we may not be able to enter into arrangements with alternative CROs or clinical trial sites, or do so on commercially reasonable terms, and in a satisfactory timeframe. If our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, or are delayed in establishing these capabilities, we will be unable to successfully commercialize our product candidates, if approved, or generate product revenue.

We currently have limited marketing capabilities and no sales organization. To commercialize our product candidates, if approved, in the U.S., Australia, Canada, the European Union, Latin America, Africa, the Middle East, and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Although our employees have experience in the marketing, sale and distribution of pharmaceutical products, and business development activities involving external alliances, from prior employment at other companies, we as a company have no prior experience in the commercial launch, marketing, sale and distribution of pharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team so they operate in an effective and compliant way. Any failure or delay in the development of our internal sales, marketing, distribution, and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products.

To commercialize sofpironium bromide in the rest of the world, we intend to leverage the commercial infrastructure of our partner, Kaken, which will provide us with resources and expertise in certain areas that are greater than we could initially build ourselves. We may choose to collaborate with additional third parties in various countries that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates, especially in other countries where we currently do not have a foreign legal presence. The inability to commercialize successfully our product candidates, either on our own or through collaborations with one or more third parties, would harm our business, financial condition, operating results, and prospects.

The COVID-19 vaccine candidate that is the subject of our collaboration agreement with AnGes, Inc. is at an early stage, it may not result in a safe and effective product candidate in a timely manner, or at all, there could be supply chain issues for both clinical and commercial contexts, and we may not be able to proceed with related development and commercialization activities. Further, any attention and resources we devote to this vaccine candidate could negatively impact our development program related to sofpironium bromide.

In September 2020, we entered into a collaboration agreement with AnGes, Inc. (“AnGes”) relating to the development and potential commercialization of AnGes’ proprietary investigational adjuvanted plasmid DNA

vaccine intended to prevent SARS-CoV-2 (COVID-19). Under the terms of the collaboration agreement, AnGes will continue to lead the development of its vaccine candidate in Japan and we will provide information and know-how that could be relevant to such development efforts. If AnGes obtains positive results from its clinical studies in Japan and we are able to satisfy certain conditions, including raising the required development funding, we would have the right to lead the development efforts in the U.S. and certain emerging markets. If ultimately approved for sale in the applicable jurisdictions, AnGes would have commercial rights to the vaccine in Japan and we would have commercial rights in the U.S. and certain emerging markets on terms and conditions to be agreed with AnGes prior to any launch of a vaccine product.

AnGes currently is conducting Phase 1/2 clinical studies with its vaccine candidate in Japan, with data readouts expected through the first quarter of 2021. The results from these studies will guide any further development efforts by AnGes and us of this novel vaccine candidate. As such, the work on this vaccine candidate is in the early stages, and it may not develop into an effective and safe vaccine in a timely manner, or at all. All product candidates are prone to significant risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by one or more regulatory authorities. Some regulatory authorities may approve a product candidate while others do not, or may provide approval on different terms or with additional conditions or limitations, or may issue any regulatory approval decisions at very different times. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, costly, and inherently unpredictable, especially for early-stage product candidates. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The development of any early-stage product candidates may be discontinued at any time for a variety of reasons, including but not limited to safety and efficacy concerns, the appearance of new technologies that make the product obsolete, competition from a competing product, supply chain considerations, intellectual property right impacts, ability to price or changes in or failure to comply with applicable regulatory requirements, or constraints on us or our product sponsor in obtaining additional financing and capital.

In addition, a substantial number of companies, individuals and institutions are working to develop a COVID-19 vaccine, many of which commenced studies much earlier than the studies commenced by AnGes and many of which have substantially greater financial, scientific and other resources than AnGes and us, and another party may be successful in producing a vaccine in a much faster timeframe and producing a safer or more efficacious vaccine or other treatment for COVID-19, or a less costly treatment, which may also lead to the diversion of governmental and quasi-governmental funding toward other companies and better insurance coverage for other COVID-19 treatments, and lead to demand being driven away from any product developed by AnGes or us, or cause AnGes and/or us to cancel or significantly scale back the introduction of a vaccine candidate based on the other available patient options. The rapid expansion of development programs directed at COVID-19 may also generate a scarcity of manufacturing capacity among contract research organizations that provide cGMP materials for development and commercialization of biopharmaceutical products, and/or could make it difficult for those conducting clinical studies to recruit in a timely manner an adequate number of trial participants, especially for companies like AnGes and us which started these studies much later than other companies.

We do not have expertise in the development of vaccine candidates in infectious disease applications. While we remain focused on our U.S. Phase 3 pivotal program for sofipirionium bromide for the treatment of primary axillary hyperhidrosis, the collaboration agreement with AnGes, including actions taken following the receipt of results from AnGes' clinical studies of the vaccine candidate in Japan, could divert our management's attention and other of our resources, which could cause delays in or otherwise negatively impact our sofipirionium bromide development

program. As a result, we cannot provide assurance that any attention we provide to the development of a vaccine candidate against COVID-19 will not adversely impact the timing and development of our other product candidates.

RISKS RELATED TO OUR FINANCIAL OPERATIONS

We will need to raise substantial additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

The advancement of the Phase 3 clinical trials for sofpironium bromide will require substantial additional financing. Pending our obtaining additional funding, we have taken, and expect to continue to take, actions to reduce our cash spend, including delaying the start of the clinical trials and/or staff reductions. Nonetheless, we will require substantial additional funds to conduct the costly and time-consuming clinical trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of sofpironium bromide in new indications or uses including completing our pivotal U.S. Phase 3 program for sofpironium bromide for treatment of primary axillary hyperhidrosis. Our future capital requirements will depend upon a number of factors, including but not limited to: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; compliance with our material contracts including the licensing agreement for sofpironium bromide; the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance for such product candidates; and overall stock market and global business conditions and trends. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit our ability to achieve our business objectives. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interests in our company will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us in one or more countries.

Our ability to raise the significant additional funds required to complete the U.S. Phase 3 clinical trials for sofpironium bromide is uncertain and is limited given our small market capitalization. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

Our operating results and liquidity needs could be affected negatively by global market fluctuations and economic downturn.

Our operating results and liquidity could be affected negatively by global economic conditions generally, both in the U.S. and elsewhere around the world, including but not limited to the ongoing COVID-19 pandemic. The market for discretionary pharmaceutical products, medical devices and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider sofpironium bromide as discretionary, and if full reimbursement for the product is not available, demand for the product may be tied to the discretionary, out-of-pocket cash-spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and

international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, or a bear market ensues in the U.S. stock market, including as a result of the recent coronavirus outbreak, our operating results and liquidity could be affected adversely by those factors in many ways, including weakening demand for sofipironium bromide, making it more difficult for us to raise funds if necessary, and our stock price may decline.

Our stock price and volume of shares traded have been and may continue to be highly volatile, and our common stock may continue to be illiquid.

The market price of our common stock following the Merger has been subject to significant fluctuations. The closing price of our common stock fluctuated from \$4.69 per share as of September 3, 2019, the first trading date following the closing of the Merger, to \$0.72 per share as of October 22, 2020. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. In addition, there has been limited liquidity in the trading market for our securities, which may adversely affect stockholders. Some of the factors that may cause the market price of our common stock to continue to fluctuate include, but are not limited to:

- material developments in, or the conclusion of, any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- our inability to increase our share price to at least \$1.00 per share for the frequency and duration required by The Nasdaq Capital Market to stay listed on this stock exchange and the impact that this lower price may have on investors;
- the entry into, or termination of, or breach by us or our partners of material agreements, including key commercial partner or licensing agreements, including the Kaken Agreement;
- our ability to obtain timely regulatory approvals for sofipironium bromide or future product candidates, and delays or failures to obtain such approvals;
- failure of sofipironium bromide, if approved, to achieve commercial success;
- issues in manufacturing or the supply chain for sofipironium bromide or future product candidates;
- the results of current and any future clinical trials of sofipironium bromide;
- failure of other product candidates, if approved, to achieve commercial success;
- announcements of any dilutive equity financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies or formulations that compete with sofipironium bromide;
- lack of commercial success of competitive products or products treating the same or similar indications;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and

- the loss of key employees and/or inability to recruit the necessary talent for new positions or to replace exiting employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment, such as the ongoing reaction of global markets to the coronavirus outbreak. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation. Such securities litigation often has ensued after a reverse merger or other merger and acquisition activity of the type we completed in 2019. Such litigation, if brought, could expose us to liability or impact negatively our business, financial condition, operating results, and prospects.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our operations to date have been limited primarily to researching and developing sofipironium bromide and undertaking preclinical studies and clinical trials of sofipironium bromide. We (and our partners) have not yet obtained regulatory approvals for sofipironium bromide in any country. Consequently, any predictions you or we make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our revenue and profitability will depend on development funding, including obtaining the additional funds needed to complete the Phase 3 clinical trials for sofipironium bromide, the achievement of sales milestones and royalties under an agreement with Kaken, as well as any potential future collaboration and license agreements and sales of sofipironium bromide or future products, if approved, and our ability to maintain the related license. These up-front and milestone payments may vary significantly from period to period, and country to country, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting, and other expenses that Private Brickell did not incur as a private company prior to the Merger and operating as a public company, including costs associated with public company reporting and other SEC requirements. We also incur costs associated with newly applicable corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new rules implemented by the SEC and The Nasdaq Stock Market LLC. These rules and regulations are expected to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. Our executive officers, directors, and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it expensive for us to operate our business.

We are a “smaller reporting company” and the reduced disclosure and governance requirements applicable to smaller reporting companies may make our common stock less attractive to some investors.

We qualify as a “smaller reporting company” under Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”). As a smaller reporting company, we are entitled to rely on certain exemptions and reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements, in our SEC filings. These exemptions and decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock price may be more volatile. We will remain a “smaller reporting company” under Item 10(f)(1) of SEC Regulation S-K as long as we maintain a public float as defined by that regulation of less than \$250.0 million; or we have less than \$100.0 million in annual revenues and (i) either no public float, or (ii) a public float of less than \$700.0 million.

Provisions of Delaware law and our restated certificate of incorporation and amended and restated bylaws may discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law and our restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include, but are not limited to:

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our current certificate of incorporation and bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Although we believe these provisions collectively provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

If the holders of our company’s stock options and warrants exercise their rights to purchase our common stock, the ownership of our stockholders will be diluted.

As of October 20, 2020, we had outstanding warrants 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) 17,500,000 shares of our common stock at an exercise price of \$1.25 per share; and (v) 1,556,420 shares of our common stock at an exercise price of \$1.16 per share. As of October 20, 2020, we also had 4,743,537 options issued and outstanding to purchase our common stock at a weighted average exercise price of \$4.67 per share and 204,233 shares of common stock underlying unvested restricted stock units outstanding. If the holders of our outstanding stock options and warrants exercise their rights to acquire our common stock and service conditions related to restricted stock units are met, the percentage ownership of our stockholders existing prior to the exercise of such rights will be diluted.

We may not be able to access the full amounts available under our purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), which could prevent us from accessing the capital we need to continue our operations, which could have an adverse effect on our business.

On February 17, 2020, we entered into the Purchase Agreement with Lincoln Park pursuant to which Lincoln Park agreed to purchase from us up to an aggregate of \$28.0 million of our common stock (subject to certain limitations) from time to time over the 36-month period commencing on the date the conditions set forth in the Purchase Agreement are satisfied. All funds available under the Purchase Agreement are subject to the satisfaction of certain conditions specified in the Purchase Agreement, including that our common stock remains listed on The Nasdaq Capital Market, the effectiveness of a registration statement relating to the resale of the shares to be sold to Lincoln Park under the Purchase Agreement and that no event of default has occurred under the Purchase Agreement. Additionally, depending upon the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park if such a sale would result in us issuing to Lincoln Park more than 9.99% of our shares outstanding prior to entering into the Purchase Agreement. In the event that we are unable to satisfy the conditions specified, the purchase commitment made by Lincoln Park will be unavailable to us and Lincoln Park will not be required to purchase any shares of our common stock. If obtaining funding from Lincoln Park were to prove unavailable, we will need to secure other sources of funding in order to satisfy our working capital needs. Additionally, even if we are able to sell all shares under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On August 17, 2020, we received a notice from the Listing Qualifications Department of the Nasdaq Stock Market ("**Nasdaq**") informing us that because the closing bid price for our common stock listed on Nasdaq was below \$1.00 per share for 30 consecutive business days, we were not in compliance with the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2) (the "**Rule**"). In accordance with Nasdaq's Listing Rules, we have a period of 180 calendar days, or until February 16, 2021, to regain compliance with the Rule. If at any time during this 180-day period, the closing bid price of our common stock is at least \$1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written confirmation that we have achieved compliance with the Rule.

The notice also disclosed that in the event we do not regain compliance with the Rule by February 16, 2021, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital

Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we meet these requirements, Nasdaq will inform us that we have been granted an additional 180 calendar days. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting. We intend to continue to monitor the bid price for our common stock between now and February 16, 2021, and will consider available options to resolve the deficiency and regain compliance with the Rule, including seeking stockholder approval of a reverse split of our common stock in order to increase the trading price of our common stock in compliance with The Nasdaq Capital Market rules. There is no assurance, however, that we will be eligible for an additional compliance period or that our common stock will not be delisted from Nasdaq.

The perception among investors that we are at a heightened risk of delisting could negatively affect the market price and trading volume of our common stock. If our common stock is delisted from Nasdaq, the delisting could: substantially decrease trading in our common stock; adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; adversely affect our ability to issue additional securities or obtain additional financing in the future on acceptable terms, if at all; result in the potential loss of confidence by investors, suppliers, partners and employees and fewer business development opportunities; and result in limited news and analyst coverage. Additionally, the market price of our common stock may decline further and shareholders may lose some or all of their investment.

We do not anticipate paying any dividends in the foreseeable future.

Our current expectation is that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our shares will be your sole source of gain, if any, for the foreseeable future.

If we fail to attract and retain management and other key personnel and directors, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel, and directors of our board of directors. We are highly dependent on our management, scientific personnel, and our directors. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan and in a way that complies with all applicable laws. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel or directors in the future due to the intense competition for qualified individuals among biotechnology, pharmaceutical, and other businesses.

Our ability to use our net operating loss carryforwards and other tax assets to offset future taxable income may be subject to certain limitations and it is possible that this offering may materially reduce or eliminate our net operating loss carryforwards.

As of December 31, 2019, we had approximately \$403.9 million of federal and \$350.6 million of state operating loss ("NOL") carryforwards available to offset future taxable income, which expire in varying amounts beginning in 2020 for federal and state purposes if unused. Utilization of these NOLs depends on many factors, including our

future income, which cannot be assured. Under the U.S. Tax Cuts and Jobs Acts (“**Tax Act**”), U.S. federal NOLs incurred in 2018 and later years may be carried forward indefinitely, but our ability to utilize such U.S. federal NOLs to offset taxable income is limited to 80% of the current-year taxable income. It is uncertain if and to what extent various states within the U.S. will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986 and corresponding provisions of state law, if a corporation undergoes an “ownership change” (which is generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not determined whether we have experienced Section 382 ownership changes in the past, or may have any potential Section 382 ownership changes in connection with this offering, and if a portion of our NOLs is therefore subject to an annual limitation under Section 382. Therefore, we cannot provide any assurance that a change in ownership within the meaning of the Internal Revenue Code of 1986 and corresponding provisions of state law has occurred in the past or will occur in connection with this offering. There is a risk that changes in ownership could have occurred. We may experience ownership changes as a result of subsequent changes in our stock ownership, as a result of offerings of our stock (including this offering) or subsequent shifts in our stock ownership, some of which may be outside of our control. In that case, the ability to use net operating loss carryforwards to offset future taxable income will be limited following any such ownership change, and could be eliminated. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance on our financial statements.

We may be adversely affected by natural disasters and other catastrophic events and by man-made problems such as war or terrorism or labor disruptions that could disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate office is located in Boulder, Colorado, near a major flood and blizzard zone. If a disaster, power outage, computer hacking, or other event occurred that prevented us from using all or a significant portion of our office, that damaged critical infrastructure (such as enterprise financial systems, IT systems, manufacturing resource planning or enterprise quality systems), or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers’ and suppliers’ facilities are located in multiple locations where other natural disasters or similar events, such as tornadoes, earthquakes, storms, fires, explosions or large-scale accidents or power outages, or IT threats, could severely disrupt our operations, could expose us to liability and could have a material adverse effect on our business, financial condition, operating results, and prospects. In addition, acts of terrorism and other geo-political unrest or labor unrest, or natural disasters, or global developments like the coronavirus outbreak, could cause disruptions in our business or the businesses of our partners, manufacturers, or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners’ or manufacturers’ disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution, or commercialization of sofpronium bromide, this could expose us to liability, and our business, financial condition, operating results, and prospects would suffer.

Our business and operations would suffer in the event of system failures, cyber-attacks, or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants, and even the regulators who we rely on to advance our business, are vulnerable to damage from computer viruses, unauthorized access, computer hacking or breaches, natural disasters, epidemics and pandemics, terrorism, war, labor unrest, and telecommunication and electrical failures. The risk of a

security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. In addition, since we sponsor clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in us to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products and product candidates could be delayed.

RISKS RELATED TO OUR BUSINESS

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our product candidates in the U.S.

The research, testing, manufacturing, safety surveillance, efficacy, quality assurance and control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our investigational drug products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and in foreign countries, and such regulations differ from country to country and frequently are revised.

Even after we or our partners achieve regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations, including on how the product is commercialized. For example, with respect to our product candidates for the U.S., the FDA may impose significant restrictions on the approved indicated use(s) for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product or include in the approved label restrictions on the product and how it may be used or sold. We also will be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and adverse event reporting, storage, advertising, promotion, and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with cGMP requirements and with the FDA's GCP requirements and GLP requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval, as well as continued compliance with the FDA's laws governing commercialization of the approved product, including but not limited to the FDA's Office of Prescription Drug Promotion regulation of promotional activities and direct-to-consumer advertising, fraud and abuse, antikickback, product sampling, debarment, scientific speaker engagements and activities, formulary interactions as well as interactions with healthcare practitioners, including various conflict-of-interest reporting requirements for any healthcare practitioners we may use as consultants, and laws relating to the pricing of drug products, including federal "best price" regulations that if not met can prohibit us from participating in federal reimbursement programs like Medicare or Medicaid. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar or more onerous (e.g., prohibition on direct-to-consumer

advertising and price controls that do not exist in the U.S.) restrictions and requirements imposed by laws and government regulators, and even private institutions, in those countries.

In addition, manufacturers of drug and biologic products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the manufacturing, processing, distribution or storage facility where, or processes by which, the product is made, a regulatory agency may impose restrictions on that product or us, including requesting that we initiate a product recall, or requiring notice to physicians or the public, withdrawal of the product from the market, or suspension of manufacturing.

If we, our partners, our product candidates, or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the sale, marketing, advertising, or manufacturing of the product, or amend, suspend, or withdraw product approvals, or revoke necessary licenses;
- mandate modifications to or prohibit promotional and other product-specific materials or require us to provide corrective information to healthcare practitioners and other customers and/or patients, or in our advertising and promotion;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, penalties for noncompliance and, in extreme cases, require an independent compliance monitor to oversee our activities;
- issue warning letters, bring enforcement actions, initiate surprise inspections, issue show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- debar certain healthcare professionals;
- exclude us from participating in or being eligible for government reimbursement and formulary inclusion;
- initiate audits, inspections, accounting and civil investigations or litigation;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend or cancel any ongoing clinical trials;
- place restrictions on the kind of promotional activities that can be done;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the U.S.;

- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- change or restrict our product labeling; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies, or guidance of the FDA, Japan's Pharmaceuticals and Medical Devices Agency ("PMDA"), and other applicable government agencies may change quickly, and new or additional statutes or government laws or regulations may be enacted, including at federal, state, and local levels, or case law may issue, which can differ by geography and could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities, including commercial efforts. We cannot predict the likelihood, nature or extent of adverse government regulations that may arise from future legislation or administrative action, or judicial outcomes based on litigation, either in the U.S. or abroad. If we are not able to achieve and maintain regulatory or other legal compliance, we may not be permitted to commercialize our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

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 COVID-19 has evolved into a global pandemic. 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.

The effects of the COVID-19 pandemic could delay or interrupt our business operations. 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. 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 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 U.S.' and other countries' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay 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 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.

We have sponsored or supported and may in the future sponsor or support clinical trials for our product candidates outside the U.S. and Japan, and the FDA, PMDA and applicable foreign regulatory authorities may not accept data from such trials.

We have sponsored or supported and may in the future choose to sponsor or support one or more of our clinical trials outside of the U.S. Although the FDA or applicable foreign regulatory authorities may accept data from clinical trials conducted outside the U.S. or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authorities may be subject to certain conditions or exclusion. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will not approve the application on the basis of foreign data alone unless such data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authorities will accept data from trials conducted outside of the U.S. or the applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our business plan.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability or similar causes of action as a result of the clinical testing (and use) of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and is manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding that we comply with applicable laws on promotional activity. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in actual or perceived injury to a patient that may or may not be reversible or potentially even cause death. We cannot offer any assurance that we will not face product liability or other similar suits in the future or that we will be successful in defending them, nor can we assure that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical

companies or others selling or otherwise coming into contact with our product candidates, among others, and under some circumstances even government agencies. If we cannot successfully defend against product liability or similar claims, we will incur substantial liabilities, reputational harm and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize, or restrictions on commercializing, our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing, or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- significant delay in product launch;
- debarment of our clinical trial investigators or other related healthcare practitioners working with our company;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

We have obtained product liability insurance coverage for our clinical trials. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. Our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, restrictive, and narrow, and, in the future, we may not be able to maintain adequate insurance coverage at a reasonable cost, or through self-insurance, in sufficient amounts or upon adequate terms to protect us against losses due to product liability or other similar legal actions. We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all and for all geographies in which we wish to launch. A successful product liability claim or series of claims brought against us could, if judgments exceed our insurance coverage, decrease our cash, expose us to liability and harm our business, financial condition, operating results, and prospects.

Our employees, independent contractors, principal investigators, other clinical trial staff, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, officers, directors, independent contractors, principal investigators, other clinical trial staff, consultants, advisors, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal or unethical activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; product sampling; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, anti-kickback and Medicare/Medicaid rules, debarment laws, promotional laws, securities laws, and/or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal or state healthcare programs, debarments, contractual damages, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of our operations, any of which could expose us to liability and adversely affect our business, financial condition, operating results, and prospects.

We may be subject to risks related to pre-approval promotion or off-label use, or unauthorized direct-to-consumer advertising of our product candidates.

In the U.S., the FDA strictly regulates the advertising and promotion of drug products, and drug products may only be marketed or promoted for their FDA-approved uses, consistent with the product's approved labeling and to appropriate patient populations. Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, the Department of Justice, the Office of Inspector General of the Department of Health and Human Services, state attorneys general, members of Congress, the public, and others. Violations, including promotion of our products for unapproved or off-label uses, or inappropriate direct-to-consumer advertising, are subject to enforcement letters, inquiries and investigations, and civil, criminal, and/or administrative sanctions by the FDA and other government agencies or tribunals and lawsuits by competitors, healthcare practitioners, consumers, investors, or other plaintiffs. Additionally, advertising and promotion of any product candidate that obtains approval outside of the U.S. will be heavily scrutinized by relevant foreign regulatory authorities.

Even if we obtain regulatory approval for our product candidates, the FDA or comparable foreign regulatory authorities may require labeling changes or impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In the U.S., engaging in impermissible promotion of our product candidates for off-label uses, or engaging in pre-approval promotion of an unapproved drug candidate, also can subject us to false claims litigation under federal and state statutes, which can lead to civil, criminal and/or administrative penalties and fines and agreements, such as a corporate integrity agreement, that materially restrict the manner in which we promote or distribute our product candidates. If we do not lawfully promote our products once they have received regulatory approval, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could expose us to liability and could have a material adverse effect on our business, financial condition, operating results, and prospects and even result in having an independent compliance monitor assigned to audit our ongoing operations at our cost for a lengthy period of time.

Other than sofpironium bromide, our other product candidates are at the early stages of clinical and regulatory development.

We are evaluating the next clinical development steps for various early-stage clinical product candidates (prior to Phase 3). The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, costly, and inherently unpredictable, especially for early-stage product candidates. The time required to obtain approval for early stage product candidates from the FDA and comparable foreign authorities is unpredictable but typically takes many years, involves significant expenditures, and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Our early stage product candidates will require substantial additional preclinical and clinical development before we will be able to submit an application to the FDA, if at all. Accordingly, we cannot provide assurance that we will be able to seek or obtain regulatory approval for any of our early stage product candidates.

We may choose not to continue developing or commercializing any of our early-stage product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our early-stage product candidates for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product including entry of generics, supply chain considerations, intellectual property right impacts, ability to price or changes in or failure to comply with applicable regulatory requirements, or constraints on obtaining additional financing and capital. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment, and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

Healthcare reform measures could hinder or prevent the commercial success of our product candidates.

The current presidential administration and certain members of the majority of the U.S. Congress have sought to repeal all or part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (or collectively, the “**Affordable Care Act**”) and implement a replacement program. For example, the so-called “individual mandate” was repealed as part of tax reform legislation adopted in December 2017, such that the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code was eliminated beginning in 2019. In addition, litigation may prevent some or all of the Affordable Care Act legislation from taking effect. For example, on December 14, 2018, the U.S. District Court for the Northern District of Texas held that the individual mandate is a critical and inseparable feature of the Affordable Care Act, and therefore, because it was repealed as part of the tax reform legislation, the remaining provisions of the Affordable Care Act are invalid as well. The impact of this ruling is stayed as it was appealed to the Fifth Circuit Court of Appeals. While the ruling will have no immediate effect, it is unclear how this decision, and subsequent appeals, if any, will impact the law. In 2020 and beyond, we may face additional uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Affordable Care Act. There is no assurance that the Affordable Care Act, as amended in the future, will not adversely affect our business and financial results.

Additionally, in October 2018, the U.S. President proposed to lower Medicare Part B drug prices, in addition to contemplating other measures to lower or prescribe certain mandatory prescription drug prices or drug substitution

policies. While these proposals have not yet been enacted, we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

There are also calls to severely curtail or ban all direct-to-consumer advertising of pharmaceuticals, or restrict activities by pharmaceutical sales representatives to have access to prescribers, which would limit our ability to market our product candidates. With regard to marketing directly to consumers and patients, the U.S. is in a minority of jurisdictions that even allow this kind of advertising and its removal could limit the potential reach of a marketing campaign.

We also may be subject to stricter healthcare laws, regulation and enforcement, and our failure to comply with those laws could expose us to liability or adversely affect our business, financial condition, operating results, and prospects.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights and privacy are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct business. The healthcare laws and regulations that may affect our ability to operate include: the Federal Food, Drug and Cosmetic Act, as amended; Title 21 of the Code of Federal Regulations Part 202 (21 CFR Part 202); the 21st Century Cures Act, the federal Anti-Kickback Statute; federal civil and criminal false claims laws and civil monetary penalty laws; the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act; the Prescription Drug Marketing Act (for sampling of drug product); the federal Best Price Act and Medicaid drug rebate program; the federal physician sunshine reporting requirements under the Affordable Care Act and state disclosure laws; the Foreign Corrupt Practices Act as it applies to activities both inside and outside of the U.S.; the new federal Right-to-Try legislation; and state law equivalents of many of the above federal laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business and result in reputational damage. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, including punitive damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or corporate criminal liability, or the curtailment or restructuring of our operations, and injunctions, any of which could expose us to liability and could adversely affect our business, financial condition, operating results, and prospects.

Subject to obtaining available financing, we intend to in-license and acquire product candidates and may engage in other strategic transactions, which could impact our liquidity, increase our expenses, and present significant distractions to our management.

One of our strategies is to in-license and acquire product candidates and we may engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including mergers and acquisitions, spin-offs, strategic partnerships, joint ventures, co-marketing, co-promotion, distributorships, development and co-development, restructurings, divestitures, business combinations and investments on a global basis. Any such transaction(s) may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures, grow and expand rapidly putting pressure on current resources and capabilities, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could expose us to liability, delays, and implementation obstacles that could harm our business, financial condition, operating results, and prospects. We have no current commitment or obligation to enter into any transaction described above other than ones to which we are already committed.

Our failure to in-license, acquire, develop, and market successfully additional product candidates or approved products would impair our ability to grow our business.

We intend to in-license, acquire, develop, and market additional products and product candidates. Because our internal research and development capabilities are limited, we may be dependent on pharmaceutical or other companies, investment groups or funds, academic or government scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly on our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners, and finance these arrangements.

The process of proposing, negotiating, and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales, legal and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities for the targeted use(s), or present with significant integration issues. All product candidates are prone to significant risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably, obtain reimbursement, be subject to patents and other intellectual property rights that provide any form of market or regulatory exclusivity, sustain historical levels of performance that made the acquisition initially attractive, or achieve/maintain market acceptance.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

We expect to rely on our collaboration with third-party out-license partners for the successful development and commercialization of our product candidates.

We expect to rely upon the efforts of third-party out-license partners for the successful development and commercialization of our current and future product candidates. The clinical and commercial success of our product candidates may depend upon maintaining successful relationships with third-party out-license partners which are subject to a number of significant risks, including the following:

- our partners' ability to execute their responsibilities in a timely, cost-efficient, and compliant manner;
- reduced control over supply, delivery, and manufacturing schedules;
- price increases and product reliability;
- manufacturing deviations from internal or regulatory specifications;
- quality or integrity incidents;
- the failure of partners to perform their obligations for technical, market, legal or other reasons;
- misappropriation of our current or future product candidates; and
- other risks in potentially meeting our current and future product commercialization schedule or satisfying the requirements of our end-users.

We cannot assure you that we will be able to establish or maintain third-party out-license partner relationships to successfully develop and commercialize our product candidates.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or internal capability to supply, store, manufacture or distribute preclinical, clinical, or commercial quantities of drug substances or products. Additionally, we have not entered into a long-term commercial supply agreement to provide us with such drug substances or products. As a result, our ability to develop our product candidates is dependent, and our ability to supply our products commercially will depend, in part, on our ability to obtain the APIs and other substances and materials used in our product candidates successfully from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply and other technical relationships with these third parties, or global conditions like the coronavirus outbreak significantly and adversely impact such third parties, we may be unable to continue to develop or commercialize our products and product candidates.

We do not have direct control over whether our contract suppliers and manufacturers will maintain current pricing terms, be willing to continue supplying us with APIs and finished products or maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. We are dependent on our contract suppliers and manufacturers for day-to-day compliance with applicable laws and cGMPs for production of both APIs and finished products. If the safety or quality of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to commercialize or obtain regulatory approval for the affected product or product candidate successfully, and we may be held liable for injuries sustained as a result.

In order to conduct larger or late-stage clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our drug substances and product candidates in larger quantities, more cost-effectively and, in certain cases, at higher yields than they currently achieve. If our third-party contractors are unable to scale up the manufacture of any of our product candidates successfully in sufficient quality and quantity and at commercially reasonable prices, or are shut down or put on clinical hold by government regulators, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to transfer the processes successfully on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results, and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment, even by force majeure, may significantly impair our ability to have our products and product candidates manufactured on a timely basis. Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the U.S. This may give rise to difficulties in importing our products or product candidates or their components into the U.S. or other countries.

Manufacturing and supply of the APIs and other substances and materials used in our product candidates and finished drug products is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality control and assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed.

Manufacturing and supply of APIs, other substances and materials and finished drug products is technically challenging. Changes beyond our direct control can impact the quality, volume, price and successful delivery of our products and product candidates and can impede, delay, limit or prevent the successful development and commercialization of our products and product candidates. Mistakes and mishandling, and/or disruptions in the supply chain, are not uncommon despite reasonable best efforts and can affect successful production and supply. Some of these risks include but are not limited to:

- failure of our manufacturers to follow cGMP or other legal requirements or mishandling of or adulterating product while in production or in preparation for transit;

- inability of our contract suppliers and manufacturers to efficiently and cost-effectively increase and maintain high yields and batch quality, consistency, and stability;
- difficulty in establishing optimal drug delivery substances and techniques, production and storage methods and packaging and shipment processes;
- challenges in designing effective drug delivery substances and techniques especially in light of competitor options;
- transportation and import/export risk, particularly given the global nature of our supply chain;
- delays in analytical results or failure of analytical techniques that we depend on for quality control/assurance and release of a product;
- natural disasters, strikes and labor disputes, epidemics or pandemics, war and terrorism, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and
- latent defects that may become apparent after a product has been released and even sold and used and that may result in recall and destruction of the product.

Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of our products, which could expose us to liability or harm our business, financial condition, operating results, and prospects.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover sofipironium bromide and related technologies that are of sufficient breadth.

Our success with respect to sofipironium bromide will depend, in part, on our ability to protect patent and other intellectual property protections in both the U.S. and other countries, to preserve our trade secrets and to prevent third parties from infringing on our proprietary rights. Our ability to prevent unauthorized or infringing use of sofipironium bromide by third parties depends in substantial part on our ability to leverage valid and enforceable patents and other intellectual property rights around the world.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner in all the countries that may be desirable. It is also possible that we or our current licensors and licensees, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection by others on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, our competitors independently may develop equivalent knowledge, methods and know-how or discover workarounds to our patents that would not constitute infringement. Our partners or licensees may inappropriately take or use our intellectual property and/or confidential information to infringe our patents or otherwise violate their contractual obligations as to us related to protection of our intellectual property. Any of these outcomes could impair our ability to enforce the

exclusivity of our patents effectively, which may have an adverse impact on our business, financial condition, operating results, and prospects.

Due to constantly shifting global legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to protect patents in any jurisdiction is uncertain and involves complex legal and factual questions especially across countries. Accordingly, rights under any applicable patents that apply to us may not cover our product candidates or may not provide us with sufficient protection for our product candidates to afford a sustainable commercial advantage against competitive products or processes, including those from branded, generic, and OTC pharmaceutical companies. In addition, we cannot guarantee that any patents or other intellectual property rights will issue from any pending or future patent or other similar applications related to us. Even if patents or other intellectual property rights have issued or will issue, we cannot guarantee that the claims of these patents and other rights are or will be held valid or enforceable by the courts or other legal authorities, through injunction or otherwise, or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target, or that a legislative or executive branch of government may alter the rights and enforceability thereof at any time.

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, abstracts, posters, presentations, patents and patent applications and other public disclosures including on the Internet and various social media. Our ability to protect valid and enforceable patents and other intellectual property rights depends on whether the differences between our proprietary technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in securing, if any. Even if the patents do issue successfully, third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents or intellectual property that apply to us, which may result in such patents and/or other intellectual property being narrowed, invalidated, or held unenforceable. If the breadth or strength of protection provided by the patents and other intellectual property we hold or pursue with respect to our product candidates is challenged, regardless of our future success, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize or finance, our product candidates.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent or duration as in the U.S., and many companies have encountered significant difficulties in acquiring, maintaining, protecting, defending, and especially enforcing such rights in foreign jurisdictions. If we encounter such difficulties in protecting, or are otherwise precluded from effectively protecting, our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed, especially internationally.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after it is filed, with patent term extensions granted in certain instances to compensate for part of the period in which the drug was under development and could not be commercialized while under the patent. Without patent protection for sofpironium bromide, we may be open to competition from generic versions of sofpironium bromide. The issued U.S. patents relating to sofpironium bromide run through 2031, including expected extensions just described. Other patent rights we are seeking in the U.S. would provide expected coverage through 2040, but only in the event of a grant of such rights.

Proprietary trade secrets and unpatented know-how and confidential information are also very important to our business. Although we have taken steps to protect our trade secrets, unpatented know-how and confidential

information by entering into confidentiality and nondisclosure agreements with third parties and intellectual property protection agreements with officers, directors, employees, and certain consultants and advisors, there can be no assurance that binding agreements will not be breached or enforced by courts or other legal authorities, that we would have adequate remedies for any breach, including injunctive and other equitable relief, or that our trade secrets, unpatented know-how and confidential information will not otherwise become known, be inadvertently disclosed by us or our agents and representatives, or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use, and if we and our agents or representatives inadvertently disclose trade secrets, unpatented know-how, and/or confidential information, we may not be allowed to retrieve the inadvertently disclosed trade secret, unpatented know-how, and/or confidential information and maintain the exclusivity we previously enjoyed.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on our product candidates does not guarantee exclusivity. The requirements for patentability differ in certain countries, particularly developing countries, and can change over time in the same country. In addition, the laws of some other countries do not protect intellectual property rights to the same extent as laws in the U.S., especially when it comes to granting use and other kinds of patents and what kind of enforcement rights will be allowed, especially injunctive relief in a civil infringement proceeding. Consequently, we may not be able to prevent third parties from practicing our inventions in countries outside the U.S. and even in launching an identical version of our product notwithstanding us having a valid patent or other intellectual property rights in that country. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent or other protections to develop their own products, or produce copy products, and, further, may export otherwise infringing products to territories where we have patent and other protections but enforcement against infringing activities is inadequate or where we have no patents or other intellectual property rights. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from commercialization or other uses.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly in developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, and the judicial and government systems are often corrupt, apathetic or ineffective, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our global patents and other rights at risk of being invalidated or interpreted narrowly and our global patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuit that we initiate or infringement action brought against us, and the damages or other remedies awarded, if any, may not be commercially meaningful when we are the plaintiff. When we are the defendant, we may be required to post large bonds to stay in the market while we defend ourselves from an infringement action.

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patentholder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. Further, there is no guarantee that any country will not adopt or impose compulsory licensing in the future. In these situations, the royalty the court requires to be paid by the licenseholder receiving the compulsory license may not be calculated at

fair market value and can be inconsequential, thereby disaffecting the patentholder's business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the U.S. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. For example, in Brazil, pharmaceutical patents require prior initial approval of the Brazilian health agency, ANVISA. Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent and similar agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the U.S. Patent and Trademark Office ("USPTO") and foreign patent agencies in several stages over the lifetime of a patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction just for failure to know about and/or timely pay such fee. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees in prescribed time periods, and failure to properly legalize and submit formal documents in the format and style the country requires. If we or our licensors fail to maintain the patents and patent applications covering our product candidates for any reason, our competitors might be able to otherwise enter the market, which would have an adverse effect on our business, financial condition, operating results, and prospects.

In addition, countries continue to increase the fees that are charged to acquire, maintain, and enforce patents and other intellectual property rights, which may become prohibitive to initiate or continue paying in certain circumstances.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, or increase our financial or other obligations to our licensors.

We have entered into in-license arrangements with respect to certain of our product candidates. These license agreements impose various diligence, milestone, royalty, insurance, reporting and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate or modify the license, or trigger other more disadvantageous contract clauses, in which event we may not be able to finance, develop or market the affected product candidate. The loss of such rights could expose us to liability and could materially adversely affect our business, financial condition, operating results, and prospects.

Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties and do this in one or more countries. We cannot assure that marketing and selling such product candidates and using such technologies will not infringe existing or future patents or other intellectual property rights. Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents and other intellectual property rights are issued, the risk increases that others may assert that our product candidates, technologies, or methods of delivery or use(s) infringe their patent or other intellectual property rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems and formulations, manufacturing processes, or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent or other rights encompassing our product candidates, technologies, or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies notwithstanding the patents we may possess. Because some patent applications in the U.S. and other countries may be maintained in confidence until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until eighteen (18) months or some other time after filing, and because publications in the scientific literature or other public disclosures often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to our technology. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or royalties, or the like. If another party has filed a U.S. patent application on inventions similar to ours, we or the licensor, may have to participate in the U.S. in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing in the U.S. under Paragraph IV of the Hatch-Waxman Act or other countries' laws similar to the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug, and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court or other legal authority would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court or other legal authority will order us to pay the other party significant damages for having violated the other party's patents or intellectual property rights.

Because we rely on certain third-party licensors, licensees, and partners and will continue to do so in the future, around the world, if one of our licensors, licensees, or partners is sued for infringing a third party's intellectual property rights, this could expose us to liability and our business, financial condition, operating results, and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors, licensees, and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some of our licensors, licensees, and partners that could require us to pay some of the costs of patent or other intellectual property rights litigation brought against those third parties whether or not the alleged infringement is caused by our

proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could expose us to liability or adversely affect our business, financial condition, operating results, and prospects at any time.

We may be subject to claims that our employees, officers, directors, advisors, consultants, or independent contractors have wrongfully used or disclosed to us alleged trade secrets or other confidential and proprietary information of their former employers or their former or current partners or customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees, officers, and directors were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of advisors, consultants, and independent contractors to assist us in the development of our products and product candidates, many of whom were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, officers, directors, advisors, consultants, and independent contractors or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary confidential information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any litigation like this could be protracted, expensive, a distraction to our management team, and/or Board, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

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 the combined public offering price of \$0.72 per share of common stock and accompanying common warrant and \$0.719 per pre-funded warrant and accompanying common warrant being sold in this offering, and assuming that all of the pre-funded warrants to purchase 1,829,812 shares of our common stock were immediately exercised for cash at an exercise price of \$0.001 per share, and our net tangible book value as of June 30, 2020, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$0.01 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, either by us or by our existing stockholders, 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, shares held by our existing stockholders or shares issued upon exercise of our outstanding stock options or warrants, 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.

Low trading volume of our common stock may adversely affect the price of our shares.

Our common stock has experienced limited trading volume since the Merger. There can be no assurance the volume of trading in our common stock will increase after this offering or that a liquid market for our common stock will develop or be sustained. Limited trading volume subjects our common stock to greater price volatility and may make it difficult for you to sell your shares at a price that is attractive to you.

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 \$13.7 million from the sale of the securities offered by us in this offering, 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 pre-funded warrants and the common warrants issued in this offering.

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 U.S.

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 June 30, 2020 was \$19.9 million, or \$0.75 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 June 30, 2020.

After giving effect to the sale of 19,003,510 shares of common stock and pre-funded warrants to purchase up to 1,829,812 shares of common stock in this offering at the public offering price of \$0.72 per share of common stock and accompanying common warrant, and \$0.719 per pre-funded warrant and accompanying common warrant, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and assuming that all of the pre-funded warrants were immediately exercised for cash at an exercise price of \$0.001 per share, our as adjusted net tangible book value as of June 30, 2020 would be \$33.6 million, or \$0.71 per share of common stock. This amount represents an immediate increase in as adjusted net tangible book value of \$0.04 per share to our existing stockholders and an immediate dilution of \$0.01 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 | | \$ | 0.72 |
| Historical net tangible book value per share as of June 30, 2020 | | \$ | 0.75 |
| Increase in as adjusted net tangible book value per share attributable to this offering | | | 0.04 |
| As adjusted net tangible book value per share after giving effect to this offering | | | 0.71 |
| Dilution per share to new investors in this offering | | \$ | 0.01 |

The discussion and table above assumes no exercise of the common warrants accompanying the shares of common stock and pre-funded warrants sold in this offering.

DESCRIPTION OF CAPITAL STOCK

As of October 20, 2020, our restated certificate of incorporation authorized us to issue 100,000,000 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 October 20, 2020, we had 32,682,154 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) 17,500,000 shares of our common stock at an exercise price of \$1.25 per share; and (v) 1,556,420 shares of our common stock at an exercise price of \$1.16 per share. As of October 20, 2020, we also had (i) 4,743,537 options issued and outstanding to purchase our common stock at a weighted average exercise price of \$4.67 per share and (ii) 204,233 shares of common stock underlying unvested restricted stock units outstanding. As of October 20, 2020, we had 1,997,623 shares remaining available for future grant under the 2020 Omnibus Long-Term Incentive Plan. 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.

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. 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) 19,003,510 shares of our common stock, (ii) pre-funded warrants to purchase 1,829,812 shares of our common stock and (iii) common warrants to purchase up to an aggregate of 20,833,322 shares of our common stock. Each share of common stock and each pre-funded warrant is being sold together with a common warrant to purchase one share of our common stock. The shares of common stock, 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 \$0.72. 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 one share of our common stock will be issued for every 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. Pursuant to a warrant agency agreement between us and American Stock Transfer & Trust Company, LLC, as warrant agent, the common warrants initially will be issued in book-entry form and will be represented by one or more global certificates deposited with The Depository Trust Company (“DTC”) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

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 underwriters named below on October 22, 2020. Oppenheimer & Co. Inc. is acting as the sole book-running manager and representative of the underwriters. The underwriting agreement provides for the purchase of a specific number of shares of common stock, pre-funded warrants and accompanying common warrants to purchase shares of common stock by the underwriters. Subject to the terms and conditions of the underwriting agreement, each 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. | 16,152,983 | 1,555,340 | 17,708,323 |
| Lake Street Capital Markets, LLC | 2,850,527 | 274,472 | 3,124,999 |
| Total | 19,003,510 | 1,829,812 | 20,833,322 |

The underwriters have 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 underwriters are offering the shares of common stock, pre-funded warrants and accompanying common warrants subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that it proposes initially to offer the shares of common stock, 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 \$0.0259 per share and accompanying common warrant or \$0.0259 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, pre-funded warrants and accompanying common warrants are released for sale to the public, the representative 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 underwriters 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 | \$ 0.71 | \$ 0.709 | \$ 0.01 | \$ 0.72 | \$ 0.719 |
| Underwriting discounts and commissions ⁽¹⁾ | \$ 0.0426 | \$ 0.0426 | \$ 0.0006 | \$ 0.0432 | \$ 0.0432 |
| Proceeds, before expenses, to us | \$ 0.6674 | \$ 0.6664 | \$ 0.0094 | \$ 0.6768 | \$ 0.6758 |

(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 \$425,000, which includes the fees and expenses for which we have agreed to

reimburse the underwriters, provided that any such fees and expenses in excess of an aggregate of \$75,000 will be subject to our prior written approval.

We have agreed to indemnify the underwriters 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 (a) to Lincoln Park pursuant to the Purchase Agreement, dated February 17, 2020, between us and Lincoln Park, will be limited to a period of 60 days following the date of this prospectus and (b) pursuant to the At Market Issuance Sales Agreement, dated April 14, 2020, between us and Oppenheimer & Co., Inc., will be limited to a period of 60 days following the date of this prospectus.

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

- Stabilizing transactions - the representative 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 representative 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 - market makers in the shares who are underwriters or prospective underwriters 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 underwriters’ 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 underwriters make 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 underwriters 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 an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part.

The underwriters and their 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 underwriters and their 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 underwriters and their 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 50.0 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 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 reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020 filed with the SEC on May 14, 2020 and August 12, 2020, respectively;
- 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, April 3, 2020, April 14, 2020, April 20, 2020, June 2, 2020, June 15, 2020, June 18, 2020, June 26, 2020, August 21, 2020, September 1, 2020, September 25, 2020, and October 6, 2020 (in each case, except for information contained therein which is furnished rather than filed);
- our definitive proxy statements on Schedule 14A filed with the SEC on March 30, 2020 (as amended April 3, 2020) and July 27, 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, Minneapolis, Minnesota. Lowenstein Sandler LLP, New York, New York, has acted as counsel to the underwriters 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.



19,003,510 Shares of Common Stock
Pre-Funded Warrants to Purchase 1,829,812 Shares of Common Stock
Warrants to Purchase up to 20,833,322 Shares of Common Stock

PROSPECTUS

Sole Book-Running Manager

Oppenheimer & Co.

Lead Manager

Lake Street

The date of this prospectus is October 22, 2020.
