PROSPECTUS

⊖ BrickellBio

2,598,829 Shares of Common Stock

This prospectus relates to the resale, from time to time, of up to 2,598,829 shares of our common stock by Lincoln Park Capital Fund, LLC (the **selling stockholder**" or "**Lincoln Park**"). The shares of our common stock that may be offered by Lincoln Park are issuable pursuant to a Purchase Agreement that we entered into with Lincoln Park on February 17, 2020 (the "**Purchase Agreement**") relating to the sale of up to \$28,000,000 in shares of our common stock. See the section of this prospectus entitled "The Lincoln Park Transaction" for a description of the Purchase Agreement and the section entitled "Selling Stockholder" for additional information about the selling stockholder.

The shares of common stock described in this prospectus may be sold from time to time pursuant to this prospectus by the selling stockholder in ordinary brokerage transactions, in transactions in which brokers solicit purchases, in negotiated transactions, or in a combination of such methods of sale, at market prices prevailing at the time of sale, at prices related to such prevailing market prices, at fixed prices or prices subject to change, or at negotiated prices. See "Plan of Distribution." We cannot predict when or in what amounts the selling stockholder may sell any of the shares offered by this prospectus.

We are not selling any shares of our common stock, and we will not receive any of the proceeds from any sale of shares by the selling stockholder. However, we may receive gross proceeds of up to \$28,000,000 under the Purchase Agreement. The selling stockholder will pay all brokerage fees and commissions and similar sale-related expenses. We are only paying expenses relating to the registration of the shares with the Securities and Exchange Commission (the "SEC"). The registration of the shares of our common stock does not necessarily mean that any of such shares will be issued by us or offered and sold by the selling stockholder.

The selling stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See Plan of Distribution for more information about how the selling stockholder may sell the shares of common stock being registered pursuant to this prospectus. The selling stockholder is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended (the "Securities Act").

You should read this prospectus, together with the documents we incorporate by reference, carefully before you invest in shares of our common stock.

Our common stock is listed on The Nasdaq Capital Market under the symbol "BBI." On August 12, 2020, the last reported sale price of our common stock on The Nasdaq Capital Market was \$0.889 per share.

INVESTING IN OUR SHARES INVOLVES RISKS. SEE THE SECTION ENTITLED "RISK FACTORS" BEGINNING ON PAGE 7 OF THIS PROSPECTUS AND IN OUR MOST RECENT ANNUAL REPORT FILED ON FORM 10-K AND ANY SIMILAR SECTION CONTAINED IN ANY DOCUMENTS THAT ARE INCORPORATED BY REFERENCE INTO THIS PROSPECTUS BEFORE INVESTING IN OUR SHARES.

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

The date of this prospectus is August 13, 2020.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC. Pursuant to this prospectus, the selling stockholder may, from time to time, sell up to 2,598,829 shares of our common stock that it may purchase from us from time to time at our sole discretion in the future pursuant to the Purchase Agreement.

This prospectus provides you with a general description of our common stock. The selling stockholder is required to provide you with this prospectus and, in certain cases, a prospectus supplement containing specific information about the selling stockholder and the terms upon which the securities are being offered. A prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with the additional information described under the headings "Information Incorporated by Reference" and "Where You Can Find More Information" below.

We may also add, update or change information contained in this prospectus by incorporating by reference information that we file or furnish to the SEC. The registration statement that we filed with the SEC includes exhibits that provide more detail on the matters discussed in this prospectus. If the information in this prospectus is inconsistent with a prospectus supplement, you should rely on the information in that prospectus supplement. Please carefully read this prospectus and any prospectus supplement, together with the additional information described under the headings "Information Incorporated by Reference" and "Where You Can Find More Information" before purchasing any shares.

You should rely only on the information contained or incorporated by reference in this prospectus, any prospectus supplement and any issuer free writing prospectus. "Incorporated by reference" means that we can disclose important information to you by referring you to another document filed separately with the SEC. We have not authorized any other person to provide you with different information. If anyone provides you with different information, you should not rely on it. The selling stockholder is not making an offer of these shares in any state or jurisdiction where the offer is not permitted. You should only assume that the information in this prospectus or in any prospectus supplement or issuer free writing prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed since those dates.

In this prospectus, "Brickell," the "Company," "we," "us" and "our" refer to Brickell Biotech, Inc. and its consolidated subsidiaries, except where the context otherwise requires.

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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.



SUMMARY INFORMATION

This summary does not contain all the information that you should consider before investing in our Company. You should carefully read the entire prospectus and any accompanying prospectus supplement, including all documents incorporated by reference herein and therein.

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-ready clinical-stage product candidate, sofpironium bromide, is a proprietary new molecular entity. It belongs to a class of medications called anticholinergics. Anticholinergics block the action of acetylcholine, a chemical that transmits signals within the nervous system that are responsible for a range of bodily functions, including activation of the sweat glands. Sofpironium bromide was retrometabolically designed. Retrometabolic drugs are designed to exert their action topically and are potentially rapidly metabolized once absorbed into the blood. This proposed mechanism of action may allow for highly effective doses to be used while limiting systemic side effects. We intend to develop sofpironium bromide as a potential best-in-class, self-administered, once daily, topical therapy for the treatment of primary axillary hyperhidrosis.

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

We and our development partner in Asia, Kaken Pharmaceutical Co., Ltd., ("**Kaken**"), have conducted 19 clinical trials of sofpironium bromide gel that encompass over 1,300 subjects in the United States and Japan. These trials evaluated the potential safety, tolerability, pharmacokinetics (PK), and efficacy of sofpironium bromide gel in adult and pediatric primary axillary hyperhidrosis patients and healthy adult subjects. Under our License, Development and Commercialization Agreement with Kaken, dated March 31, 2015, in exchange for paying us an upfront, nonrefundable payment, we granted Kaken the exclusive right to develop, manufacture and commercialize sofpironium bromide in Japan and certain other Asian countries. In March 2019, Kaken completed a Phase 3 trial in patients with primary axillary hyperhidrosis in Japan, achieving statistical significance (p<0.05) on all primary and secondary endpoints.

Based on the positive results in the clinical trials for sofpironium bromide globally to date, we intend to initiate two pivotal Phase 3 clinical trials in up to 350 subjects per trial with primary axillary hyperhidrosis in the United States. Assuming the results of the Phase 3 clinical trials are favorable, we plan thereafter to submit a new drug application ("NDA") to the U.S. Food and Drug Administration (the "FDA"), for the treatment of primary axillary hyperhidrosis by sofpironium bromide.

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.

Recent Developments

Study Announcements

- In July 2020, we completed the analysis of our 12-month Phase 3 open-label long-term safety study, in 300 subjects 9 years and older with primary axillary hyperhidrosis, sofpironium bromide gel, 5% and 15%. The study results confirmed that sofpironium bromide gel, at both concentrations, was safe and generally well tolerated, which was consistent with the earlier Phase 2 clinical trial results. No treatment-related serious adverse events were observed. We expect to release additional details at an upcoming scientific forum.
- In June 2020, we announced positive Phase 3 pivotal study results in Japan from Kaken. All primary and secondary efficacy endpoints of the study were achieved and sofpironium bromide was safe and generally well tolerated. The study evaluated a total of 281 Japanese patients randomized 1:1 to apply sofpironium bromide gel, 5% (SB) or vehicle gel (placebo) to the axillae (i.e., underarm) for 42 days. These study results were presented as part of the Late-Breaking Research Program during the American Academy of Dermatology (AAD) Virtual Meeting Experience.
- In January 2020, Kaken announced submission of an NDA in Japan requesting approval to manufacture and market sofpironium bromide gel for primary axillary hyperhidrosis based on the positive Phase 3 data.

Upcoming Milestones

- Plan to initiate the U.S. Phase 3 pivotal program for sofpironium bromide in the fourth quarter of 2020. The planned program will be comprised of two pivotal Phase 3 trials to evaluate approximately 350 subjects per trial with primary axillary hyperhidrosis in the U.S. The first Phase 3 study is expected to begin in the fourth quarter of 2020.
- Expect Kaken to receive regulatory approval for sofpironium bromide in Japan, as early as the fourth quarter of 2020. Under the agreement with Kaken, we are entitled
 to receive commercial milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide in Japan.

Public Offering of Common Stock and Warrants

In June 2020, we entered into an underwriting agreement with Oppenheimer & Co. Inc. (**Oppenheimer**"), as representative of several underwriters, relating to the public offering, issuance and sale of 14,790,133 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 2,709,867 shares of our common stock, and accompanying common warrants to purchase up to an aggregate of 17,500,000 shares of our common stock (the "**Offering**"). Each share of common stock and pre-funded warrant to purchase one share of our common stock was sold together with a common warrant to purchase one share of our common warrant was \$1.15 and \$1.149 for each pre-funded warrant and accompanying common warrant, respectively. The pre-funded warrants were immediately exercisable at a price of \$0.001 per share of our common stock. The common warrants were immediately exercisable at a price of \$0.001 per share of our common stock. The shares of common stock and pre-funded warrants, were issued separately and were immediately separable upon issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The Offering resulted in approximately \$18.7 million of net proceeds after deducting underwriting commissions and discounts and other offering expenses of \$1.4 million and excluding the proceeds, if any, from the exercise of the warrants. We anticipate using the proceeds from the Offering for research and development, including clinical trials, working capital, and general corporate purposes.

At Market Issuance Sales Agreement

In April 2020, we entered into an At Market Issuance Sales Agreement (the "**ATM Agreement**") with Oppenheimer as our sales agent (the "**Agent**"). Pursuant to the terms of the ATM Agreement, we may sell from time to time through the Agent shares of our common stock having an aggregate offering price of up to \$8.0 million (the "**Shares**"). Any Shares will be issued pursuant to our shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the Shares, if any, will be made by means of ordinary brokers' transactions on the Nasdaq Capital Market at market prices or as otherwise



agreed by us and the Agent. Under the terms of the ATM Agreement, we may also sell the Shares from time to time to the Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the Shares to the Agent as principal would be pursuant to the terms of a separate placement notice between us and the Agent.

Amended and Restated License Agreement with Bodor

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

The Amended and Restated License Agreement retains with us a worldwide, exclusive license to develop, manufacture, market, sell and sublicense products containing the proprietary compound sofpironium bromide based upon the patents referenced in the Amended and Restated License Agreement for a defined field of use. In exchange for entering into the Amended and Restated License Agreement, settling the previously disclosed dispute, and resolving the associated litigation between us and Bodor, we made an upfront payment of \$1.0 million in cash to Bodor following the execution of the Amended and Restated License Agreement agreement by and among the Company, Brickell Subsidiary, Inc., and Bodor, dated February 17, 2020. Additionally, under the original license agreement with Bodor and the Amended and Restated License Agreement, we are required to pay Bodor (i) a royalty on sales of product outside Kaken's territory, including a low single-digit royalty on sales of certain product not covered by the patent estate licensed from Bodor; (ii) a specified percentage of all royalties we receive from Kaken for sales of product within its territory; (iii) a percentage of non-royalty sublicensing income we receive from Kaken or other sublicensees; and (iv) up to an aggregate of \$1.8 million (plus an additional \$0.1 million for approvals of additional products) in cash payments and \$1.5 million of shares of our common stock upon the achievement of certain development, regulatory and other milestones, including the enrollment of the first patient in the U.S. Phase 3 trials. During the three months ended June 30, 2020, based on the foregoing, we made a \$0.5 million milestone payment to Bodor following the closing of the public offering in June 2020 and accrued an additional \$1.0 million related to our plan to initiate our U.S. Phase 3 pivotal program in the fourth quarter of 2020. As a result, we recorded an aggregate of \$1.5 million as research and development expense in the condensed consolidated statements of operations during

The Lincoln Park Private Placement

In February 2020, we entered into a securities purchase agreement (the 'Securities Purchase Agreement') with Lincoln Park. Pursuant to the Securities Purchase Agreement, Lincoln Park purchased, and we sold, (i) an aggregate of 950,000 shares of common stock (the "Common Shares"), (ii) a warrant to initially purchase an aggregate of up to 606,420 shares of common stock at an exercise price of \$0.01 per share (the "Series A Warrant"), and (iii) a warrant to initially purchase an aggregate of up to 1,556,420 shares of common stock at an exercise price of \$1.16 per share (the "Series B Warrant", and together with the Series A Warrant, the "Warrants"). The aggregate gross purchase price for the Common Shares and the Warrants was \$2.0 million.

The Lincoln Park Transaction

Also in February 2020, we entered into (i) the Purchase Agreement and (ii) a registration rights agreement (the '**Registration Rights Agreement**') with Lincoln Park. Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$28.0 million in the aggregate of shares of our common stock. Sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the date the conditions set forth in the Purchase Agreement are satisfied (such date on which all of such conditions are satisfied, the "**Commencement Date**").

Following the Commencement Date, under the Purchase Agreement, on any business day we select, we may direct Lincoln Park to purchase up to 100,000 shares of common stock on such business day (each, a "**Regular Purchase**"), provided, however, that (i) the Regular Purchase may be increased to up to 125,000 shares, provided that the closing sale price of the common stock is not below \$3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below \$5.00 on the purchase date; subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed \$1,000,000. The purchase price per



share for each such Regular Purchase will be based off of prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, we may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, we may not sell shares of our common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of our common stock.

We agreed with Lincoln Park that we will not enter into any "variable rate" transactions with any third party, subject to certain exceptions, for a period defined in the Purchase Agreement. We have the right to terminate the Purchase Agreement at any time, at no cost or penalty.

Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of our common stock and our determinations as to the appropriate sources of funding for us and our operations. We expect that any net proceeds we receive from such sales to Lincoln Park will be used for research and development, working capital and general corporate purposes.

The Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions by, among and for the benefit of the parties. Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

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RISK FACTORS

An investment in our shares involves risks. We urge you to carefully consider all of the information contained in or incorporated by reference in this prospectus and other information which may be incorporated by reference in this prospectus or any prospectus supplement as provided under "Information Incorporated by Reference." In particular, you should consider the risk factors under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, which is incorporated by reference in this prospectus, as those risk factors are amended or supplemented by our subsequent filings with the SEC. This prospectus also contains forward-looking statements that involve risks and uncertainties. Please read "Cautionary Note Concerning Forward-Looking Statements." Our actual results could differ materially from those anticipated in the forward-looking statements as a result of certain factors, including the risks described in the documents incorporated by reference into this prospectus or any prospectus you could lose all or part of your investment.

RISKS RELATED TO OUR BUSINESS

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

The outbreak of the novel Coronavirus (COVID-19) has evolved into a global pandemic. The 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 coronavirus 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, 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 United States' and other countries' 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 is of our clinical trials.

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.

Under our Clinical Supply Agreement with Kaken, we owe an outstanding sum for Active Pharmaceutical Ingredient ("API") for further development of sofpironium 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 June 30, 2020, we owed Kaken approximately \$2.7 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.

RISKS RELATED TO THIS OFFERING

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On February 17, 2020, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to \$28,000,000 of shares of our common stock. The 2,598,829 shares of our common stock being registered for resale hereunder that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion.

We may not have access to the full amount available under the Purchase Agreement with Lincoln Park.

Under the Purchase Agreement with Lincoln Park, we may direct Lincoln Park to purchase up to a Regular Purchase on any business day, provided, however, that (i) the share limit for a Regular Purchase may be increased to up to 125,000 shares, provided that the closing sale price of the common stock is not below \$3.00 on the purchase date; and (ii) the share limit for a Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below \$5.00 on the purchase date; and (ii) the share limit for a Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below \$5.00 on the purchase date. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed \$1,000,000. Although the Purchase Agreement provides that we may sell up to \$28,000,000 of our common stock to Lincoln Park, only 2,598,829 shares of our common stock are being offered under this prospectus which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement. As a result, depending on the market prices of our common stock, we may not be able to sell the full \$28,000,000 commitment amount contemplated by the Purchase Agreement. For example, assuming that we sell all of the 2,598,829 shares of our common stock an average purchase price of \$0.889 per share (which was the closing price of our common stock on The Nasdaq Capital Market on August 12, 2020), our total gross proceeds would only be \$2,310,359.

In the event that the market prices of our common stock increases, we may be able to issue and sell more than the 2,598,829 shares of our common stock to Lincoln Park in an effort to obtain up to the full \$28,000,000 commitment amount



contemplated by the Purchase Agreement; provided in such case we will need to register for resale under the Securities Act such incremental additional shares of our common stock, which will require additional time, resources and cost to us. In addition, the issuance and sale of such additional shares could cause substantial dilution to our stockholders.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all \$28,000,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects.

Our management might apply the net proceeds from this offering in ways with which you do not agree and in ways that may impair the value of your investment.

We currently intend to use the net proceeds from this offering for general corporate purposes. Our management has broad discretion as to the use of these proceeds and you will be relying on the judgment of our management regarding the application of these proceeds. We might apply these proceeds in ways with which you do not agree, or in ways that do not yield a favorable return. If our management applies these proceeds in a manner that does not yield a significant return, if any, on our investment of these net proceeds, it could compromise our ability to pursue our growth strategy and adversely affect the market price of our common stock.

USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholder. We will receive no proceeds from the sale of shares of common stock by the selling stockholder in this offering. However, we may receive gross proceeds of up to \$28,000,000 under the Purchase Agreement, including the sale of up to 2,598,829 shares of common stock issuable pursuant to the Purchase Agreement, which are being registered hereunder for resale by the selling stockholder. These proceeds received from our sale of common stock to the selling stockholder under the Purchase Agreement will be used for research and development, working capital and general corporate purposes. Please see "Selling Stockholder."

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DILUTION

The sale of our common stock to Lincoln Park pursuant to the Purchase Agreement will have a dilutive impact on our stockholders. In addition, the lower our stock price is at the time we exercise our right to sell shares to Lincoln Park, the more shares of our common stock we will have to issue to Lincoln Park pursuant to the Purchase Agreement and our existing stockholders would experience greater dilution.

Our net tangible book value as of June 30, 2020 was approximately \$19.9 million, or \$0.75 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of June 30, 2020. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by Lincoln Park in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 2,598,829 shares of our common stock to Lincoln Park pursuant to the Purchase Agreement at an assumed average sale price of \$0.889 per share of our common stock, the last reported sale price of our common stock on The Nasdaq Capital Market on August 12, 2020, and after deducting estimated offering expenses payable by us, our as-adjusted net tangible book value as of June 30, 2020 would have been approximately \$22.2 million, or \$0.76 per share. This represents an immediate increase in net tangible book value of \$0.01 per share to existing stockholders and dilution of \$0.13 per share of as-adjusted net tangible book value to new investors based on the assumed average sales price of \$0.889 per share of common stock.

Each \$0.10 increase or decrease in the assumed average sale price of \$0.889 per share, which was the last reported sale price of our common stock on The Nasdaq Capital Market on August 12, 2020, would increase or decrease the as-adjusted net tangible book value per share by \$0.01 per share and the dilution per share to new investors participating in this offering by \$0.14 per share, after giving effect to the sale of 2,598,829 shares of our common stock to Lincoln Park pursuant to the Purchase Agreement.

To the extent that stock options or warrants outstanding as of June 30, 2020 have been or may be exercised or other shares are issued, investors purchasing our common stock in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

THE LINCOLN PARK TRANSACTION

General

On February 17, 2020, we entered into the Purchase Agreement with Lincoln Park. Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$28,000,000 in the aggregate of shares of our common stock. Sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the Commencement Date. Also, in connection with the Purchase Agreement, we entered into the Registration Rights Agreement with Lincoln Park, pursuant to which we agreed, *inter alia*, to register shares of common stock that have been or may be issued under the Purchase Agreement under the registration statement of which this prospectus is a part.

Actual sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of our common stock and our determinations as to the appropriate sources of funding for us and our operations. We expect that any net proceeds we receive from such sales to Lincoln Park will be used for research and development, working capital and general corporate purposes.

Under applicable rules of The Nasdaq Capital Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement shares of our common stock in excess of 1,740,452 shares (inclusive of any shares which may be aggregated with sales under the Purchase Agreement pursuant to the rules of The Nasdaq Capital Market), which represents 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement (the "**Exchange Cap**"), unless (i) we obtain stockholder approval to issue shares of our common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds the lower of (i) the Nasdaq official closing price immediately preceding the execution of the Purchase Agreement or (ii) the average of the five Nasdaq official closing prices for our common stock immediately preceding the execution of the Purchase Agreement, plus an incremental amount such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules.

The Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions by, among and for the benefit of the parties. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement, and we have the right to terminate the Purchase Agreement at any time, at no cost or penalty.

Purchase of Shares under the Purchase Agreement

Following the Commencement Date, under the Purchase Agreement, on any business day we select, we may direct Lincoln Park to purchase a Regular Purchase, provided, however, that (i) the Regular Purchase may be increased to up to 125,000 shares, provided that the closing sale price of the common stock is not below \$3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below \$5.00 on the purchase date; subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed \$1,000,000. The purchase price per share for each such Regular Purchase will be based off of prevailing market prices of common stock is may direct Lincoln Park to purchase of the common stock as additional accelerated purchases if the closing sale price of the common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of our common stock (the "Beneficial Ownership Cap").

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.



Events of Default

Events of default under the Purchase Agreement include the following:

- (a) the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;
- (b) the suspension of our common stock from trading on The Nasdaq Capital Market for a period of one (1) business day, provided that we may not direct Lincoln Park to purchase any shares of our common stock during any such suspension;
- (c) the delisting of our common stock from The Nasdaq Capital Market, provided, however, that our common stock is not immediately thereafter trading on the New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market, the NYSE American, the NYSE Arca, the OTC Bulletin Board or the OTCQB or OTCQX operated by the OTC Markets Group, Inc. (or nationally recognized successor to any of the foregoing);
- (d) If at any time after the Commencement Date, the Exchange Cap is applicable and we have issued more than 19.99% of our common stock under the Purchase Agreement unless and until stockholder approval is obtained pursuant to the Purchase Agreement. The Exchange Cap shall be deemed to be exceeded at such time if, upon submission of a purchase notice under the Purchase Agreement, the issuance of such shares of our common stock would exceed that number of shares of common stock which we may issue under the Purchase Agreement without breaching our obligations under the rules or regulations of The Nasdaq Capital Market;
- (e) the transfer agent's failure for three business days to issue to Lincoln Park shares of our common stock which Lincoln Park is entitled to receive under the Purchase Agreement;
- (f) any breach of the representations or warranties or covenants contained in the Purchase Agreement or any related agreement which has or which could have a material adverse effect on us subject to a cure period of five business days;
- (g) any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or
- (h) if at any time we are not eligible to transfer our common stock electronically.

In addition to any other rights and remedies under applicable law and the Purchase Agreement, so long as an Event of Default has occurred and is continuing, or if any event which, after notice and/or lapse of time, would become an Event of Default, has occurred and is continuing, we shall not deliver to Lincoln Park any Regular Purchase notice or accelerated purchase notice.

Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Prohibitions on Variable Rate Transactions

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement other than a prohibition on entering into a "Variable Rate Transaction," as defined in the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

All 2,598,829 shares registered in this offering which may be issued or sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 36-months from August of 2020. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock to Lincoln Park, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any additional sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to \$28,000,000 of our common stock. The Purchase Agreement prohibits us from issuing or selling to Lincoln Park (i) shares of our common stock in excess of the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of our common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds the lower of (i) the Nasdaq official closing price immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for our common stock immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for our common stock immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for our common stock immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for our common stock immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for our common stock immediately preceding the execution of the Purchase Agreement or (ii) the arithmetic average of the five Nasdaq official closing prices for our common stock immediately preceding the execution of the Purchase Agreement or (ii) the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules. Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal t

The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices:

Number of Registered Shares to be Issued if Full Purchase ⁽¹⁾	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park ⁽²⁾	Proceeds from the Sale of Shares to Lincoln Park Under the \$28 Million Purchase Agreement
1,740,452	5.9%	\$870,226
1,740,452	5.9%	\$1,547,262
1,740,452	5.9%	\$1,740,452
2,598,829	8.6%	\$5,197,658
2,598,829	8.6%	\$7,796,487
	Registered Shares to be Issued if Full Purchase (1) 1,740,452 1,740,452 1,740,452 2,598,829	Number of Registered Shares to be Issued if Full Purchase (1)Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (2)1,740,4525.9%1,740,4525.9%1,740,4525.9%2,598,8298.6%

(1) Although the Purchase Agreement provides that we may sell shares of common stock valued at up to \$28,000,000, the shares of common stock registered hereunder may or may not cover all the shares of common stock we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a



result, we have included in this column only those shares of common stock that we are registering in this offering, while giving effect to the Exchange Cap and without regard for the Beneficial Ownership Cap.

(2) The denominator is based on 27,787,081 shares outstanding as of August 12, 2020, adjusted to include the number of shares of common stock set forth in the adjacent column which we would have issued to Lincoln Park based on the applicable assumed average purchase price per purchase share.

(3) The closing sale price of our shares on August 12, 2020.

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DESCRIPTION OF CAPITAL STOCK

As of June 30, 2020, our restated certificate of incorporation authorized us to issue 50,000,000 shares of common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share. As of June 30, 2020, we had 26,671,573 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 \$1.25 per share; (iv) 1,556,420 shares of our common stock at an exercise price of \$1.25 per share and (vi) 1,113,424 shares of our common stock at an exercise price of \$1.001 per share. As of June 30, 2020, we also had (i) 1,578,231 options issued and outstanding to purchase our common stock at a weighted average exercise price of \$1.303 per share and (ii) 253,045 shares of common stock underlying unvested restricted stock units outstanding. At our 2020 Annual Meeting of Stockholders on April 20, 2020, our stockholders approved the 2020 Omnibus Long-Term Incentive Plan (the "**Omnibus Plan**"), pursuant to which 679,389 shares of common stock are reserved for future issuance. If the holders of our outstanding stock options and warrants exercise to acquire our common stock, the percentage ownership of our stockholders existing prior to the exercise of such rights will be diluted. No shares of preferred stock were outstanding.

As described in our definitive proxy statement filed with the SEC on July 15, 2020, we plan to hold a special meeting of stockholders on August 31, 2020, at which stockholders will be requested to approve an amendment to our restated certificate of incorporation to increase the number of authorized shares of common stock from 50,000,000 to 100,000,000. If stockholders approve that amendment, our board of directors plans to utilize a portion of those additional authorized shares to again reserve for issuance the number of shares available for grant under the Omnibus Plan. At the special meeting, our stockholders will also be requested to approve an amendment to the Omnibus Plan to increase the number of shares available for issuance thereunder by 4,500,000 shares.

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 our liquidation, dissolution or winding up, 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, expense, mortgage, pledge, transfer or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- · subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- · any transaction involving the corporation that has the effect of increasing the proportionate share of its stock owned by the interested stockholder; or
- · the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

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

Certificate of Incorporation and Bylaws

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

- provide for a board comprised of three classes of directors with each class serving a staggered three-year term;
- authorize our board of directors to issue preferred stock from time to time, in one or more classes or series, without stockholder approval;
- require the approval of at least two-thirds of our outstanding voting stock to amend specified provisions of our restated certificate of incorporation;
- require the approval of at least two-thirds of our total number of authorized directors, or two-thirds of our outstanding voting stock, to amend our amended and restated bylaws;
- provide that special meetings of our stockholders may be called only by our Chief Executive Officer, or by our board of directors pursuant to a resolution adopted by a
 majority of the total number of authorized directors;
- provide that vacancies on our board of directors and newly created directorships may be filled only by a majority of the directors then in office, though less than a quorum, or by a sole remaining director; and
- do not include a provision for cumulative voting for directors (under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors).

The Nasdaq Capital Market Listing

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

Transfer Agent and Registrar

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



SELLING STOCKHOLDER

The shares of common stock being offered by the selling stockholder are those which may be issued to such selling stockholder pursuant to the Purchase Agreement. We are registering these shares of common stock in order to permit the selling stockholder, to offer the shares for resale from time to time. Should we direct the selling stockholder to purchase shares of our common stock, it may resell such shares pursuant to the shares being registered hereunder pursuant to the Purchase Agreement.

We do not know how long the selling stockholder will hold the shares before selling them or how many shares the selling stockholder will sell and we currently have no agreements, arrangements or understandings with the selling stockholder regarding the sale of any of the shares of common stock registered under the registration statement of which this prospectus is a part.

The following table sets forth the maximum number of shares of our common stock to be sold by the selling stockholder. The table also sets forth the name of the selling stockholder, the nature of any position, office, or other material relationship which the selling stockholder has had, within the past three years, with us or with any of our predecessors or affiliates, and the number of shares of our common stock to be owned by such selling stockholder after completion of the offering.

We prepared the table based on information provided to us by the selling stockholder. We have not sought to verify such information. Additionally, the selling stockholder may have sold or transferred some or all of its shares of our common stock in transactions exempt from the registration requirements of the Securities Act since the date on which the information in the table was provided to us. Other information about the selling stockholder may also change over time.

Except as otherwise indicated, each selling stockholder has sole voting and dispositive power with respect to such shares.

	Shares of Common Stock Beneficially Owned Prior to the Offering(1)(2)		Shares of Common Stock Being Offered Hereby(4)	Shares of Common Stock Beneficially Owned After Completion of the Offering(5)	
Name of Selling Stockholder	Number	Percent(3)	Number	Number	Percent(3)
Lincoln Park Capital Fund, LLC	2,775,929	9.99%	2,598,829	3,035,552	9.99%

(1) Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the 'Exchange Act'). In computing the number of shares beneficially owned by a person and the percentage ownership of the selling stockholder, securities that are currently exercisable into shares of our common stock, or exercisable into shares of our common stock within 60 days of the date hereof are deemed outstanding.

(2) Ownership prior to the offering excludes the 2,598,829 shares of common stock which may be issued to the selling stock under the Purchase Agreement and are registered hereunder. Ownership prior to the offering consists of (i) 1,808,169 shares directly owned by the selling stockholder, (ii) 3,432,289 shares issuable upon the exercise of the warrants held by the selling stockholder, which are subject to beneficial ownership limitations which restrict the exercise of such warrants if, as a result of such exercise, the selling stockholder, the holder, together with its affiliates and any other person whose beneficial ownership of common stock would be aggregated with the selling stockholder for purposes of Section 13(d) of the Exchange Act would exceed 9.99% of the number of shares of our common stock outstanding.

(3) Calculated based on 27,787,081 shares of our common stock outstanding on August 12, 2020.

(4) Although the Purchase Agreement provides that we may sell up to \$28,000,000 of our common stock to the selling stockholder, only 2,598,829 shares of our common stock are being offered under this prospectus. Depending on the price per share at which we sell our common stock to the selling stockholder pursuant to the Purchase Agreement, we may need to sell to the selling stockholder under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal to the \$28,000,000 total commitment available to us under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares. The number of shares ultimately offered for resale by the selling stockholder is dependent upon the number of shares we sell to the selling stockholder under the Purchase Agreement.

(5) Calculated by dividing (i) the total number of shares beneficially owned by the selling stockholder on June 30, 2020, assuming all shares of common stock registered hereunder have been resold by the selling stockholder, by (ii) the number of shares of our common stock outstanding as of June 30, 2020, as adjusted to include the 2,598,829 shares which may be issued to the selling stockholder hereunder in connection with the Purchase Agreement that are registered hereunder.

PLAN OF DISTRIBUTION

The shares of common stock listed in the table appearing under "Selling Stockholder" are being registered to permit the resale of the shares by the selling stockholder from time to time after the date of this prospectus. There can be no assurance that the selling stockholder will sell any or all of the common stock offered hereby. We will not receive any of the proceeds from the sale of the common stock by the selling stockholder. We will pay substantially all of the expenses incident to this offering of the shares by the selling stockholder to the public other than commissions and discounts of underwriters, brokers, dealers or agents.

The selling stockholder may sell all or a portion of the shares of common stock beneficially owned by it and offered hereby from time to time directly to purchasers or through one or more underwriters, broker-dealers or agents, at market prices prevailing at the time of sale, at prices related to such market prices, at a fixed price or prices subject to change or at negotiated prices, by a variety of methods including the following:

- on any national securities exchange or over-the-counter market on which the shares of common stock may be listed or quoted at the time of sale;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which a broker-dealer may attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- · purchases by a broker-dealer, as principal, and a subsequent resale by the broker-dealer for its account;
- in "at the market" offerings to or through market makers into an existing market for the shares;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- · in transactions otherwise than on such exchanges or in the over-the-counter market;
- · through a combination of any such methods; or
- through any other method permitted under applicable law.

Lincoln Park is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

In effecting sales, brokers-dealers engaged by the selling stockholder may arrange for other brokers-dealers to participate. If the selling stockholder effects such transactions by selling the common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholder or commissions from purchasers of the common stock for whom they may act as agent or to whom they may sell as principal. Underwriters may sell securities to or through dealers, and dealers may receive compensation in the form of discounts, concessions or commissions from the purchasers for whom they may act as agent.

The selling stockholder and any underwriters, brokers, dealers or agents that participate in such distribution may be deemed to be "underwriters" within the meaning of the Securities Act, and any discounts, commissions or concessions received by any underwriters, brokers, dealers or agents might be deemed to be underwriting discounts and commissions under the Securities Act. Any selling stockholder who is an "underwriter" within the meaning of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act and the provisions of the Exchange Act and the rules thereunder relating to stock manipulation.

In order to comply with the securities laws of some states, the shares sold in those jurisdictions may only be sold through registered or licensed brokers or dealers. In addition, in some states, the shares may not be sold unless the shares have been registered or qualified for sale in that state or an exemption from registration or qualification is available and is complied with.



Underwriters, dealers and agents who participate in the distribution of securities and their controlling persons may be entitled, under agreements that may be entered into with us, to indemnification by us and the selling stockholder against certain liabilities, including liabilities under the Securities Act, or to contribution with respect to payments that the underwriters, dealers or agents and their controlling persons may be required to make in respect of those liabilities.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference information into this document. This 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 quarter ended<u>March 31, 2020</u> filed with the SEC on May 14, 2020 and the quarter ended<u>June 30, 2020</u> filed with the SEC on August 12, 2020;
- our current reports on Form 8-K filed with the SEC on February 10, 2020, February 10, 2020, February 10, 2020, February 18, 2020, March 18, 2020 (with respect to Item 8.01 only), April 3, 2020, April 14, 2020, April 20, 2020 (as amended on June 26, 2020) June 2, 2020 and June 15, 2020 and June 18, 2020 (in each case, except for information contained therein which is furnished rather than filed);
- our definitive proxy statement on Schedule 14A filed with the SEC on March 30, 2020, as amended April 3, 2020; and
- the description of our common stock contained in our registration statement on Form S-8 filed with the SEC on September 10, 2019, including any amendment or report filed for the purpose of updating such description.

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

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

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

You may also access these filing on our website at www.brickellbio.com. You should rely only on the information incorporated by reference or provided in this prospectus or in any prospectus supplement. 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 or any prospectus supplement is accurate as of any date other than the date of those 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 Mayer Brown LLP, New York, New York.

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.

O BrickellBio

2,598,829 Shares of Common Stock

PROSPECTUS

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