

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2019

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 000-21088

BRICKELL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

93-0948554

(I.R.S. Employer Identification No.)

5777 Central Avenue, Suite 102, Boulder, CO

(Address of principal executive offices)

80301

(Zip Code)

(720) 505-4755

(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant, based upon the closing sale price of the registrant's common stock on June 28, 2019, as reported on The Nasdaq Capital Market, was \$19.4 million. Shares of common stock held by each executive officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 12, 2020, there were 9,669,402 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2020 annual meeting of shareholders (the "2020 Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2020 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

BRICKELL BIOTECH, INC.
FORM 10-K
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PART I.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (“Annual Report”) 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 Annual Report 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. Unless otherwise mentioned or unless the context requires otherwise, all references in this Annual Report, to “Brickell,” “Brickell Subsidiary,” “company,” “we,” “us,” and “our,” or similar references, refer to Brickell Biotech, Inc., and our consolidated subsidiaries.

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 Part I, Item IA, “Risk Factors” in this Annual Report, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (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 Annual Report, 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 Annual Report 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 and on our website.

ITEM 1. BUSINESS

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, (the “Kaken Agreement”) 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. In January 2020, we announced that Kaken submitted a new drug application (“NDA”) for approval in Japan of manufacturing and marketing of sofpironium bromide for primary axillary hyperhidrosis.

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, subject to obtaining substantial additional funding. Assuming the results of the Phase 3 clinical trials are favorable, we plan thereafter to submit an NDA to the U.S. Food and Drug Administration (the “FDA”), for the treatment of primary axillary hyperhidrosis by sofpironium bromide.

Our Strategy

Our strategy is to develop and commercialize innovative and differentiated medical dermatology products that we believe can be successful in the dermatology marketplace to transform lives by solving currently unmet patient needs. The key components of our patient-focused strategy are to:

Advance our lead late-stage product candidate, sofpironium bromide, through pivotal Phase 3 clinical trials and engage appropriately with patients and members of the dermatology community. We believe that our management team’s expertise in designing and executing product development programs in dermatology and other therapeutic areas, combined with the relative efficiencies of dermatology product development, will enable us to commence and advance sofpironium bromide through pivotal Phase 3 clinical trials. If approved, we intend to promote awareness of sofpironium bromide, and also the disease being targeted, among key opinion leaders, including prescribing dermatologists and pediatricians, patient advocacy groups like the International Hyperhidrosis Society, and directly to patients and their families coping with primary axillary hyperhidrosis. Consumer activation through a variety of media, including social media, will be essential to educate patients appropriately regarding hyperhidrosis and the potential benefits associated with a safe, effective, and differentiated treatment option for this debilitating condition.

Evaluate our existing early-stage product candidates and/or in-license and acquire new product candidates and, potentially, commercial-stage products while maintaining a strong relationship with our current strategic partner. We intend to continue to evaluate our existing pipeline of product candidates and will also explore other potential external product opportunities. We intend to continue to identify, evaluate, in-license and acquire attractive product candidates at the right level of investment from a variety of strategic sources. We entered into an out-license transaction with Kaken, for the development and commercialization of sofpironium bromide in Japan and certain other Asian countries. We expect to continue to engage with Kaken and further develop our strong global partnership to create value for sofpironium bromide in the United States, Japan, and other countries.

Expand our team of enthusiastic, committed, and experienced professionals. We intend to expand our team by selectively identifying and hiring diverse, dedicated, talented, experienced, and patient-centric employees who align with our culture, values, and patient-centric mission and can make significant contributions to our company, consistent with our current (and any future) financing.

Hyperhidrosis

Hyperhidrosis is a debilitating life-altering skin disorder of chronic excessive sweating beyond what is necessary for thermoregulation of the body. Current estimates show that primary axillary hyperhidrosis (excessive sweating without an alternative origin) affects approximately 4.8% of the U.S. population, or roughly 15.3 million people, with the prevalence rate of 8.8% and 17.1% among the U.S. population ages 18 to 39 and 12 to 17, respectively. Of hyperhidrosis sufferers, 70% report severe excessive sweating that they cannot control or shut off in at least one body area. The most common area is the underarms (axilla), followed by the face (42%), palms of the hands (40%), and the soles of the feet (38%). It is estimated that nearly half (49%) of people with hyperhidrosis have not discussed their condition with a healthcare professional, either because they do not yet know it is a medical condition or believe that no adequate treatment options exist. Furthermore, in one survey, 75% of subjects with hyperhidrosis said that it has had negative impacts on their professional and social lives, sense of well-being, and emotional and mental health. We believe that, due to the lack of diagnosis and available treatment options, and general lack of knowledge about the disease, hyperhidrosis presents a substantial market opportunity for a new, innovative, effective, well-tolerated, topical treatment. We believe such a therapy could not only further penetrate the segment of patients who currently seek treatment from a physician, but also encourage more patients to seek treatment for this condition that causes them to deal with (and try to hide) it each and every day.

Current Hyperhidrosis Treatment Options and Limitations

The market for products to control sweating is large and highly underpenetrated by innovative prescription pharmaceutical products thoroughly tested in clinical trials. More specifically, current hyperhidrosis treatment options generally fall into one of the following categories:

- **Self-administered topicals**, which include topical antiperspirants, some of which are prescription only, containing metal salts like aluminum that block the release of sweat to the skin surface by clogging the opening of the duct and Qbrexza® (glycopyrronium), approved in June 2018 by the FDA for the topical treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older. For decades, topical antiperspirants containing metal salts have been the most widely used treatment option for hyperhidrosis. Over-the-counter (“OTC”) antiperspirants contain low concentrations of metal salts and are generally well-tolerated but limited in efficacy. Prescription antiperspirants containing higher concentrations of metal salts are typically recommended as the treatment of choice when OTC antiperspirants are ineffective. However, these are only marginally more effective, and their tolerability is limited by skin irritation associated with increased metal salt concentrations, which react with water to form irritating hydrochloric acid on the skin. Qbrexza is administered by prescription using a single-use cloth pre-moistened with the active ingredient, 2.4% glycopyrronium solution, packaged in individual pouches. Qbrexza inhibits the action of acetylcholine on sweat glands, thereby reducing sweating. While Qbrexza has shown to be effective in treating primary axillary hyperhidrosis, we believe that there is room in the market for products with improved efficacy and/or tolerability profiles.
- **Injectable, systemic, and other treatments** that block activation of the sweat glands. Therapeutic options for patients who are not satisfied with topical therapies are largely limited to more cumbersome or invasive treatment strategies directed either to blocking the activation of, destroying, or removing altogether the sweat glands. Intra-dermal injections of botulinum toxin type A, or BOTOX®, a neurotoxin that blocks the release of acetylcholine, are effective but can be painful, costly, and must be administered by a physician with patients receiving on average 20 to 40 injections to each

arm pit every six to nine months. A microwave device, MiraDry®, is designed to overheat and destroy sweat glands as a different option. However, treatment with MiraDry® may be painful, require multiple physician visits, cause permanent destruction of the sweat glands, and is not generally covered by insurance. All these treatments are time-consuming and require a significant investment of physician training and administration time and, in the case of microwave treatment, capital investment by the treating physician. As a result, these treatments have limited attractiveness both to doctors and their patients. Furthermore, they are also not approved or well-suited for application to the hands or feet. Iontophoresis, which involves soaking the hands or feet in water through which an electrical current is passed, can be performed in a physician's office or at home, but requires repeated, time-consuming, and often bothersome treatments.

- ***Surgical and other procedures intended to destroy or remove sweat glands.*** Some patients with severe hyperhidrosis may choose to be treated with invasive surgical techniques that involve removal of sweat glands or destruction of nerves that transmit activating signals to the glands. Surgery is a significant and costly permanent undertaking that can be associated with numerous severe side effects, including increased compensatory sweat production in other body areas.

Deciding among these available treatments depends on many factors including the affected area, severity of the disease and impact on the patient's quality of life due to the disease being uncontrolled. As a result of the limitations of these currently available treatment options, we believe that there is a significant unmet patient need for a new, effective, safe, well-tolerated, self-administered, prescription topical hyperhidrosis therapy.

Sofpironium Bromide for Primary Axillary Hyperhidrosis

Sofpironium bromide is a potentially best-in-class topical anticholinergic product candidate we intend to develop for once-daily treatment of primary axillary hyperhidrosis in adult and pediatric patients nine years of age and older. Sofpironium bromide was designed as a structural analog of a well-known potent anticholinergic, glycopyrrolate, to achieve its therapeutic effect at the application site (skin) similar to glycopyrrolate. However, it differs from glycopyrrolate in that sofpiroonium bromide was retrometabolically designed. Retrometabolic drugs are intended to exert their action topically and are potentially more rapidly metabolized once absorbed into the blood. This retrometabolic approach to drug design is intended to allow for highly effective doses to be used while limiting systemic side effects.

Key design attributes of a retrometabolic drug include:

- The synthesis of a retrometabolic drug is achieved by starting with a known inactive metabolite of a known active drug (e.g., glycopyrrolate).
- The inactive, or less active, metabolite is then structurally modified to an active form (an analogue of active drug in this case; glycopyrrolate) that will undergo a predictable one-step transformation back into the inactive metabolite in vivo.
- Thus, the retrometabolic drug concept is based upon predictable metabolic deactivation processes by enzymes found predominantly in the systemic circulation.

Sofpironium bromide is delivered as a gel formulation in a metered-dose pump with an applicator that allows patients to avoid unwanted direct contact to the hands or other non-axillary body parts. We believe that this will help avoid certain side effects that could be caused by the unintended transference of the drug such as to the eyes.

Clinical Development of Sofpironium Bromide

We, together with our partner Kaken, have conducted 19 clinical trials of sofpiroonium bromide gel that encompass over 1,300 subjects in the United States and Japan. These trials evaluated the safety, tolerability, PK, and efficacy of sofpiroonium bromide gel in adult and pediatric primary axillary hyperhidrosis patients and healthy adult subjects.

In clinical studies conducted to date, all three concentrations of sofpiroonium bromide gel tested (5%, 10%, and 15%) were safe and well tolerated. Treatment-emergent adverse events ("TEAEs") were mostly mild or moderate in severity. There has been one death unrelated to sofpiroonium bromide and no serious adverse reactions have been reported in any clinical studies with sofpiroonium bromide gel. Twelve serious adverse events have been reported and all were determined to be unrelated to sofpiroonium bromide gel administration. Consistent with a retrometabolic drug design, a low incidence of systemic TEAEs has been found in all clinical studies of sofpiroonium bromide gel with a trend toward dose-dependency observed. The most common TEAEs were dry mouth and blurred vision. Of note, the TEAEs were predominantly mild or moderate in severity and transient

in duration (i.e., resolving gradually with continued use). Local application site tolerability reactions of burning, itching, pain, erythema, and dryness at the axillae were predominantly minimal in severity and typically transient.

Overall, all three sofpironium bromide gel concentrations, 5%, 10%, and 15%, exhibited a larger absolute mean reduction in gravimetric sweat production (“GSP”) from baseline to end of treatment (“EOT”), compared with vehicle, with the reduction with the 15% concentration being statistically significant. However, while there was a slight trend toward dose response, all gel concentrations were essentially similar in patient-reported outcome measures based on the Hyperhidrosis Disease Severity Measure-Axillary (“HDSM-Ax”), modified Dermatology Life Quality Index (“DLQI”), and Hyperhidrosis Disease Severity Score (“HDSS”). The HDSM-Ax responses were seen as early as Day 8 and remained consistent throughout the applicable treatment period.

Phase 2b U.S. Clinical Trial (BBI-4000-CL-203)

The Phase 2b U.S. clinical trial was a multicenter, randomized, double blind, vehicle-controlled clinical trial to evaluate the safety and efficacy of topically-applied sofpironium bromide gel, 5%, 10%, and 15%, in patients with primary axillary hyperhidrosis. The trial enrolled a total of 227 patients across 23 clinical sites in the United States, with patients randomized to either sofpironium bromide gel, 5% (n=57), 10% (n=57), 15% (n=56), or vehicle gel (placebo; n=57) who applied the assigned product to the axillae (underarms) once daily, at bedtime, for 42 days. The objectives of this trial were to evaluate (1) the effect of sofpironium bromide gel, 5%, 10%, and 15% on hyperhidrosis disease severity as it relates to HDSM-Ax, GSP, HDSS, and modified DLQI; and (2) the safety and local tolerability of sofpironium bromide gel, 5%, 10%, and 15%.

Changes in HDSM-Ax measures indicated statistically significant differences from placebo (vehicle gel) in all sofpironium gel dose groups with all methods of analysis. Statistically significant differences in favor of active treatment groups were observed as early as Day 8 and were sustained over time. A significant higher proportion of active treatment subjects had at least a 2-point change from baseline to EOT in HDSM-Ax-11 items scale (5% gel: 47.4%, p=0.007; 10% gel: 49.1%, p=0.006; 15% gel: 50.0%, p=0.002; vehicle: 22.8%). Larger absolute mean reductions in GSP from baseline to EOT were found for all sofpironium bromide gel concentrations compared to vehicle gel, with the results with sofpironium bromide gel, 15% being statistically significant. Treatment with sofpironium bromide gel, 15% (pivotal Phase 3 active dose group) resulted in statistically significant reduction in GSP from baseline to EOT (-217 mg, p=0.06; vehicle -143 mg). The 5% and 10% dose groups resulted in -163 mg (p=0.32) and -174 mg (p=0.26) reduction in GSP from baseline to EOT, respectively. Consistently, superior ranked values indicating GSP reduction from baseline to EOT were observed for sofpironium bromide gel, 15% in comparison to vehicle. The ranked order analysis did not indicate a baseline to EOT reduction in GSP for the vehicle group; a p-value of 0.04 comparing sofpironium bromide, 15% gel to vehicle indicated the sofpironium bromide, 15% improvement to be real and not observed by chance. All sofpironium bromide gel groups met the secondary efficacy endpoints for HDSS and modified DLQI. It was prespecified in the study protocol and statistical analysis plan that as a Phase 2 study, a 1-sided p<0.10 in favor of an active treatment would be regarded as statistically significant. All p-values cited in this study were 1-sided per the protocol and statistical analysis plan.

Among the safety population (includes all subjects who received study drug at least once; n=225), the subject incidence of TEAEs was higher in the sofpironium bromide gel 15% group (51.9%) compared to the other groups (5% gel, 29.8%; 10% gel, 33.6%; vehicle gel, 15.8%). The majority of the systemic TEAEs were consistent with adverse events due to anticholinergic activity. The most common TEAEs included dry mouth (5% gel, 15.8%; 10% gel, 17.5%; 15% gel, 22.2% and vehicle gel, 1.8%) and blurred vision (5% gel, 3.5%; 10% gel, 10.5%; 15% gel, 9.3% and vehicle gel, 0.0%). The majority of TEAEs in each group were mild or moderate in severity. Severe TEAEs were reported by 4 subjects in the 15% group and 2 subjects each in the 10% and 5% groups. The vast majority of severe TEAEs were anticholinergic TEAEs (dry mouth and vision blurred) or application site TEAEs (application site pain, application site pruritus, application site erythema, application site dryness, and application site exfoliation). There was one case of osteomyelitis which was severe and an SAE and was not related to sofpironium bromide. Treatment in all dose groups was well-tolerated. Local tolerability assessments indicated that all three active treatment groups; 15%, 10%, and 5% were well tolerated over the 42-day treatment period. Each local tolerability symptom/sign (burning, itching, dryness, scaling, and erythema) was absent in the majority of subjects in each group at each study visit. The incidence of these symptoms/signs was generally higher in the sofpironium bromide gel groups compared to the vehicle group. The majority of tolerability symptoms/signs were minimal to mild in severity and most resolved by the Day 57 visit. Severe tolerability symptoms/signs (burning, itching, and erythema) were reported only in the sofpironium gel groups.

Phase 3 Clinical Trials

Kaken has completed its pivotal Phase 3 clinical trial in subjects with primary axillary hyperhidrosis in Japan and achieved statistical significance (p<0.05) for primary and all secondary efficacy endpoints. In January 2020, we announced that Kaken

submitted an NDA for approval of manufacturing and marketing for sofipironium bromide in Japan for primary axillary hyperhidrosis.

Based on the positive results in the clinical trials conducted by us and Kaken 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, subject to obtaining substantial additional funding. Assuming the results of the Phase 3 clinical trials are favorable, we plan thereafter to submit an NDA to the FDA for the treatment of primary axillary hyperhidrosis.

Other Pipeline Programs

We have the rights to several other dermatology focused compounds in pre-clinical and clinical stages. We are primarily focused on the development of sofipironium bromide for primary axillary hyperhidrosis and will continue to evaluate the development of our pipeline.

Competition

Our industry is highly competitive and subject to rapid and significant change. While we believe that our team's extensive development and commercialization pharmaceutical experience in launching blockbuster drugs across multiple therapeutic areas, scientific knowledge, and global industry relationships provide us with competitive advantages, we face competition from pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, as well as generic drug companies, OTC companies, academic institutions, government agencies and research institutions.

Many of our competitors have significantly greater financial, technical, and human resources than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated amongst a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer, or less costly than our current or future product candidates or obtain regulatory approval for their products more rapidly than we may obtain approval for our product candidates. Our success will be based in part on our ability to identify, develop and manage a patented portfolio of product candidates that are safer and more effective than competing products and which will transform patient lives suffering from debilitating skin disorders that are chronic and do not go away even with conventional treatment options.

Competition in Hyperhidrosis

If approved for the treatment of primary axillary hyperhidrosis, we anticipate that sofipironium bromide would compete with other therapies used for hyperhidrosis, including:

- 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 could be used off-label by the administering physician.
- Non-Surgical Office-Based Procedures. Office-based procedures have been approved for the treatment of 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.

In addition to approved and off-label hyperhidrosis treatments, there are also several treatments under development that could potentially be used to treat hyperhidrosis and may compete with sofipironium bromide.

Intellectual Property and In-Licensing Agreements

Our success depends in large part upon our ability to secure proprietary protection for our products and technologies, including those in development, and to operate without infringing the proprietary rights of others. We seek to avoid the latter by monitoring patents and publications that may affect our business, and to the extent we identify such threats, evaluate and take appropriate courses of action.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

We also intend to use regulatory exclusivity (also called data package exclusivity) as a means of acquiring intellectual property protections that are separate and distinct to patents. This kind of right involves being given exclusivity for varying periods of time depending on the country to incentivize innovators who invest in and conduct clinical trials to produce data to demonstrate a drug is safe and effective for its intended use(s) and, as such, the data package in an NDA for the FDA should receive protection even if no patent is available. Other countries to varying extents do the same. In addition, there are other forms of intellectual property protection we may seek worldwide, including but not limited to trademarks, copyrights, trade secrets, orphan drug protection, pediatric exclusivity and the like, where available and appropriate for our business interests.

We further protect our proprietary information by requiring our directors, officers, employees, consultants, contractors, and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to our company without adequate permission to do so. In addition, we require confidentiality or service agreements from third parties that receive our confidential information or materials.

As of December 31, 2019, regarding our complete patent portfolio, we own or possess an exclusive license to 21 issued U.S. patents and 50 issued foreign patents, which include granted European patent rights that have been validated in various EU member states. We also own or possess an exclusive license to eight pending U.S. patent applications and 77 pending international and foreign patent applications. With regard to our lead product candidate, sofipironium bromide, we own or possess an exclusive license to seven U.S. and 37 foreign patents as well as eight pending U.S. and 67 foreign patent applications which, if issued, may provide patent term coverage until 2040.

We also use other forms of protection besides regulatory exclusivity, such as trademark, copyright, and trade secret protection, to enhance our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We aim to take advantage of all of the intellectual property rights that are available to us and believe that this comprehensive approach will provide us with proprietary exclusive positions for our product candidates, where available.

Manufacturing and Supply

We currently contract with third parties for the manufacture of small-molecule drug substances and drug products for preclinical studies and clinical trials and intend to continue to do so in the future. To our knowledge, all of our clinical drug product manufacturing activities are in compliance with current good manufacturing practice (“cGMP”). We have assembled a team of experienced employees and consultants to provide the necessary technical, quality, and regulatory oversight over the contract manufacturing organizations (“CMOs”) with which we contract. We rely on third-party cGMP manufacturers for scale-up and process development work and to produce sufficient quantities of development product candidates for use in clinical and preclinical trials.

Employees

As of December 31, 2019, we had 15 regular full-time employees, including eight in research and development. From time to time, we retain independent contractors. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages, and we consider our relations with our employees to be excellent.

Corporate History

On August 31, 2019, the Delaware corporation formerly known as “Vical Incorporated,” 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, Private Brickell and Merger Sub, pursuant to which the 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.” On August 31, 2019, in connection with, and prior to the consummation of the Merger, Vical effected a reverse stock split of its common stock, par value \$0.01 per share, at a ratio of 1-for-7.

On August 31, 2019, in connection with, and prior to the consummation of the Merger, Vical effected a reverse stock split of its common stock, par value \$0.01 per share at a ratio of 1-for-7 (the "Reverse Stock Split"). Unless otherwise noted herein, references to share and per-share amounts give retroactive effect to the Reverse Stock Split. On August 31, 2019, all shares of preferred stock of Private Brickell converted into shares of common stock of Private Brickell on a one-for-one basis.

At the effective date of the Merger, the Company issued shares of its common stock to Private Brickell stockholders, at an exchange rate of approximately 2.4165 shares of common stock in exchange for each share of Private Brickell common stock outstanding immediately prior to the Merger (the "Exchange Ratio"). The exchange rate was calculated by a formula that was determined through arms-length negotiations between the Vical and Private Brickell. Unless otherwise noted herein, references to share and per-share amounts give retroactive effect to the Reverse Stock Split and the Exchange Ratio, which was effected upon the Merger.

Immediately following the consummation of the Merger, there were 7,810,680 shares of common stock issued and outstanding, with Private Brickell's former securityholders beneficially owning approximately 57% of the outstanding shares of common stock and Vical's former securityholders beneficially owning approximately 43% of the outstanding shares of common stock. The Company's common stock is listed on The Nasdaq Capital Market, on a post-split basis (giving effect to the Reverse Stock Split) under the new name on September 3, 2019. The trading symbol also changed on that date from "VICL" to "BBI." The common stock is represented by CUSIP number 10802T 105.

Corporate Information

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.

This Annual Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, 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.

ITEM 1A. RISK FACTORS

Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price. The following information should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report.

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

The successful development, regulatory approval, and commercialization of sofpironium 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 United States not yet initiated, 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 FDA or similar foreign regulatory agencies to conduct additional clinical trials beyond those currently planned to support the approval and commercialization of sofpironium 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 sofipirionium bromide;
- ability of third parties with which we contract to manufacture consistently adequate clinical trial and commercial supplies of sofipirionium 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 sofipirionium bromide;
- ability to obtain favorable labeling for sofipirionium 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 sofipirionium bromide successfully in the United States 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 sofipirionium 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 sofipirionium bromide;
- ability to price sofipirionium 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 sofipirionium 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 sofipirionium bromide. Even if regulatory approvals are obtained, we may never be able to successfully commercialize sofipirionium bromide. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of sofipirionium 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 sofipirionium 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 sofipirionium bromide gel in the third quarter of 2018 and intend to initiate two pivotal Phase 3 clinical trials in subjects with primary axillary hyperhidrosis in the United States, subject to obtaining substantial additional funding. 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 sofipirionium bromide and could prevent us from, or delay us in, receiving development- or regulatory-based milestone payments and commercializing sofipirionium 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 sofipirionium bromide, subjecting us to significant contract liabilities, including but not limited to loss of rights in and to sofipirionium bromide.

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

Clinical development for sofipirionium 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 (“IRB”), 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 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 (“GSP”) 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 market acceptance of sofpironium bromide and could substantially increase the costs (and extent) of commercializing sofpironium bromide, potentially even leading to withdrawal of the drug.

Kaken substantially controls the development of sofpironium 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 Asian markets.

The Kaken Agreement granted Kaken an exclusive Japan license and certain rights to additional Asian countries to develop and commercialize sofpironium bromide. Under the terms of the 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 United States and the other territories where we maintain exclusive rights. Additionally, Kaken is responsible for conducting certain nonclinical and API (chemistry, manufacturing, and controls)-related activities that will be required for FDA approval in the United States, 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 United States and other territories in which we maintain exclusive rights. We will not receive additional milestone or other payments from Kaken if Kaken is not successful in its development 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 United States, 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 United States, 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 United States and in international markets, potentially based on changes in law and/or payor practices. Third-party coverage and reimbursement for sofipironium bromide may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results, and prospects.

Even if sofipronium 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 sofipronium 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 sofipronium bromide, if approved, especially in the United States, 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;
- the safety and effectiveness of sofipronium 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 sofipronium bromide;
- the cost of treatment with sofipronium bromide in relation to alternative hyperhidrosis treatments and willingness to pay for sofipronium 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 sofipronium 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 sofipronium bromide;
- patient satisfaction with the results and administration of sofipronium 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 sofipronium 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 sofipronium 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 sofipronium bromide.

If sofipronium 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.

Sofpironium 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 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 sofipironium bromide and contribute to downward pressure on the pricing of sofipironium 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 United States. 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 United States.

We may in the future face generic competition for sofipironium 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 United States (and any other countries where patent coverage exists) for sofipironium bromide, we could lose a significant portion of then-existing sales of sofipironium 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 sofipironium 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, sofipironium bromide.

We have in the past relied, and expect to continue to rely, on third-party CROs to conduct and oversee our sofipironium 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, 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 United States, Canada, the European Union, Latin America 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 sofipronium bromide in certain parts of Asia, 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.

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 sofipirionium 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 sofipirionium bromide in new indications or uses including commencing the Phase 3 clinical trials for sofipirionium 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 sofipirionium 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 commence the Phase 3 clinical trials for sofipirionium 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 United States and elsewhere around the world. The market for discretionary pharmaceutical products, medical devices and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider sofipirionium 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, or recession, ensues in the U.S. stock market given the current bull market is the longest on record, and the impact recently seen associated with the coronavirus outbreak as it has affected our licensee in Asia, our operating results and liquidity could be affected adversely by those factors in many ways, including weakening demand for sofipirionium bromide, making it more difficult for us to raise funds if necessary, and our stock price may decline.

Our stock price has 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 \$[•] per share as of March 13, 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;
- 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 License Agreement and 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 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 recently completed. 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 commence 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 will 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 as determined by our board of directors 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 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 million; or we have less than \$100 million in annual revenues and (i) either no public float, or (ii) a public float of less than \$700 million.

Provisions of Delaware law and our amended 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 amended 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 March 13, 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) 606,420 shares of our common stock at an exercise price of \$0.01 per share;

and (v) 1,556,420 shares of our common stock at an exercise price of \$1.16 per share. As of March 13, 2020, we also had 1,654,198 options issued and outstanding to purchase our common stock at a weighted average exercise price of \$12.95 per share. 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.

We may not be able to access the full amounts available under the Purchase Agreement with 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 a purchase agreement with Lincoln Park (the “Purchase Agreement”) 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 term of the agreement. 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 Nasdaq, 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.

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 to offset future taxable income may be subject to certain limitations.

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 losses to offset taxable income is limited to 80% of the current-year taxable income. It is uncertain if and to what extent various U.S. states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of U.S. 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 and if a portion of our NOLs is therefore subject to an annual limitation under Section 382. We may experience ownership changes as a result of subsequent changes in our stock ownership, as a result of offerings of our stock 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.

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 that has affected our licensee in Asia, 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 sopiponium 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.

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 United States 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 the company 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 United States) 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 United States;

- 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 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 United States 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.

We have sponsored or supported and may in the future sponsor or support clinical trials for our product candidates outside the United States, and the FDA 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 United States. Although the FDA or applicable foreign regulatory authorities may accept data from clinical trials conducted outside the United States 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 United States, 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 United States 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 United States, 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 United States 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 United States 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 United States, 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 soffipirionium 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 United States 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 (FDCA), 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 among other things); 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 United States; 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 like our licensee in Asia, 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 United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States 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 United States 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 United States, 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 United States, 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 United States 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 United States, 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 United States 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 licensee 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 United States. 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, or 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 United States and other countries may be maintained in confidence until the patents are issued, because patent applications in the United States 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 United States 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 United States 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Boulder, Colorado, occupying 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. While we may seek to expand our current facilities or place certain operations in other states in the next 12 to 18 months, we believe that our current facilities are adequate for our current needs.

ITEM 3. LEGAL PROCEEDINGS

On February 17, 2020, the Company, Brickell Subsidiary, Inc., a wholly-owned subsidiary of the Company (“Brickell Subsidiary”) and Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor (collectively, “Bodor”) entered into a settlement agreement in connection with the resolution of the previously disclosed dispute. See “Amended and Restated License Agreement with Bodor.”

Although we do not believe the action is likely to be material, nor that the claims will be determined to be meritorious, Dr. Patricia S. Walker, our former President and Chief Scientific Officer, commenced litigation against us, an officer, our Board Chairperson and others, alleging wrongful termination for unspecified damages, claiming discrimination based on age, gender, and association with a person with a disability. We will contest these claims vigorously.

From time to time, we may become involved in other legal proceedings arising in the ordinary course of our business. We are not presently a party to any other legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on the Company.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

On August 31, 2019, Vical and Private Brickell completed the Merger. In accordance with the Merger, Merger Sub merged with and into Private Brickell, with Private Brickell surviving as a wholly-owned subsidiary of Vical. On August 31, 2019, immediately after the completion of the Merger, the Company changed its name from "Vical Incorporated" to "Brickell Biotech, Inc." and Private Brickell changed its name from "Brickell Biotech, Inc." to "Brickell Subsidiary, Inc." Subsequent to the Merger, our common stock is traded on The Nasdaq Capital Market under the symbol "BBI," which was previously traded under the symbol "VICL."

Holder

As of December 31, 2019, we had 215 registered holders of record of our common stock. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares of record are held by banks, brokers, other financial institutions, and registered clearing agencies. There were no repurchases made by us or on our behalf, or by any "affiliated purchaser," of shares of our common stock during the year ended December 31, 2019.

Dividend Policy

We historically have not, and do not anticipate in the future, paying dividends on our common stock. We currently intend to retain all of our future earnings, as applicable, to finance the growth and development of our business. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Subject to these limitations, any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data is derived from our audited consolidated financial statements and should be read in conjunction with the consolidated financial statements, the notes to such statements, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report. Historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Collaboration revenue	\$ 7,917	\$ 10,888
Operating expenses:		
Research and development	20,214	12,960
General and administrative	12,171	6,379
Total operating expenses	32,385	19,339
Loss from operations	(24,468)	(8,451)
Investment and other income, net	157	61
Gain on extinguishment	2,318	—
Interest expense	(2,096)	(1,090)
Change in fair value of derivative liability	(11)	—
Change in fair value of warrant liability	223	244
Net loss	(23,877)	(9,236)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	10,274	(5,936)
Net loss attributable to common stockholders	\$ (13,603)	\$ (15,172)
Net loss per share attributable to common stockholders, basic and diluted	\$ (4.50)	\$ (25.85)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	3,023,023	586,969

	December 31,	
	2019	2018
	(in thousands)	
Cash and cash equivalents	\$ 7,232	\$ 8,067
Marketable securities, available-for-sale	4,497	—
Total assets	18,144	8,749
Note payable	—	4,639
Total liabilities	10,570	22,077
Total stockholders' equity (deficit)	7,574	(71,618)

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 sofipironium bromide as a potential best-in-class, self-administered, once-daily, topical therapy for the treatment of primary axillary hyperhidrosis.

Recent Developments

Private Placement Offerings

In February 2020, we entered into (i) a securities purchase agreement (the "Securities Purchase Agreement"); (ii) a purchase agreement (the "Purchase Agreement"); and (iii) a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("Lincoln Park"). Pursuant to the Securities Purchase Agreement, Lincoln Park agreed to purchase, and we agreed to sell, upon the terms and subject conditions stated therein (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.

Amended and Restated License Agreement with Bodor

On February 17, 2020, the Company, Brickell Subsidiary, and Bodor entered into an amended and restated license agreement (the "Amended and Restated License Agreement"). The Amended and Restated License Agreement supersedes the Bodor license agreement, dated December 15, 2012, entered into between the Company 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 the Company a worldwide, exclusive license to develop, manufacture, market, sell and sublicense technology products containing the proprietary compound sofipironium 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 the Company and Bodor, the Company made an upfront payment of \$1.0 million in cash to Bodor following the execution of the Amended and Restated License Agreement and the Settlement Agreement. The Company is required to further pay Bodor (i) a specified percentage of all royalties received from covered sales in territories pursuant to the license and collaboration agreement the Company previously entered into with Kaken Pharmaceutical, Co., Ltd. (the "Kaken Agreement"); (ii) a modified percentage of any sublicensing income the Company receives pursuant to the Kaken Agreement; (iii) a low single-digit royalty related to a newly filed provisional patent application anywhere outside of the territories in the Kaken Agreement by the Company; and (iv) a specified cash amount following the occurrence of certain new milestone events.

The Company also agreed to issue to Bodor shares of the common stock, as further described in the Amended and Restated License Agreement. The Amended and Restated License Agreement also imposes various diligence, sublicensing, milestone, royalty, notice, disbursement, dispute resolution and other obligations and restrictions on the Company. Consistent with the original license agreement, if the Company were to fail to comply with its material obligations under the Amended and Restated License Agreement, and if the Company does not successfully cure such alleged breach, then Bodor maintains the right to terminate the license, subject to the dispute procedures as set forth therein, in which event the Company might not be able to develop or market sofipironium bromide for its licensed use, if such termination is deemed valid.

Financial Overview

Our operations to date have been limited to business planning, raising capital, developing our pipeline assets (in particular sofipironium bromide), identifying product candidates, and other research and development. To date, we have financed operations primarily through private placements of common stock, convertible preferred stock, debt, funds received from license and collaboration agreements, and the funds received in connection with the Merger. We do not have any products approved for sale and have not generated any product sales. Since inception and through December 31, 2019, we have raised or generated an aggregate of \$124.6 million to fund our operations, of which \$39.1 million was through license and collaboration agreements, \$37.0 million was from cash and investments acquired in the Merger, \$33.6 million was from the sale of convertible preferred stock, \$7.5 million was from the sale of debt, and \$7.4 million was from the sale of convertible notes. As of December 31, 2019,

we had cash and cash equivalents and marketable securities of \$11.7 million. In addition, we had approximately \$4.0 million in refundable prepaid expenses related to the Phase 3 program of sofipironium bromide.

Since inception, we have incurred operating losses. We recorded a net loss of \$23.9 million and \$9.2 million for the year ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of \$85.0 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

- initiate and complete our two pivotal Phase 3 clinical trials for sofipironium bromide in the United States;
- contract to manufacture product candidates;
- advance research and development-related activities to develop and expand our product pipeline;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, and management personnel;
- and
- add operational and finance personnel to support product development efforts and to support operating as a public company.

We do not expect to generate significant revenue unless and until we successfully complete development of, obtain marketing approval for, and commercialize product candidates, either alone or in collaboration with third parties. We expect these activities may take several years and our success in these efforts is subject to significant uncertainty, especially in light of our need to raise substantial funding in order to commence our Phase 3 program. Accordingly, we expect we will need to raise substantial additional capital prior to the regulatory approval and commercialization of any of our product candidates. Until such time, if ever, that we generate substantial product revenues, we expect to finance our operations through public or private equity or debt financings, collaborations or licenses, or other available financing transactions. However, we may be unable to raise additional funds through these or other means when needed.

Key Components of Operations

Collaboration Revenue

Collaboration revenues generally consist of revenues recognized under our strategic collaboration agreements for the development and commercialization of our product candidates. Our strategic collaboration agreements generally outline overall development plans and include payments we receive at signing, payments for the achievement of certain milestones, and royalties. For these activities and payments, we utilize judgment to assess the nature of the performance obligations to determine whether the performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. We have not recognized any royalty revenue to date. Other than the revenue we may generate in connection with these agreements, we do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaborative agreements with third parties.

Research and Development Expenses

Research and development expenses principally consist of payments to third parties known as Clinical Research Organizations, or CROs. These CROs help plan, organize, and conduct clinical and nonclinical studies under our direction. Personnel costs, including wages, benefits, and share-based compensation, related to our research and development staff in support of product development activities are also included, as well as costs incurred for supplies, preclinical studies and toxicology tests, consultants, and facility and related overhead costs.

Below is a summary of our research and development expenses related to sofipironium bromide by categories of costs for the periods presented. The other expenses category includes travel, lab and office supplies, clinical trial management software, license fees, and other miscellaneous expenses.

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Direct program expenses related to sofipironium bromide	\$ 16,917	\$ 9,029
Personnel and other expenses		
Salaries, benefits, and stock-based compensation	3,068	3,111
Regulatory and compliance	177	650
Other expenses	52	170
Total research and development expenses	<u>\$ 20,214</u>	<u>\$ 12,960</u>

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including wages, benefits, and share-based compensation, related to our executive, sales, marketing, finance, and human resources personnel, as well as impairment expense and professional fees, including legal, accounting, and sublicensing fees.

We expect our general and administrative expenses to increase in the near term, both in absolute dollars and as a percentage of revenue largely. We also expect significant additional expenses associated with operating as a public company. Such increases may include increased insurance premiums, investor relations expenses, legal and accounting fees associated with the expansion of our business and corporate governance, financial reporting expenses, and expenses related to Sarbanes-Oxley and other regulatory compliance obligations.

Total Other Income (Expense)

Investment and Other Income, Net

Investment and other income, net consists primarily of interest earned on cash and cash equivalent and marketable securities balances. Our interest income will vary each reporting period depending on our average cash balances during the period and market interest rates. We expect interest income to fluctuate in the future with changes in average cash balances and market interest rates.

Gain on Extinguishment

Gain on extinguishment consists of the gain realized on the conversion of the convertible promissory notes to common stock in August 2019.

Interest Expense

Interest expense consists primarily of interest and amortization related to the issuance of \$7.4 million of convertible promissory note principal in 2019 and principal borrowings of \$7.5 million provided by the loan and security agreement entered into with Hercules Capital, Inc. on February 18, 2016 (the "Loan Agreement"). Subsequent to the Merger, there was no interest expense related to these agreements.

Change in Fair Value of Warrant Liability

In connection with the Loan Agreement, we issued warrants to Hercules Capital, Inc., which are exercisable for 9,005 shares of common stock at a per share exercise price of \$33.31. In connection with the convertible promissory notes, we issued warrants which are exercisable for 490,683 shares of common stock at a per share exercise price of \$10.36.

We accounted for the warrants as liabilities at their estimated fair value. The warrants were subject to remeasurement to fair value at each balance sheet date, and any fair value adjustments were recognized as changes in fair value of warrant liability in the consolidated statements of operations. The liability was adjusted for changes in fair value through August 31, 2019, and at that time the final warrant liability fair value was reclassified to equity in the consolidated balance sheets and no longer remeasured to fair value each period.

Critical Accounting Policies and Estimates

We have prepared the consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“US GAAP”). The preparation of these consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the consolidated financial statements. On an ongoing basis, management evaluates its critical estimates, including those related to revenue recognition, accrued research and development expenses, convertible promissory notes, redeemable convertible preferred stock, warrants, and stock-based compensation. We base our estimates on our historical experience and on assumptions that we believe are reasonable; however, actual results differ materially from these estimates under different assumptions or conditions.

For information on our significant accounting policies, please refer to Note 2 of the notes to our consolidated financial statements included elsewhere in this Annual Report.

Revenue Recognition

We currently recognize revenue generated primarily from licensing fees received under a license, development, and commercialization agreement entered into in March 2015 with Kaken, which is referred to as the “Kaken Agreement.” The terms of the agreements include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of milestones, and royalties on net product sales.

Under Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (“Topic 606”) an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the promised goods or services in the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the entity satisfies a performance obligation.

At contract inception, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. We utilize judgment to assess the nature of the performance obligation to determine whether the performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Licenses of Intellectual Property

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer, and the customer can use and benefit from the license.

Milestone payments

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission) is included in the transaction price, which is then allocated to each performance obligation. Milestone payments that are not within our control or the control of our partner, such as approvals from regulators, are not considered probable of being achieved until those approvals are received. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and, if necessary, adjust our estimate of the overall transaction price. Any such

adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration, and other revenues and earnings in the period of adjustment and in future periods through the end of the performance obligation period.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and where the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

For a complete discussion of accounting for collaborative licensing agreements, see Note 2 of the notes to our consolidated financial statements included elsewhere in this Annual Report. Our revenue to date has been generated primarily from licensing and development fees received under the Kaken Agreement.

Research and Development

Research and development costs are charged to expense when incurred and consist of costs incurred for independent and collaborative research and development activities. The major components of research and development costs include formulation development, clinical studies, clinical manufacturing costs, salaries and employee benefits, toxicology studies, allocations of various overhead, and occupancy costs. Research costs typically consist of applied research, preclinical, and toxicology work. Pharmaceutical manufacturing development costs consist of product formulation, chemical analysis, and the transfer and scale up of manufacturing at contract manufacturers.

As part of the process of recording research and development costs, we are required to estimate and accrue expenses. This process involves the following:

- communicating with appropriate internal personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- payments to CROs in connection with preclinical and toxicology studies and clinical trials;
- payments to investigative sites in connection with clinical trials;
- payments to CMOs in connection with the production of clinical trial materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing costs, we estimate the period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Stock-Based Compensation

Stock options granted to employees and non-employees under our stock option plan are accounted for by using a fair value-based method. Stock-based payments to employees and non-employees are measured based on their fair values at the date of grant, net of forfeitures, and are recorded on a straight-line basis over the requisite employee service period. We use the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. For performance-based awards where the vesting of the options may be accelerated upon the achievement of certain milestones, vesting and the related stock-based compensation is recognized as an expense when it is probable the milestone will be met.

When awards are modified, we compare the fair value of the affected award measured immediately prior to modification to its value after modification. To the extent that the fair value of the modified award exceeds the original award, the incremental fair value of the modified award is recognized as compensation on the date of modification for vested awards, and over the remaining vesting period for unvested awards.

One of the inputs in the Black-Scholes option-pricing model is the estimated fair value of common stock. After the date of the Merger, the estimated value of common stock is based on closing price of the common stock on The Nasdaq Capital Market at the date of grant. Prior to the Merger there had been no public market for the our common stock, and the fair value was determined with the assistance of a third-party valuation firm at each balance sheet date by considering a number of objective and subjective factors, including valuation of comparable companies, sales of capital stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors. The valuations were prepared in accordance with methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation.

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding our future performance, including the successful completion of future clinical trials and the time to liquidity, as well as the determination of the appropriate valuation methods at each valuation date. If different assumptions were used, our valuation could have been different. The foregoing valuation methodologies are not the only methodologies available, and they are not be used to value the common stock after the date of the Merger. Accordingly, stockholders and investors should not place undue reliance on the foregoing valuation methodologies as an indicator of the Company's future stock price.

Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock was classified as a mezzanine instrument outside of our capital accounts prior to the Merger. Accretion of redeemable convertible preferred stock included the accrual of dividends on and accretion of issuance costs of our redeemable convertible preferred stock. The carrying values of the redeemable convertible preferred stock were increased or reduced by periodic accretion or reduction to their respective redemption values from the date of issuance to August 31, 2019, the date that all outstanding shares of redeemable convertible preferred stock converted into shares of common stock. At the date of conversion, the carrying value was reclassified to stockholders' equity.

Convertible Promissory Notes

From time to time, in the past as a private company, we entered into debt financing transactions whereby such convertible debt contains conversion features into preferred or common shares. We account for such instruments under ASC, 470-20 "Debt with Conversion and Other Options" which requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. We account for instruments issued with convertible debt that have been determined to be free standing derivative financial instruments or embedded derivatives in accordance with ASC 815 "Derivatives and Hedging". Under ASC 815, a portion of the proceeds received upon the issuance of the convertible debt is allocated to the fair value of the derivative and a corresponding discount is recorded on the convertible debt. The derivative is subsequently marked to market at each reporting date based on current fair value, with the changes in fair value reported in the statements of operations.

During the year ended December 31, 2019, we issued an aggregate principal amount of \$7.4 million of convertible debt to investors containing a redemption feature, which was deemed an embedded derivative and required us to bifurcate and separately account for the embedded derivative as a liability. The warrants also required fair value accounting and were accounted as a liability. The discount on the debt was amortized through interest expense based on the effective interest method. On August 31,

2019, the convertible promissory notes and related accrued interest converted into 1,069,740 shares of common stock, which resulted in a gain on extinguishment of \$2.3 million.

Recent Accounting Pronouncements

For information on the recent accounting pronouncements which may impact our business, see Note 3 of the notes to the consolidated financial statements included elsewhere in this Annual Report.

Results of Operations

Comparison of the Year Ended December 31, 2019 and 2018

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Collaboration revenue	\$ 7,917	\$ 10,888
Research and development expenses	(20,214)	(12,960)
General and administrative expenses	(12,171)	(6,379)
Total other income (expense), net	591	(785)
Net loss	\$ (23,877)	\$ (9,236)

Collaboration Revenue

Collaboration revenue decreased by \$3.0 million, or 27%, for the year ended December 31, 2019 from the year ended December 31, 2018. The revenue recognized for the year ended December 31, 2019 was due to research and development activities related to the Kaken Agreement for which Kaken provided funding. The revenue recognized for the year ended December 31, 2018 was primarily the result of research and development activities related to the Kaken Agreement for which Kaken provided funding and a milestone payment in March 2018 from Kaken in the amount of \$5.0 million for the achievement of a certain regulatory milestone.

Research and Development

Research and development expenses increased by \$7.3 million, or 56%, for the year ended December 31, 2019 from the year ended December 31, 2018, primarily due to an increase of \$7.9 million in clinical study and drug supply costs associated with sofipronium bromide and a decrease of \$0.6 million in regulatory and compliance costs and other administrative costs.

General and Administrative Expenses

General and administrative expenses increased by \$5.8 million, or 91%, for year ended December 31, 2019 from the year ended December 31, 2018. This increase includes \$4.1 million in added fees for accounting, auditing, and legal services, including Merger-related costs, \$1.0 million in stock compensation expense and increased headcount, \$1.0 million in legal settlement accrual, \$0.7 million in impairment expense, partially offset by a decrease of \$1.0 million in sub-licensing fees.

Total Other Income (Expense), Net

Total other income, net increased by \$1.4 million, or 175%, for the year ended December 31, 2019 from the year ended December 31, 2018, due primarily to a gain of \$2.3 million related to the conversion of the convertible promissory notes in August 2019, which was partially offset by an increase of \$1.0 million in interest expense related to issuance of convertible promissory notes in 2019 and principal borrowings provided by the Loan Agreement.

Liquidity and Capital Resources

We have incurred significant operating losses and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the year ended December 31, 2019 and 2018, we had a net loss of \$23.9 million and \$9.2 million, respectively.

As of December 31, 2019 and December 31, 2018, we had an accumulated deficit of \$85.0 million and \$71.6 million, respectively. As of December 31, 2019, we had cash, cash equivalents, and marketable securities of \$11.7 million. Since inception, we have financed operations primarily through sales of equity securities, convertible promissory notes, and warrants, as well as payments received under strategic collaboration and licensing agreements.

We believe that our cash, cash equivalents, and marketable securities as of December 31, 2019, combined with the refundable prepaid research and development expenses and periodic sales of our stock under the Purchase Agreement, are sufficient to fund our operations for at least the next 12 months from the issuance of this Annual Report. In order to sell additional shares of common stock under the Purchase Agreement, Lincoln Park will need to purchase shares of common stock from us, subject to the conditions under the Purchase Agreement, and we will be required to have an additional effective registration statement. We have filed a registration statement on Form S-3 covering the resale of the initial shares sold to Lincoln Park, which we will request the SEC to declare effective following the filing of this Form 10-K. If we are unable to raise additional capital, including under the Purchase Agreement, we expect to conserve resources, including reducing cash compensation arrangements to management and further reductions in operating expenditures. We expect to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Additional funding beyond the sale of additional shares of common stock to Lincoln Park will be required in the future to proceed with our current and proposed research activities, including conducting the pivotal Phase 3 clinical trials of sofpironium bromide.

Cash Flows

Since inception, we have primarily used our available cash to fund expenditures related to product discovery and development activities. The following table sets forth a summary of cash flows for the periods presented:

	Year Ended December 31,	
	2019	2018
(in thousands)		
Net cash provided by (used in) operating activities	\$ (35,981)	\$ 3,967
Net cash provided by (used in) investing activities	32,510	(12)
Net cash provided by (used in) financing activities	2,636	(1,287)
Net increase (decrease) in cash and cash equivalents	<u>\$ (835)</u>	<u>\$ 2,668</u>

Operating Activities

Net cash used in operating activities of \$36.0 million during the year ended December 31, 2019 increased compared to cash provided by operating activities of \$4.0 million during the same period in the prior year primarily due to \$20.6 million milestone and research and development funding received from Kaken during the year ended December 31, 2018 as well as an increase in net loss of \$14.6 million, a gain on extinguishment of the convertible promissory note of \$2.3 million, an increase in other changes in working capital of \$5.3 million, partially offset by an increase of other non-cash expenses of \$3.3 million.

Investing Activities

Net cash provided by investing activities of \$32.5 million during the year ended December 31, 2019 increased compared to cash used in investing activities of \$12 thousand during the same period in the prior year. The \$32.5 million increase was primarily the result of the cash acquired in the Merger and maturities of marketable securities in 2019.

Financing Activities

Net cash provided by financing activities of \$2.6 million during the year ended December 31, 2019 increased compared to net cash used in financing activities of \$1.3 million during the prior year. The increase was primarily related to proceeds of \$7.4 million from the issuance of convertible promissory notes in 2019, partially offset by payments of \$4.8 million in 2019 towards the note payable pursuant to the Loan Agreement.

In November 2019, we entered into a settlement and termination agreement with our then financing source, NovaQuest Co-Investment Fund X, L.P. ("NovaQuest"), which had the effect of terminating the funding agreement we had entered into in

conjunction with the Vical merger. The agreement was terminated as a result of the then pending license agreement-related disputed with Bodor. In connection with termination, NovaQuest agreed to cancel and surrender the warrant it previously received in connection with the funding agreement, and we repaid to NovaQuest the \$5.6 million that had been advanced plus accrued interest.

Off-Balance Sheet Arrangements

As of December 31, 2019 and December 31, 2018, we had not been involved in any material off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Brickell Biotech, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Brickell Biotech, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

Denver, Colorado
March 18, 2020

BRICKELL BIOTECH, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,232	\$ 8,067
Marketable securities, available-for-sale	4,497	—
Prepaid expenses and other current assets	6,240	204
Total current assets	17,969	8,271
Property and equipment, net	16	37
Operating lease right-of-use asset	159	—
Intangible assets	—	441
Total assets	<u>\$ 18,144</u>	<u>\$ 8,749</u>
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,245	\$ 4,067
Accrued liabilities	6,379	3,272
Lease liability, current portion	78	—
Deferred revenue, current portion	1,795	8,117
Note payable	—	4,639
Total current liabilities	10,497	20,095
Lease liability, net of current portion	73	—
Contingent consideration	—	145
Warrant liability	—	242
Deferred revenue, net of current portion	—	1,595
Total liabilities	10,570	22,077
Redeemable convertible preferred stock (Series A, B, C and C-1), \$0.01 par value, 5,000,000 and 4,182,943 shares authorized at December 31, 2019 and 2018, respectively; 0 and 1,256,466 shares issued and outstanding at December 31, 2019 and 2018, respectively; aggregate liquidation preference of \$0 and \$46,985 at December 31, 2019 and 2018, respectively	—	58,290
Commitments and contingencies (Note 7)		
Stockholders' equity (deficit):		
Common stock, \$0.01 par value, 50,000,000 and 8,000,000 shares authorized at December 31, 2019 and 2018, respectively; 8,480,968 and 589,001 shares issued and outstanding at December 31, 2019 and 2018, respectively	85	6
Additional paid-in capital	92,497	—
Accumulated other comprehensive loss	(28)	—
Accumulated deficit	(84,980)	(71,624)
Total stockholders' equity (deficit)	7,574	(71,618)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 18,144</u>	<u>\$ 8,749</u>

See accompanying notes to these consolidated financial statements.

BRICKELL BIOTECH, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2019	2018
Collaboration revenue	\$ 7,917	\$ 10,888
Operating expenses:		
Research and development	20,214	12,960
General and administrative	12,171	6,379
Total operating expenses	32,385	19,339
Loss from operations	(24,468)	(8,451)
Investment and other income, net	157	61
Gain on extinguishment	2,318	—
Interest expense	(2,096)	(1,090)
Change in fair value of derivative liability	(11)	—
Change in fair value of warrant liability	223	244
Net loss	(23,877)	(9,236)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	10,274	(5,936)
Net loss attributable to common stockholders	\$ (13,603)	\$ (15,172)
Net loss per share attributable to common stockholders, basic and diluted	\$ (4.50)	\$ (25.85)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	3,023,023	586,969

See accompanying notes to these consolidated financial statements.

BRICKELL BIOTECH, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,	
	2019	2018
Net loss	\$ (23,877)	\$ (9,236)
Other comprehensive loss:		
Unrealized loss on available-for-sale marketable securities arising during holding period, net of tax benefit of \$0	(28)	—
Total comprehensive loss	<u>\$ (23,905)</u>	<u>\$ (9,236)</u>

See accompanying notes to these consolidated financial statements.

BRICKELL BIOTECH, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In- Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Carrying Value	Shares	Par Value				
Balance, December 31, 2017	1,256,466	\$ 52,354	585,262	\$ 6	\$ —	\$ —	\$ (59,942)	\$ (59,936)
Effect of adoption of Topic 606	—	—	—	—	—	—	2,734	2,734
Stock-based compensation	—	—	—	—	711	—	—	711
Issuance of common stock through exercise of stock options	—	—	3,739	—	45	—	—	45
Accretion of redeemable convertible preferred stock to redemption value	—	5,936	—	—	(756)	—	(5,180)	(5,936)
Net loss	—	—	—	—	—	—	(9,236)	(9,236)
Balance, December 31, 2018	1,256,466	58,290	589,001	6	—	—	(71,624)	(71,618)
Reduction of redeemable convertible preferred stock to redemption value	—	(10,274)	—	—	(247)	—	10,521	10,274
Conversion of redeemable convertible preferred stock and preferred stock dividends to common stock	(1,256,466)	(48,016)	2,783,951	28	47,988	—	—	48,016
Common stock issued in recapitalization	—	—	3,367,988	34	36,059	—	—	36,093
Conversion of convertible notes payable and accrued interest to common stock	—	—	1,069,740	10	5,082	—	—	5,092
Reclassification of warrant liability to equity	—	—	—	—	1,511	—	—	1,511
Common stock warrants issued in connection with the research and development funding liability, net of cancellations	—	—	—	—	532	—	—	532
Issuance of common stock through exercise of warrants	—	—	670,288	7	40	—	—	47
Stock-based compensation	—	—	—	—	1,532	—	—	1,532
Unrealized loss on available-for-sale marketable securities	—	—	—	—	—	(28)	—	(28)
Net loss	—	—	—	—	—	—	(23,877)	(23,877)
Balance, December 31, 2019	—	\$ —	8,480,968	\$ 85	\$ 92,497	\$ (28)	\$ (84,980)	\$ 7,574

See accompanying notes to these consolidated financial statements.

BRICKELL BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (23,877)	\$ (9,236)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	28	49
Accretion of discount on marketable securities	(41)	—
Non-cash interest expense	666	—
Impairment expense	441	—
Change in fair value of derivative liability	11	—
Change in fair value of warrant liability	(223)	(244)
Change in fair value of contingent consideration	(145)	(3)
Gain on extinguishment	(2,318)	—
Amortization of discounts and financing costs	1,575	489
Stock-based compensation	1,532	711
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(4,562)	(115)
Accounts payable	(1,822)	2,845
Accrued liabilities	671	(241)
Deferred revenue	(7,917)	9,712
Net cash provided by (used in) operating activities	<u>(35,981)</u>	<u>3,967</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash and cash equivalents acquired in recapitalization	13,017	—
Maturities of marketable securities	19,500	—
Capital expenditures	(7)	(12)
Net cash provided by (used in) investing activities	<u>32,510</u>	<u>(12)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of principal of note payable	(4,808)	(1,282)
Payment of issuance costs associated with note payable	—	(50)
Proceeds from issuance of convertible promissory notes	7,397	—
Proceeds from the exercise of warrants	47	—
Proceeds from the exercise of stock options	—	45
Net cash provided by (used in) financing activities	<u>2,636</u>	<u>(1,287)</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>(835)</u>	<u>2,668</u>
CASH AND CASH EQUIVALENTS—BEGINNING	<u>8,067</u>	<u>5,399</u>
CASH AND CASH EQUIVALENTS—ENDING	<u>\$ 7,232</u>	<u>\$ 8,067</u>

BRICKELL BIOTECH, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)
(in thousands)

Supplement Disclosure of Cash Flow Information:		
Interest paid	\$ 432	\$ 608
Supplement Disclosure of Non-Cash Investing and Financing Activities:		
Conversion of redeemable convertible preferred stock and preferred stock dividends to common stock	\$ 48,016	\$ —
Accretion (reduction) of redeemable convertible preferred stock to redemption value	\$ (10,377)	\$ 5,896
Shares issued in recapitalization	\$ 23,076	\$ —
Conversion of the convertible promissory notes and interest to common stock	\$ 8,063	\$ —
Accretion of redeemable convertible preferred stock issuance costs	\$ 103	\$ 40
Derivative liability issued with convertible promissory notes	\$ 1,442	\$ —
Warrants to purchase common stock issued with funding agreement	\$ 876	\$ —
Warrants to purchase common stock issued with convertible promissory notes	\$ 1,492	\$ —
Change in unrealized loss on available-for-sale marketable securities	\$ (28)	\$ —

See accompanying notes to these consolidated financial statements.

BRICKELL BIOTECH, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

Brickell Biotech, Inc. (the “Company” or “Brickell”) is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. The Company’s pipeline consists of potential novel therapeutics for hyperhidrosis and other prevalent dermatological conditions. The Company’s pivotal Phase 3-ready clinical-stage product candidate, sofpironium bromide, is a proprietary new molecular entity that belongs to a class of medications called anticholinergics. The Company intends to develop sofpironium bromide as a potential best-in-class, self-administered, once daily, topical therapy for the treatment of primary axillary hyperhidrosis. The Company’s operations to date have been limited to business planning, raising capital, developing its pipeline assets (in particular sofpironium bromide), identifying product candidates, and other research and development.

On August 31, 2019, the Company, then known as Vical Incorporated (“Vical”), and Brickell Biotech, Inc., a then privately-held Delaware corporation that began activities in September 2009 (“Private Brickell”), completed a recapitalization in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated June 2, 2019, as further amended on August 20, 2019 and on August 30, 2019 (the “Merger Agreement”), by and among Vical, Vical Subsidiary, Inc., a wholly-owned subsidiary of Vical (“Merger Sub”), and Private Brickell. Pursuant to the Merger Agreement, Merger Sub merged with and into Private Brickell, with Private Brickell surviving 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.” and Private Brickell changed its name from “Brickell Biotech, Inc.” to “Brickell Subsidiary, Inc.”

The accompanying consolidated financial statements and related notes reflect the historical results of Private Brickell prior to the Merger and of the combined company following the Merger, and do not include the historical results of Vical prior to the completion of the Merger. These financial statements and related notes should be read in conjunction with the audited financial statements of Private Brickell for the year ended December 31, 2018, included in the Company’s Form 8-K/A filed with the Securities and Exchange Commission (the “SEC”) on February 10, 2020.

On August 31, 2019, in connection with, and prior to the consummation of the Merger, Vical effected a reverse stock split of its common stock, par value \$0.01 per share, at a ratio of 1-for-7 (the “Reverse Stock Split”). Unless otherwise noted herein, references to share and per-share amounts give retroactive effect to the Reverse Stock Split. On August 31, 2019, all shares of preferred stock of Private Brickell converted into shares of common stock of Private Brickell on a one-for-one basis.

At the effective date of the Merger, the Company issued shares of its common stock to Private Brickell stockholders, at an exchange rate of approximately 2.4165 shares of common stock in exchange for each share of Private Brickell common stock outstanding immediately prior to the Merger (the “Exchange Ratio”). The exchange rate was calculated by a formula that was determined through arms-length negotiations between Vical and Private Brickell. Unless otherwise noted herein, references to share and per-share amounts give retroactive effect to the Reverse Stock Split and the Exchange Ratio, which was effected upon the Merger.

Immediately following the consummation of the Merger, there were 7,810,680 shares of the Company’s common stock issued and outstanding, with Private Brickell’s former securityholders beneficially owning approximately 57% of the outstanding shares of common stock and Vical’s former securityholders beneficially owning approximately 43% of the outstanding shares of common stock.

Liquidity and Capital Resources

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has incurred significant operating losses and has an accumulated deficit as a result of ongoing efforts to develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the year ended December 31, 2019, the Company had a net loss of \$23.9 million and net cash used in operating activities of \$36.0 million. As of December 31, 2019, the Company had cash, cash equivalents, and marketable securities of \$11.7 million, and an accumulated deficit of \$85.0 million.

The Company believes that its cash, cash equivalents, and marketable securities as of December 31, 2019, combined with the refundable prepaid research and development expenses and periodic sales of the Company's common stock under the Purchase Agreement (see Note 12. "Subsequent Events"), are sufficient to fund its operations for at least the next 12 months from the issuance of these consolidated financial statements. In order to sell additional shares of common stock under the Purchase Agreement, Lincoln Park Capital Fund, LLC ("Lincoln Park") will need to purchase shares of common stock from the Company, subject to the conditions under the Purchase Agreement, and the Company will be required to have an additional effective registration statement. The Company has filed a registration statement on Form S-3 covering the resale of the initial shares sold to Lincoln Park, which management will request the SEC to declare effective following the filing of this Form 10-K. If the Company is unable to raise additional capital, including under the Purchase Agreement, the Company expects to conserve resources, including reducing cash compensation arrangements to management and further reductions in operating expenditures. The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Additional funding beyond the sale of additional shares of common stock to Lincoln Park will be required in the future to proceed with the Company's current and proposed research activities, including conducting the pivotal Phase 3 clinical trials of sofipironium bromide.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Brickell Subsidiary, Inc., and are presented in U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position, results of operations, and cash flows for the periods presented. All significant intercompany balances have been eliminated in consolidation. The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein. The Company's management performed an evaluation of its activities through the date of filing of these financial statements and concluded that there are no subsequent events requiring disclosure, other than as disclosed.

The Merger has been accounted for as a recapitalization. Prior to the Merger, Vical wound down its pre-merger business assets and liabilities. The owners and management of Private Brickell have actual and effective voting and operating control of the combined company. In the Merger transaction, Vical is the accounting acquiree and Private Brickell is the accounting acquirer. A recapitalization is equivalent to the issuance of stock by the private operating company for the net monetary assets of the accounting acquiree accompanied by a recapitalization with accounting similar to that resulting from a reverse acquisition, except that no goodwill or intangible assets are recorded.

In connection with the Merger, 3,367,988 shares of common stock were transferred to the existing Vical stockholders and the Company assumed approximately \$36.1 million in net tangible assets from Vical, which were recorded as additional paid-in capital. The following table summarizes the net assets acquired based on their estimated fair values immediately prior to the Merger (in thousands):

Cash and cash equivalents	\$	13,017
Marketable securities		23,959
Prepaid expenses and other current assets		1,474
Accrued liabilities		(2,357)
Net acquired tangible assets	\$	<u>36,093</u>

In connection with the Merger, the Company assumed warrants previously held by Vical, which provide the warrant holder the right to purchase 891,582 shares of common stock at an exercise price of \$0.07 (the "Vical Warrants"). The Vical Warrants were classified as equity. In December 2019, warrants to purchase 670,288 shares of common stock were exercised for proceeds of \$47 thousand.

The combined company assumed all the outstanding options, under Vical's equity incentive plan (the "Vical Plan") with such options representing the right to purchase a number of shares of Brickell common stock previously represented by such options, as adjusted for the recapitalization.

Use of Estimates

The Company's consolidated financial statements are prepared in accordance with US GAAP, which requires it to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although these estimates are based on the Company's knowledge of current events and actions it may take in the future, actual results may ultimately differ from these estimates and assumptions.

Risks and Uncertainties

The Company's business is subject to significant risks common to early-stage companies in the pharmaceutical industry including, but not limited to, the ability to develop appropriate formulations, scale up and production of the compounds, dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents and other intellectual property rights, clinical implementation and success, the lengthy and expensive regulatory approval process, compliance with regulatory and other legal requirements, competition from other products; uncertainty of broad adoption of its approved products, if any, by physicians and patients; significant competition; ability to manage third-party manufacturers, suppliers, contract research organizations, business partners and other alliance management, and obtaining additional financing to fund the Company's efforts.

The product candidates developed by the Company require approvals from the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies prior to commercial sales in the United States or foreign jurisdictions, respectively. There can be no assurance that the Company's current and future product candidates will receive the necessary approvals. If the Company is denied approval or approval is delayed, it may have a material adverse impact on the Company's business and its financial condition.

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable by the Company.

Cash and Cash Equivalents

The Company considers all highly liquid debt instruments with an original maturity of three months or less from date of purchase to be cash equivalents. Cash equivalents, which are stated at cost, consist primarily of amounts held in short-term money market accounts with highly rated financial institutions.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash balances in several accounts with two financial institutions which, from time to time, are in excess of federally insured limits.

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Expenditures for major betterments and additions are charged to the asset accounts, while replacements, maintenance and repairs, which do not improve or extend the lives of the respective assets, are charged to expense as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Depreciation expense amounted to approximately \$28 thousand and \$49 thousand for the years ended December 31, 2019 and 2018, respectively.

Long-Lived Assets

The Company's intangible assets are considered indefinite-lived and are not amortized, but are tested for impairment on an annual basis, as well as between annual tests if changes in circumstances indicate a reduction in the fair value of the in-process research and development ("IPR&D") projects below their respective carrying amounts. In connection with any impairment assessment, the fair value of the intangible assets as of the date of assessment is compared to the carrying value of the intangible asset. If and when development is complete, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives.

During the year ended December 31, 2019, the Company recorded within general administrative expenses a \$0.4 million impairment charge related to two early-stage product candidates associated with the rights to an IPR&D molecular compound in the Phase 1 stage of development and with the rights to a RORg inhibitor associated with the topical treatment of mild-to-moderate psoriasis. These early-stage product candidates were acquired in 2015 in transactions that were accounted for as business combinations. Impairment was determined to have occurred in 2019 as changes in management's plans indicated a reduction in the fair value of the IPR&D projects below their respective carrying amounts. These early-stage product candidates previously had contingent liabilities of \$0.1 million associated with achieving certain future development milestones. The \$0.1 million change in the fair value of the contingent consideration was recorded as general and administrative expense during the year ended December 31, 2019.

Fair Value Measurements

Fair value is the price that the Company would receive to sell an asset or pay to transfer a liability in a timely transaction with an independent counterparty in the principal market or in the absence of a principal market, the most advantageous market for the asset or liability. A three-tier hierarchy is established to distinguish between (1) inputs that reflect the assumptions market participants would use in pricing an asset or liability developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) inputs that reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing an asset or liability developed based on the best information available in the circumstances (unobservable inputs), and establishes a classification of fair value measurements for disclosure purposes.

The hierarchy is summarized in the three broad levels listed below:

Level 1—quoted prices in active markets for identical assets and liabilities

Level 2—other significant observable inputs (including quoted prices for similar assets and liabilities, interest rates, credit risk, etc.)

Level 3—significant unobservable inputs (including the Company's own assumptions in determining the fair value of assets and liabilities)

The following tables set forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

	December 31, 2019		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	\$ 7,232	\$ —	\$ —
U.S. treasuries	4,497	—	—
Total	<u>\$ 11,729</u>	<u>\$ —</u>	<u>\$ —</u>
December 31, 2018			
	Level 1	Level 2	Level 3
Assets:			
Money market funds	\$ 8,067	\$ —	\$ —
Liabilities:			
Redeemable convertible preferred stock warrant liability	\$ —	\$ —	\$ 242
Contingent consideration	—	—	145
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 387</u>

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

	Derivative Liability	Common Stock Warrant Liability	Redeemable Convertible Preferred Stock Warrant Liability	Contingent Consideration Liabilities
Fair value as of December 31, 2018	\$ —	\$ —	\$ 242	\$ 145
Fair value of financial instruments issued	1,442	1,492	—	—
Change in fair value	11	17	(240)	(145)
Reclassification to equity	(1,453)	(1,509)	(2)	—
Fair value as of December 31, 2019	\$ —	\$ —	\$ —	\$ —

Fair Value of Financial Instruments

The following methods and assumptions were used by the Company in estimating the fair values of each class of financial instrument disclosed herein:

Money Market Funds—The carrying amounts reported as cash and cash equivalents in the consolidated balance sheets approximate their fair values due to their short-term nature and/or market rates of interest (Level 1 of the fair value hierarchy).

U.S. Treasuries—The Company has designated its investments in U.S. treasury securities as available-for-sale securities and accounts for them at their respective fair values. The securities are classified as short-term or long-term based on the nature of the securities and their availability to meet current operating requirements. Securities that are readily available for use in current operations are classified as short-term available-for-sale marketable securities and are reported as a component of current assets in the consolidated balance sheets (Level 1 of the fair value hierarchy).

Securities that are classified as available-for-sale are measured at fair value, including accrued interest, with temporary unrealized gains and losses reported as a component of stockholders' equity until their disposition. The Company reviews available-for-sale securities at the end of each period to determine whether they remain available-for-sale based on its then current intent. The cost of securities sold is based on the specific identification method. The securities are subject to a periodic impairment review. An impairment charge would occur when a decline in the fair value of the investments below the cost basis is judged to be other-than-temporary.

As of December 31, 2019, the Company's available-for-sale securities had an amortized cost of \$4.5 million, fair value of \$4.5 million, and an unrealized gain of \$3 thousand. Because the securities were acquired in August 2019 in connection with the Merger, there were no related balances as of December 31, 2018.

Contingent Consideration—These amounts represented future payments in conjunction with various business combinations related to the acquisition of certain early-stage pipeline assets. These assets were impaired during the year ended December 31, 2019, and therefore, the likelihood of future development and regulatory milestones and other potential future payments related to these assets was considered to be remote. The Company evaluated its estimates of the fair value of contingent consideration on a quarterly basis. The fair value of the contingent consideration was determined with the assistance of a third-party valuation firm applying the income approach. This approach estimated the fair value of the contingent consideration related to the achievement of future development and regulatory milestones by assigning an achievement probability and date of expected completion to each potential milestone and discounting the associated cash payment to its present value using a risk-adjusted rate of return. The probability of success of each milestone assumed that the prerequisite developmental milestones were successfully completed and was based on the asset's current stage of development and anticipated regulatory requirements. The probability of success for each milestone was determined by multiplying the preceding probabilities of success. At December 31, 2018, the unobservable inputs (Level 3 of the fair value hierarchy) to the valuation models that have the most significant effect on the fair value of the Company's contingent consideration were the probabilities that certain in-process development projects would meet specified development milestones, including ultimate approval by the FDA, with individual cumulative probabilities ranging from 2.1% to 20.9%. Other unobservable inputs used in this approach include risk-adjusted discount rates ranging from 15.5% to 27.1% and estimates of the timing of the achievement of the various product development, regulatory approval, and sales milestones.

Redeemable Convertible Preferred Stock Warrant Liability—These amounts represented potential future obligations to transfer assets to the holders at a future date. The Company remeasured these warrants to current fair value at each balance sheet date, and any change in fair value was recognized as a change in fair value of warrant liability in the consolidated statements of operations. The Company estimated the fair value of these warrants at December 31, 2018 using the Black-Scholes option-pricing model (Level 3 of the fair value hierarchy table). These warrants converted from warrants exercisable for redeemable convertible preferred stock to common stock in August 2019 in connection with the Merger (see further discussion in “Note 6. Note Payable”).

Inputs used to determine estimated fair value of the warrant liabilities included the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends, and the expected volatility of the underlying stock. The most significant unobservable inputs used in the fair value measurement of the convertible preferred stock warrant liability were the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term resulted in a directionally similar impact to the fair value measurement. The fair value of the outstanding warrants was remeasured for the following period end using the Black-Scholes option-pricing model with the following assumptions:

	2018
Expected term (in years)	7.1
Expected volatility	30.00 %
Risk free interest rate	2.59 %
Expected dividend yield	—%

The fair value of the shares of the convertible preferred stock underlying the preferred stock warrants was historically determined with the assistance of a third-party valuation firm. Because there had been no public market for the Company’s convertible preferred stock, the third-party valuation firm determined fair value of the convertible preferred stock at each balance sheet date by considering a number of objective and subjective factors, including valuation of comparable companies, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors.

Remaining Term. The Company derived the expected term based on the time from the balance sheet date until the preferred stock warrant’s expiration date.

Expected Volatility. Since the Company was previously a private entity prior to the Merger with no historical data regarding the volatility of its preferred stock, the expected volatility used was based on volatility of a group of similar entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, and size.

Risk-free Interest Rate. The risk-free interest rate was based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term of the warrants.

Expected Dividend Rate. The Company has never paid any dividends and does not plan to pay dividends in the foreseeable future and, therefore, used an expected dividend rate of zero in the valuation model.

Derivative Liability—These amounts represented potential future obligations to transfer assets to the holders at a future date. The fair value of the derivative liability has historically been determined with the assistance of a third-party valuation firm (Level 3 of the fair value hierarchy table) (see further discussion in “Note 5 Convertible Promissory Notes”). At the inception of the liability, there was no public market for the Company’s common stock, and a third-party valuation firm determined fair value of the stock by considering a number of objective and subjective factors, including valuation of comparable companies, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors. The derivative liability was marked-to-market each measurement period and any change in fair value was recorded in the consolidated statements of operations. In August 2019, in connection with the Merger, the derivative liability was reclassified to equity in the consolidated balance sheet (see further discussion in “Note 5. Convertible Promissory Notes”).

Common Stock Warrant Liability—These amounts represented potential future obligations to transfer assets to the holders at a future date. The fair value of the warrants was historically determined with the assistance of a third-party valuation firm (Level 3 of the fair value hierarchy table) (see further discussion in Note 5). At the inception of the liability, there was no public market

for the Company's common stock, and a third-party valuation firm determined fair value of the stock by considering a number of objective and subjective factors, including valuation of comparable companies, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors. The warrant liability was remeasured to fair value at each balance sheet date, and any change in fair value was recognized as a change in fair value of warrant liability in the consolidated statements of operations. The Company estimated the fair value of these warrants using the Black-Scholes option-pricing model. In August 2019, in connection with the Merger, the warrant liability was reclassified to equity in the consolidated balance sheet (see further discussion in "Note 5. Convertible Promissory Notes").

Inputs used to determine estimated fair value of the warrant liabilities included the estimated fair value of the underlying stock at the valuation date, the estimated term of the warrants, risk-free interest rates, expected dividends, and the expected volatility of the underlying stock. The most significant unobservable inputs used in the fair value measurement of the warrant liability were the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term resulted in a directionally similar impact to the fair value measurement.

Leases

On January 1, 2019, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, Leases ("ASC 842"), using the modified retrospective method for all lease arrangements at the beginning of the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under ASC 842, while prior period amounts were not adjusted and continue to be presented in accordance with the Company's historical accounting under ASC Topic 840, Leases. ASC 842 had an impact on the Company's consolidated balance sheets but did not have an impact on the Company's net loss.

Under ASC 842, the Company determines if an arrangement is a lease at inception. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected the practical expedient not to recognize on the balance sheet leases with terms of one-year or less and not to separate lease components and non-lease components for long-term real-estate leases. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company estimates the incremental borrowing rate based on industry peers in determining the present value of lease payments. The Company's facility operating lease has one single component. The lease component results in a right-of-use asset being recorded on the balance sheet, which is amortized as lease expense on a straight-line basis in the Company's consolidated statements of operations.

Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock was classified as a mezzanine instrument outside of the Company's capital accounts. Accretion of redeemable convertible preferred stock included the greater of an adjustment to fair market value or the accrual of dividends on and accretion of issuance costs of the Company's redeemable convertible preferred stock. The carrying values of the redeemable convertible preferred stock were increased or reduced by periodic accretion or reduction to their respective redemption values from the date of issuance to August 31, 2019, the date that all outstanding shares of redeemable convertible preferred stock converted into shares of common stock. The carrying value adjustments were recorded as charges against additional paid-in capital balance.

Preferred stock issuance costs represent costs related to the Company's issuance of redeemable convertible preferred stock. These amounts were included as a reduction of redeemable convertible preferred stock and were amortized over the estimated redemption period until its conversion to common stock in August 2019. For the year ended December 31, 2019 and 2018, amortization of preferred stock issuance costs amounted to approximately \$0.1 million and \$40 thousand, respectively.

Redeemable Convertible Preferred Stock Warrants

The Company accounted for warrants to purchase shares of its redeemable convertible preferred stock as liabilities at their estimated fair value because the underlying shares were redeemable, which obligated the Company to transfer assets to the holders at a future date. The warrants were subject to remeasurement to fair value at each balance sheet date, and any fair value adjustments were recognized as change in fair value of redeemable convertible preferred stock warrant liability in the consolidated statements of operations. The Company continued to adjust the liability for changes in fair value until the conversion of the

redeemable convertible preferred stock into common stock in August 2019. At that time, the redeemable convertible preferred stock warrant liability was adjusted to fair value in the consolidated statements of operations with the final fair value reclassified to equity.

Revenue Recognition

The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

To date, the Company's drug candidates have not been approved for sale by the FDA or any other country's regulatory authority, and the Company has not generated or recognized any revenue from the sale of products.

In March 2015, the Company entered into a license, development, and commercialization agreement (the "Kaken Agreement") with Kaken Pharmaceutical, Co., Ltd. ("Kaken"). Under the Kaken Agreement, the Company granted to Kaken an exclusive right to develop, manufacture, and commercialize the Company's sopironium bromide compound (formerly BBI-4000), a topical anticholinergic, in Japan and certain other Asian countries (the "Territory"). In exchange, Kaken paid the Company an upfront, non-refundable payment of \$11.0 million (the "upfront fee"). In addition, the Company was entitled to receive aggregate payments of up to \$10.0 million upon the achievement of specified development milestones, and \$30.0 million upon the achievement of commercial milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. The Kaken Agreement further provides that Kaken will be responsible for funding all development and commercial costs for the program in the Territory and, until such time, if any, as Kaken elects to establish its own source of supply of drug product, Kaken can purchase product supply from the Company to perform all non-clinical studies, and Phase 1 and Phase 2 clinical trials in Japan at cost. Kaken is also required to enter into negotiations with the Company, to supply the Company, at cost, with clinical supplies to perform Phase 3 clinical trials in the United States.

The Company evaluates collaboration arrangements to determine whether units of account within the collaboration arrangement exhibit the characteristics of a vendor and customer relationship. The Company determined that the licenses transferred to Kaken in exchange for the upfront fees were representative of this type of a relationship. If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition on a prospective basis.

Under Topic 606, the Company evaluated the terms of the Kaken Agreement and the transfer of intellectual property and manufacturing rights (the "license") was identified as the only performance obligation as of the inception of the agreement. The Company concluded that the license for the intellectual property was distinct from its ongoing supply obligations. The Company further determined that the transaction price under the arrangement was comprised of the \$11.0 million upfront payment. The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained. As part of its evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals, each of which is uncertain at this time. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur. Future potential milestone amounts would be recognized as revenue from collaboration arrangements, if unconstrained. The remainder of the arrangement, which largely consisted of both parties incurring costs in their respective territories, provides for the reimbursement of the ongoing supply costs. These costs were representative of a collaboration arrangement outside of the scope of Topic 606 as it does not have the characteristics of a vendor and customer relationship. Reimbursable program costs are recognized proportionately with the delivery of drug substance and are accounted for as reductions to research and development expense and are excluded from the transaction price.

Under Topic 606, the entire transaction price of \$11.0 million was allocated to the license performance obligation. The license was deemed to be delivered in 2015 in connection with the execution of the Kaken Agreement and upon transfer of the underlying intellectual property the performance obligation was fully satisfied. As a result, a cumulative adjustment to reduce deferred revenue and the corresponding sublicensing costs of \$2.7 million was recorded upon the adoption of Topic 606 on January 1, 2018. As of December 31, 2019, the Company does not have a deferred revenue or deferred sublicensing costs balance related to the upfront fee on the consolidated balance sheet.

In May 2018, the Company entered into an amendment to the Kaken Agreement (as further amended, "Kaken Agreement"), pursuant to which, the Company received an upfront non-refundable fee of \$15.6 million (the "Kaken R&D Payment"), which was initially recorded as deferred revenue, to provide the Company with research and development funds for the sole purpose of conducting certain clinical trials and other such research and development activities required to support the submission of a NDA for sofipironium bromide. These clinical trials have a benefit to Kaken and have the characteristics of a vendor and customer relationship. The Company has accounted for these under the provisions of Topic 606. This Kaken R&D Payment will be initially recognized using an input method over the average estimated performance period of 1.45 years in proportion to the cost incurred. Upon receipt of the Kaken R&D Payment, on May 31, 2018, a milestone payment originally due upon the first commercial sale in Japan was removed from the Kaken Agreement and all future royalties to the Company under the Kaken Agreement were reduced 150 basis points.

Consequently, during the year ended December 31, 2019 and 2018, the Company recognized revenue of \$7.9 million and \$5.9 million, respectively, related to the Kaken R&D Payment. As of December 31, 2019 and 2018, the Company had a deferred revenue balance related to the Kaken R&D Payment of \$1.8 million and \$9.7 million, respectively, which is recorded in deferred revenue, current portion and net of current portion, on the accompanying consolidated balance sheets.

Milestones

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company or the Company's collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

In October 2017, the Company entered into an amendment to the Kaken Agreement, pursuant to which, the Company granted Kaken a prepayment option (the "Kaken Option") on 50% of the Initiation of Phase 3 milestone (the "Phase 3 Milestone"). The Kaken Option was exercisable by Kaken within 25 business days of receipt of the BBI-4000-CL-203 study topline results. In December 2017, Kaken exercised the Kaken Option and paid the Company \$5.0 million (the "Kaken Option Payment"). Upon receipt of the non-refundable Kaken Option Payment, the Company provided Kaken the right to negotiate an exclusive license to develop, manufacture and commercialize each of the Company's other product candidates in Japan ("ROFN Agreement"). Under the ROFN Agreement, following the completion of any Initial Proof of Concept Clinical Trial ("Initial POC") for the Company's other product candidates, the Company must provide Kaken with certain information relating to the results of the clinical trial ("Initial POC Package"). The ROFN Agreement is exercisable by Kaken within 30 days of receipt of the Initial POC Package. In December 2017, the Company recognized collaboration revenue related to the Kaken Agreement of \$5.0 million, in connection with the Kaken Option. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

The Kaken Agreement was further amended in March 2018 to accelerate payment of the Phase 3 Milestone. The Phase 3 Milestone was modified to be due upon the successful completion of the End of Phase 2 Meeting with the PMDA by Kaken on March 8, 2018, as determined by Kaken in its reasonable discretion (the "Third Milestone"). In March 2018, Kaken triggered the Third Milestone and paid the Company \$5.0 million (the "Third Milestone Payment"). Upon receipt of the non-refundable Third Milestone Payment, the ROFN Agreement was amended (the "Amended ROFN Agreement") to grant an additional option to exercise upon completion of a Subsequent Clinical Trial (first clinical trial after the Initial POC) for the Company's other product

candidates. The Company has determined that the ROFN Agreement is not a material right and has not allocated transaction price to this provision. As of December 31, 2019, Kaken has not exercised the Amended ROFN Agreement. In March 2018, the Company recognized collaboration revenue related to the Kaken Agreement of \$5.0 million in connection with the Third Milestone. Additionally, the Company recognized sublicensing costs of \$1.0 million, which are included in general and administrative expenses.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognized revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue from any collaborative arrangement.

Under collaborative arrangements, the Company has been reimbursed for a portion of the Company's research and development expenses, including costs of drug supplies. When the research and development services are performed under a reimbursement or cost sharing model with a collaboration partner, the Company records these reimbursements as a reduction of research and development expense in the Company's consolidated statements of operations.

Net Loss per Common Share

Basic and diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing the Company's net earnings by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares.

Diluted earnings per share gives effect to all dilutive potential common shares outstanding during the period, including stock options and warrants, using the treasury stock method, and redeemable convertible preferred stock, using the if-converted method. In computing diluted earnings per share, the average stock price for the period is used in determining the number of shares assumed to be purchased from the exercise of stock options or warrants. Potentially dilutive common share equivalents are excluded from the diluted earnings per share computation in net loss periods because their effect would be anti-dilutive.

The following table sets forth the potential common shares excluded from the calculation of net loss per common share, because their inclusion would be anti-dilutive:

	Year Ended December 31,	
	2019	2018
Warrants to purchase common stock	720,982	55,344
Options to purchase common stock	525,665	376,299
Redeemable convertible preferred stock (as converted into common stock)	—	1,256,466
Warrants to purchase redeemable convertible preferred stock (as converted into common stock)	—	9,005
Total	1,246,647	1,697,114

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is identifying, developing and commercializing innovative and differentiated therapeutics for the treatment of skin diseases. No revenue from sales of product has been generated since inception, and all tangible assets are held in the United States.

NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"), which amends certain disclosure requirements over Level 1,

Level 2, and Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-13, but does not anticipate it will have a material impact on its disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842)” (“ASU 2016-02”). ASU 2016-02 is aimed at making leasing activities more transparent and comparable and requires substantially all leases be recognized by lessees on their balance sheets as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The Company adopted ASU 2016-02 on January 1, 2019 using the modified retrospective approach. The adoption did not have a material impact on the Company’s consolidated statements of operations. The new standard has required the Company to establish liabilities and corresponding right-of-use assets on its consolidated balance sheet for operating leases of \$0.2 million that existed as of the January 1, 2019 adoption date. The impact on the consolidated balance sheets as of January 1, 2019 was as follows (in thousands):

Balance Sheet	<u>Topic 840</u> January 1, 2019	<u>Topic 842</u> January 1, 2019	Impact of Adoption
Operating lease right-of-use asset	\$ —	\$ 219	\$ 219
Lease liability, current portion	—	(68)	(68)
Lease liability, net of current portion	—	(151)	(151)

NOTE 4. ACCRUED LIABILITIES

Accrued liabilities consisted of the following (in thousands):

	<u>December 31,</u>	
	<u>2019</u>	<u>2018</u>
Accrued contracted research and development services	\$ 4,532	\$ 847
Accrued professional fees	1,788	1,269
Accrued compensation	59	569
Accrued note payable issuance costs	—	587
Total	<u>\$ 6,379</u>	<u>\$ 3,272</u>

NOTE 5. CONVERTIBLE PROMISSORY NOTES

In March 2019, the Company initiated a convertible promissory notes offering pursuant to which the Company issued unsecured convertible promissory notes (the “Prom Notes”), bearing interest at 12.00% with a maturity of one year and convertible into shares of Series C-1 redeemable convertible preferred stock or the most senior preferred equity outstanding at the time of conversion at the option of the holder at a conversion price of \$31.05 per share. In addition, the Prom Notes were automatically convertible upon closing of a qualified financing of at least \$15.0 million before maturity at a conversion price equal to 80% of the effective price per share paid in the qualified financing, but not to exceed \$38.82 per share. Through August 31, 2019, the Company had raised an aggregate principal amount of \$7.4 million in Prom Notes, including \$1.7 million from certain of the Company’s management and board of directors. On August 31, 2019, immediately prior to the Merger, the Prom Notes and related accrued interest converted into 1,069,740 shares of Private Brickell common stock at a conversion price of \$7.54 per share (the “Conversion”).

The Prom Notes also provided for the issuance of warrants at 50% coverage, to acquire 490,683 shares of common stock. The warrants are exercisable for a term of five years at an exercise price of \$10.36. Prior to the Merger, the warrants were exercisable at an exercise price of \$42.70 or 10% premium to the effective price per share paid in a qualified financing. The Company evaluated the various financial instruments under ASC 480 and ASC 815 and determined the warrants required fair value accounting. The fair value of the warrants was recorded as a warrant liability upon issuance. The fair value of the warrants on the dates of issuance of \$1.5 million was determined with the assistance of a third-party valuation firm. The fair value of the warrants was recorded as a debt discount upon issuance and was amortized to interest expense over the term of the Prom Notes based on the effective interest method.

At inception of the Prom Notes offering, the Company analyzed the conversion feature of the agreement for derivative accounting consideration under ASC 815 and determined that the embedded conversion features should be classified as a derivative because

the exercise price of the Prom Notes are subject to a variable conversion rate. The Company determined that the variable conversion feature was a redemption feature that was not clearly and closely related to the Prom Notes and was therefore required to be bifurcated. In accordance with AC 815, the Company bifurcated the conversion feature of the Prom Notes and recorded a derivative liability.

The embedded derivative for the Prom Notes was carried on the Company's consolidated balance sheet at fair value. The derivative liability was marked-to-market each measurement period and any change in fair value was recorded as a component of the statements of operations. The fair value of the derivative liabilities on the date of issuance of \$1.4 million was determined with the assistance of a third-party valuation firm. The fair value of the conversion feature was recorded as a debt discount upon issuance and was amortized to interest expense over the term of the Prom Notes based on the effective interest method.

The Company evaluated the conversion option to discern whether a beneficial conversion feature existed based upon comparing the effective exercise price of the convertible notes to the fair value of the shares they were convertible into. The Company concluded no beneficial conversion feature existed. During the year ended December 31, 2019, the Company recognized \$2.0 million of interest expense, including \$0.8 million of accretion of discounts using an effective interest rate of 12.00%.

As a result of the Conversion on August 31, 2019, the Prom Notes payable, warrant liability, and derivative liability balances were reclassified to equity in the consolidated balance sheets. A gain of \$2.3 million resulted from the conversion of the Prom Notes, which is included in the gain on extinguishment line in the consolidated statements of operations.

NOTE 6. NOTE PAYABLE

On February 18, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. (the "Lender") under which the Company borrowed \$7.5 million upon the execution of the Loan Agreement on February 18, 2016. The interest rate applicable to each tranche was variable based upon the greater of either (i) 9.2% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal minus 3.5%, plus (b) 9.2%; notwithstanding the above, such rate could not exceed the permissible rates of interest on commercial loans under the laws of the State of California. Payments under the Loan Agreement were interest only until June 1, 2017, followed by equal monthly payments of principal and interest through the maturity date of September 1, 2019. The Company was required to make an end of term payment of 4.5% of the sum of (i) term loan advances, plus (ii) 50% of the aggregate unfunded term loan commitments. The Loan Agreement was further amended in December 2017, March 2018, and July 2018 (as further amended, "Loan Agreement") to provide for an additional combined interest-only period of eight months, and the outstanding loan balance continued to be paid in equal monthly installments of principal and interest. As a result of the amendments, the Company was required to increase the end-of-term payment by \$0.1 million. At the inception of the loan and the following amendment dates, the Company paid the Lender aggregate facility fees of \$0.2 million in connection with the Loan Agreement.

In connection with the Loan Agreement, the Company issued warrants to the Lender, which are exercisable for 9,005 shares of common stock at a per share exercise price of \$33.31 (the "Hercules Capital Warrants"). The Hercules Capital Warrants will terminate, if not earlier exercised, on February 18, 2026. The fair value of the Hercules Capital Warrants was recorded at inception as a redeemable convertible preferred stock warrant liability upon issuance. The fair value of the Hercules Capital Warrants on the date of issuance of \$0.3 million was determined using the Black-Scholes option-pricing model and was recorded as a debt discount upon issuance and was amortized to interest expense over the term of the loan based on the effective interest method.

On September 3, 2019, the Company repaid the remaining outstanding loan balance of \$2.6 million and an associated accrued interest and aggregate end-of-term payment of \$0.6 million, and the Loan Agreement was terminated. At the effective time of the Merger, the warrant liability was reclassified to equity in the consolidated balance sheet. As of December 31, 2019, there were no remaining unaccreted debt discounts and issuance costs.

NOTE 7. COMMITMENTS AND CONTINGENCIES

Operating Leases

In August 2016, the Company entered into a five-year lease for office space in Boulder, Colorado that expires on October 31, 2021 (the "Boulder Lease") subject to the Company's option to renew the Boulder Lease for two additional terms of three years each. Pursuant to the Boulder Lease, the Company leased 3,038 square feet of space in a multi-suite building. Rent payments under the Boulder Lease included base rent of \$4,430 per month during the first year of the Boulder Lease with an annual increase

of 3.5%, and additional monthly fees to cover the Company's share of certain facility expenses, including utilities, property taxes, insurance, and maintenance, which were \$2,160 per month during the first year of the Boulder Lease.

The Company recognized a right-of-use asset and corresponding lease liability on January 1, 2019, by calculating the present value of lease payments, discounted at 2.0%, the Company's estimated incremental borrowing rate, over the 2.8 years expected remaining term. As the Company's lease does not provide an implicit rate, the Company estimated the incremental borrowing rate based on industry peers. Industry peers consist of several public companies in the biotechnology industry with comparable characteristics, including clinical trials progress and therapeutic indications. Amortization of the operating lease right-of-use asset for the Boulder Lease amounted to \$0.1 million for the year ended December 31, 2019, and was included in operating expense. As of December 31, 2019, the remaining lease term was 1.8 years.

The terms of the Boulder Lease provide for rental payments on a monthly basis on a graduated scale. Lease expense for the years ended December 31, 2019 and 2018 was \$0.1 million.

The following is a summary of the contractual obligations related to operating lease commitments as of December 31, 2019 and the effect such obligations are expected to have on the liquidity and cash flows in future periods (in thousands):

Less than 1 year	\$	84
1-3 years		77
3-5 years		—
More than 5 years		—
Imputed interest		(10)
Total	\$	<u>151</u>

NOTE 8. CAPITAL STOCK

Common Stock

Each share of the Company's common stock is entitled to one vote, and the holders of the Company's common stock are entitled to receive dividends when and as declared or paid by its board of directors. The Company has reserved authorized shares of common stock for future issuance at December 31, 2019 as follows:

	December 31, 2019
Common stock options outstanding	1,793,602
Common stock warrants	720,982
Options available for grant under the Vical Plan	86,584
Options available for grant under the 2009 Plan	59,011
Total	<u>2,660,179</u>

Preferred Stock

In August 2019, in conjunction with the Merger, all outstanding shares of redeemable convertible preferred stock converted into shares of common stock at a ratio of 1:1 and were immediately exchanged for common stock at an Exchange Ratio of 2.4165 as a result of the Merger.

Redeemable convertible preferred stock consisted of the following prior to the conversion on August 31, 2019 (in thousands, except share data):

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Carrying Value	Common Stock Issued Upon Conversion
Series A	1,162,505	401,309	\$ 4	\$ 12,164	401,309
Series B	882,216	286,151	3	10,084	286,151
Series C	869,565	256,583	3	11,630	256,583
Series C-1	1,531,942	312,423	3	14,138	312,423
	4,446,228	1,256,466	\$ 13	\$ 48,016	1,256,466

Redeemable convertible preferred stock consisted of the following as of December 31, 2018 (in thousands, except share data):

	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Par Value	Carrying Value	Common Stock Issuable Upon Conversion
Series A	1,162,505	401,309	\$ 4	\$ 16,098	401,309
Series B	882,216	286,151	3	13,011	286,151
Series C	869,565	256,583	3	13,018	256,583
Series C-1	1,268,657	312,423	3	16,163	312,423
	4,182,943	1,256,466	\$ 13	\$ 58,290	1,256,466

As of December 31, 2019, the Company had no outstanding shares of redeemable convertible preferred stock and had not designated the rights, preferences, or privileges of any class or series of preferred stock. Although, the Company's board of directors has the authority, at its discretion, to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences, and the number of shares constituting any class or series of preferred stock, without further vote or action by the stockholders.

NOTE 9. STOCK-BASED COMPENSATION

Equity Incentive Plans

The Company's 2009 Equity Incentive Plan, as amended and restated (the "2009 Plan"), provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors, and consultants of the Company. At December 31, 2019, the total shares authorized under the 2009 Plan were 1,634,655 shares. The board of directors or a designated committee of the board of directors is responsible for the administration of the 2009 Plan and determines the term, exercise price, and vesting terms of each option. Options granted under the 2009 Plan have an exercise price equal to the market value of the common stock at the date of grant and expire ten years from the date of grant. At December 31, 2019, a total of 59,011 shares were available for grant under the 2009 Plan.

In connection with the Merger, the Company adopted Vical's Equity Incentive Plan (the "Vical Plan"). At December 31, 2019, the total shares authorized under the Vical Plan were 413,710 shares. The Vical Plan, as amended, provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors, and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares, including restricted stock. The exercise price of stock options must equal at least the fair market value of the underlying common stock on the date of grant. The maximum term of options granted under the plan is ten years. The Vical Plan also limits the number of options that may be granted to any plan participant in a single calendar year to 1,300,000 shares. At December 31, 2019, a total of 86,584 shares were available for grant under the Vical Plan.

A summary of stock option activity under the 2009 Plan and the Vical Plan is as follows, as converted associated with stock split and conversion:

	Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (In Years)
Outstanding at December 31, 2018	696,842	\$ 13.21		
Acquired under Vical Plan	184,087	\$ 75.98		
Granted	1,088,260	\$ 4.67		
Exercised	—	\$ —		
Forfeited or expired	(175,587)	\$ 28.22		
Outstanding at December 31, 2019	1,793,602	\$ 13.00	\$ 4,971	8.49
Options vested and exercisable at December 31, 2019	525,665	\$ 28.41	\$ 73,878	5.97

Share-based Compensation Expense

Total stock-based compensation expense related to stock options granted under the 2009 Plan and the Vical Plan was allocated as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Research and development	\$ 349	\$ 340
General and administrative	1,183	371
Total stock-based compensation expense	\$ 1,532	\$ 711

As of December 31, 2019, the Company had \$5.7 million of total unrecognized share-based compensation expense, which is expected to be recognized over a period of approximately 3.32 years.

Fair Value Assumptions

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock-based awards. The determination of the fair value of stock-based awards on the date of grant using an option-pricing model is affected by the value of the Company's stock price, as well as assumptions regarding subjective variables. These variables include expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rate, and expected dividends.

Because the Company has a limited history of stock purchase and sale activity, the Company estimates expected volatility of the common stock by using the average share fluctuations of companies similar in size, operations, and life cycle. The expected term of stock options granted to employees, including members of the board of directors, is determined as the midpoint between the vesting date and the contractual end of the option grant. The expected term of all other stock options granted is based on the Company's historical share option exercise experience, which approximates the midpoint between the vesting date and the contractual end of the option grant. The risk-free interest rates used in the valuation model are based on U.S. Treasury yield issues in effect at the time of grant for a period commensurate with the expected term of the grant. The Company does not anticipate paying any dividends in the foreseeable future and therefore uses an expected dividend yield of zero.

Management has estimated a forfeiture rate of 7% based on past experience, forfeiture rates, and the individuals receiving the options. The Company monitors actual forfeiture experience and periodically updates forfeiture estimates based on actual experience.

Stock Options Granted to Employees

During the year ended December 31, 2019 and 2018, the Company granted 982,890 stock options and 252,681 stock options, respectively, to employees and non-employee directors to purchase shares of common stock with a weighted-average grant date

fair value of \$3.24 and \$4.16 per share, respectively, and a weighted-average exercise price of \$4.58 and \$5.68 per share, respectively.

The assumptions used to calculate the fair value of stock options granted to employees and non-employee directors under the 2009 Plan are as follows, presented on a weighted average basis:

	Year Ended December 31,	
	2019	2018
Expected term (in years)	6.1	6.1
Expected volatility	83.22%	85.43%
Risk free interest rate	1.44%	2.77%
Expected dividend yield	—%	—%

Stock Options Granted to Non-employees

During the year ended December 31, 2019 and 2018, the Company granted 105,370 stock options and 15,188 stock options, respectively, to persons other than employees and non-employee members of the Company's board of directors with a weighted-average exercise price of \$5.53 and \$5.68 per share, respectively.

The assumptions used to calculate the fair value of stock options granted to non-employees under the 2009 Plan are as follows, presented on a weighted average basis:

	Year Ended December 31,	
	2019	2018
Expected term (in years)	6.02	9.96
Expected volatility	82.82%	86.17%
Risk free interest rate	1.49%	2.69%
Expected dividend yield	—%	—%

NOTE 10. INCOME TAXES

During the years ended December 31, 2019 and 2018, the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2019	2018
Federal statutory income tax rate	21.00 %	21.00 %
State taxes, net of federal benefit	3.16	3.71
Research and development tax credits	3.25	8.77
Permanent differences and other	(2.51)	2.36
Transaction costs	(1.88)	—
Stock-based compensation	(1.02)	—
Change in tax rate	0.02	1.80
Change in deferred tax asset valuation allowance	(22.02)	(37.64)
Effective income tax rate	— %	— %

Approximate deferred tax assets (liabilities) resulting from timing differences between financial and tax bases were associated with the following items (in thousands):

	Year Ended December 31,	
	2019	2018
Net operating loss carryforwards	\$ 82,703	\$ 8,918
Research and development credit	15,509	3,207
Depreciable assets	10,443	—
Accrued expenses	719	—
Deferred revenue	449	2,040
Net book value of intangible assets	415	75
Stock-based compensation	332	520
Other	63	514
Net deferred tax asset	110,633	15,274
Less: valuation allowance	(110,633)	(15,274)
Net deferred tax assets	\$ —	\$ —

At December 31, 2019, the Company had deferred tax assets of \$110.6 million. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax asset.

As of December 31, 2019 and 2018, the Company had available federal NOL carryforwards of approximately \$403.9 million and \$36.4 million, respectively. The NOL generated in 2019 of \$25.1 million and 2018 of \$2.4 million will carry forward indefinitely and be available to offset up to 80% of future taxable income each year. NOLs generated prior to 2018 will expire from 2019 through 2038. In addition, the Company had federal research and development credits and orphan drug credit carryforwards of \$30.3 million and \$3.2 million as of December 31, 2019 and 2018, respectively, to reduce future federal income taxes, if any. These carryforwards expire from 2019 through 2038 and are subject to review and possible adjustment by the IRC. The Company also has available state NOL carryforwards of approximately \$350.6 million and \$31.0 million as of December 31, 2019 and 2018, respectively, which expire from 2028 to 2038. In addition, through the Merger, the Company acquired Vical's California research and development credits of approximately \$9.3 million as of December 31, 2019 and 2018, to reduce future California income tax, if any. The California research and development credits do not expire.

Pursuant to Sections 382 and 383 of the Internal Revenue Code "IRC," annual use of the Company's net operating loss ("NOL") and credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. Vical completed a Section 382 analysis through December 31, 2011 and as a result of an ownership change on December 29, 2006, the Company estimates that \$89.3 million of Vical's acquired NOL carryforwards were effectively eliminated under Section 382 for federal tax purposes. The Company also estimates \$10.8 million of Vical's acquired research and development credits and other tax credits were effectively eliminated under Section 383 for federal purposes. Accordingly, after consideration of these limitations, the Company recorded federal and state NOL carryforward of \$253.1 million and \$291.5 million, respectively, and federal and state credit carryforwards of \$24.6 million as a result of the Merger. Vical has not conducted a Section 382 study for periods between December 31, 2011 and the date of the Merger. As such, the Company cannot provide any assurance that a change in ownership within the meaning of the IRC has not occurred between those dates. There is a risk that additional changes in ownership could have occurred between those dates.

It is further noted, the Company has not completed an IRC 382 and 383 analysis to determine if a change in ownership has incurred since the inception of the Company. If a change in ownership were to have occurred, additional NOL and tax credit carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance.

All federal and state NOL and credit carryforwards listed above are reflected before the reduction for amounts effectively eliminated under Sections 382 and 383. Based upon statute, federal and state NOLs and credits are expected to expire as follows (in thousands):

Expiration Date:	Federal NOLs	State NOLs	Federal R&D Credit	Federal Orphan Drug Credit	State R&D Credit
2020	\$ 13,311	\$ —	\$ 334	\$ 2,288	\$ —
2021	9,866	—	334	1,962	—
2022	24,100	—	483	1,610	—
2023	24,743	—	322	929	—
2024	26,332	—	213	663	—
2025 and thereafter	242,941	350,557	7,387	13,813	—
Indefinite	62,618	—	—	—	9,265
Totals	\$ 403,911	\$ 350,557	\$ 9,073	\$ 21,264	\$ 9,265

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2019 and 2018. Management reevaluates the positive and negative evidence at each reporting period. The Company's valuation allowance increased by approximately \$95.4 million for year ended December 31, 2019, which includes a full valuation allowance against the acquired deferred tax assets from the Merger. For theyear ended December 31, 2018, the valuation allowance increased by \$3.5 million.

The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes that it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcome of examinations by tax authorities in determining the adequacy of its provision for income taxes. Before the merger, the Company had no material unrecognized tax benefits and no adjustments to its financial positions. However, the Merger brought with it certain unrecognized tax benefits.

As a result of the Merger, the Company acquired gross unrecognized tax benefits with a balance of \$21.7 million as of December 31, 2019. The Company does not anticipate any significant decreases in its unrecognized tax benefits over the next 12 months. The Company's policy is to recognize the interest expense and/or penalties related to income tax matters as a component of income tax expense. The Company had no accrual for interest or penalties on its balance sheets at December 31, 2019 and 2018, and has not recognized interest and/or penalties in its statements of operations for the years ended December 31, 2019 and 2018.

As of December 31, 2019, the Company's U.S. federal and state tax returns remain subject to examination by tax authorities beginning with the tax year ended December 31, 2016. However, due to NOLs and credit carryforwards being generated and carried forward from prior tax years, substantially all tax years may also be subject to examination.

NOTE 11. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

This information has been prepared on a basis consistent with that of the audited consolidated financial statements. We believe that all necessary adjustments, consisting of normal recurring accruals and adjustments, have been included to present fairly the quarterly financial data. The results of historical periods are not necessarily indicative of the results of operations for any future period.

The table below summarizes the Company's unaudited consolidated quarterly operating results for the year ended December 31, 2019:

	For the Quarters Ended			
	March	June	September	December
	(unaudited, in thousands, except per share data)			
Collaboration revenue	\$ 3,492	\$ 2,573	\$ 1,183	\$ 669
Loss from operations	\$ (4,593)	\$ (2,979)	\$ (6,055)	\$ (10,841)
Net loss	\$ (4,580)	\$ (3,654)	\$ (4,781)	\$ (10,862)
Net income (loss) attributable to common stockholders	\$ 5,939	\$ (3,817)	\$ (4,863)	\$ (10,862)
Basic net income (loss) per common share attributable to common stockholders	\$ 10.08	\$ (6.49)	\$ (1.65)	\$ (1.38)
Diluted net loss per common share attributable to common stockholders	\$ (2.48)	\$ (6.49)	\$ (1.65)	\$ (1.38)

The table below summarizes the Company's unaudited consolidated quarterly operating results for the year ended December 31, 2018:

	For the Quarters Ended			
	March	June	September	December
	(unaudited, in thousands, except per share data)			
Collaboration revenue	\$ 5,000	\$ 373	\$ 3,042	\$ 2,473
Income (loss) from operations	\$ 764	\$ (3,315)	\$ (2,299)	\$ (3,601)
Net income (loss)	\$ 527	\$ (3,552)	\$ (2,541)	\$ (3,670)
Net loss attributable to common stockholders	\$ (2,713)	\$ (4,417)	\$ (3,507)	\$ (4,535)
Basic and diluted net loss per common share attributable to common stockholders	\$ (4.63)	\$ (7.53)	\$ (5.98)	\$ (7.72)

NOTE 12. SUBSEQUENT EVENTS

Private Placement Offerings

On February 17, 2020, the Company and Lincoln Park entered into (i) a securities purchase agreement (the "Securities Purchase Agreement"); (ii) a purchase agreement (the "Purchase Agreement"); and (iii) a registration rights agreement (the "Registration Rights Agreement"). Pursuant to the Securities Purchase Agreement, Lincoln Park agreed to purchase, and the Company agreed to sell, upon the terms and subject conditions stated therein (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.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has 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 common stock. Sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the February 28, 2020 the "Commencement Date").

Following the Commencement Date, under the Purchase Agreement, on any business day selected by the Company, the Company 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 25,000 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 50,000 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. 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, the Company 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, the Company may not sell shares of its 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 common stock.

The Company agreed with Lincoln Park that it will not enter into any “variable rate” transactions with any third party for a period defined in the Purchase Agreement. The Company has 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 the Company from time to time, including, among others, market conditions, the trading price of the common stock and determinations by the Company as to the appropriate sources of funding for the Company and its operations. The Company expects that any net proceeds received by the Company from such sales to Lincoln Park will be used for research and development, working capital and general corporate purposes.

The Securities Purchase Agreement, the Purchase Agreement, and the Registration Rights Agreement contain customary representations, warranties, agreements and conditions to completing future sale transactions, indemnification rights and obligations of the parties.

Amended and Restated License Agreement with Bodor

On February 17, 2020, the Company, Brickell Subsidiary, Inc., 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 Bodor license agreement, dated December 15, 2012, entered into between the Company 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 the Company a worldwide, exclusive license to develop, manufacture, market, sell and sublicense technology products containing the proprietary compound sofipironium 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 the Company and Bodor, the Company made an upfront payment of \$1.0 million in cash to Bodor following the execution of the Amended and Restated License Agreement and the Settlement Agreement. The Company is required to further pay Bodor (i) a specified percentage of all royalties received from covered sales in territories pursuant to the Kaken Agreement; (ii) a modified percentage of any sublicensing income the Company receives pursuant to the Kaken Agreement; (iii) a low single-digit royalty related to a newly filed provisional patent application anywhere outside of the territories in the Kaken Agreement by the Company; and (iv) a specified cash amount following the occurrence of certain new milestone events.

The Company also agreed to issue to Bodor shares of its common stock upon the occurrence of certain new milestone events, as further described in the Amended and Restated License Agreement. The Amended and Restated License Agreement also imposes various diligence, sublicensing, milestone, royalty, notice, disbursement, dispute resolution and other obligations and restrictions on the Company. Consistent with the original license agreement, if the Company were to fail to comply with its material obligations under the Amended and Restated License Agreement, and if the Company does not successfully cure such alleged breach, then Bodor maintains the right to terminate the license, subject to the dispute procedures as set forth therein, in which event the Company might not be able to develop or market sofipironium bromide for its licensed use, if such termination is deemed valid.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive and financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act as of the end of the period covered by this Annual Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of December 31, 2019.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our 2020 Proxy Statement to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

Our board of directors has adopted a Code of Conduct applicable to all officers, directors, and employees, which is available on our website (www.ir.brickellbio.com) under "Governance". We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Conduct by posting such information on the website address and location specified above.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our 2020 Proxy Statement to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our 2020 Proxy Statement to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our 2020 Proxy Statement to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our 2020 Proxy Statement to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

PART IV.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The financial statements required by this item are submitted in a separate section beginning on page F-1 of this Annual Report.

(a)(2) Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required, not applicable, or the information is otherwise included.

(a)(3) Exhibits

See Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit	Filed Herewith
3.1	Restated Certificate of Incorporation, as currently in effect (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).	
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).	
3.3	Certificate of Merger (incorporated by reference to Exhibit 3.4 to the Company's Current Report on 8-K filed with the SEC on September 3, 2019).	
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed with the SEC on September 10, 2019).	
10.1†	License, Development and Commercialization Agreement, as amended, dated March 31, 2015, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).	
10.2†	Right of First Negotiation Agreement, as amended, dated March 31, 2015, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).	
10.3.1†	Amended and Restated License Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).	
10.3.2†	Settlement Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).	
10.4†	UAB Research Foundation License Agreement, as amended, dated June 26, 2012, by and between Brickell Biotech, Inc. and the UAB Research Foundation (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).	
10.5†	License Agreement, as amended, dated June 6, 2013, by and among Brickell Biotech, Inc., Orca Pharmaceuticals LLC, and the New York University (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).	

10.6†	Orca Pharmaceuticals LLC Asset Purchase Agreement, dated November 23, 2015 by and between Brickell Biotech, Inc. and Orca Pharmaceuticals (incorporated by reference to Exhibit 10.8 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.7†	Panmira Pharmaceuticals LLC Purchase Agreement, dated January 30, 2015, by and between Brickell Biotech, Inc. and Panmira Pharmaceuticals (incorporated by reference to Exhibit 10.9 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.8	Boulder Lease Agreement, as amended, dated August 4, 2016, by and between Brickell Biotech, Inc. and BMC Properties, LLC (incorporated by reference to Exhibit 10.10 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.9+	Employment Agreement, dated November 16, 2018, by and between Brickell Biotech, Inc. and Robert Brown (incorporated by reference to Exhibit 10.11 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.10+	Second Amended and Restated Employment Agreement, dated November 27, 2018, by and between Brickell Biotech, Inc. and Andy Sklawer (incorporated by reference to Exhibit 10.12 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.11+	Employment Agreement, dated August 1, 2016, and Amendment to Employment Agreement, dated August 28, 2019, by and between Brickell Biotech, Inc. and Deepak Chadha (incorporated by reference to Exhibit 10.13 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.12+	Brickell Biotech, Inc. Letter Agreement, dated July 10, 2018 by and between Brickell Biotech Inc. and Jose Breton (incorporated by reference to Exhibit 10.14 to the Company’s Current Report on Form 8-K filed with the, SEC on September 3, 2019).
10.13+	Employment Agreement, dated July 1, 2019, and Amendment to Employment Agreement, dated August 27, 2019, by and between Brickell Biotech, Inc. and David R. McAvoy (incorporated by reference to Exhibit 10.15 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.14+	Employment Agreement, dated August 1, 2019, by and between Brickell Biotech, Inc. and Adam Levy (incorporated by reference to Exhibit 10.16 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.15	Registration Rights Agreement, dated August 31, 2019, by and between Brickell Biotech, Inc. and NovaQuest Co-Investment Fund X, L.P. (incorporated by reference to Exhibit 10.17 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.16†	U.S. Security Agreement, dated August 31, 2019, by and between Brickell Biotech, Inc. and NovaQuest Co-Investment Fund X, L.P. (incorporated by reference to Exhibit 10.18 to the Company’s Current Report on Form 8-K filed with the SEC on September 3, 2019).
10.17	Settlement and Termination Agreement, dated November 25, 2019, by and between Brickell Subsidiary, Inc., Brickell Biotech, Inc. and NovaQuest Co-Investment Fund X, L.P. (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the SEC on November 25, 2019).
10.18	Securities Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (schedules omitted) (incorporated by reference to Exhibit 10.3 to the Company’s Current Report on Form 8-K filed with the SEC on February 18, 2020).
10.19	Series A Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.4 to the Company’s Current Report on Form 8-K filed with the SEC on February 18, 2020).
10.20	Series B Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.5 to the Company’s Current Report on Form 8-K filed with the SEC on February 18, 2020).
10.21	Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.6 to the Company’s Current Report on Form 8-K filed with the SEC on February 18, 2020).
10.22	Registration Rights Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.7 to the Company’s Current Report on Form 8-K filed with the SEC on February 18, 2020).

21.1	List of Subsidiaries.	•
23.1	Consent of Ernst & Young LLP.	•
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.	•
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.	•
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	•
101.INS**	XBRL Instance Document	•
101.SCH**	XBRL Taxonomy Extension Schema Document	•
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document	•
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document	•
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document	•
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document	•

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

+ Indicates a management contract or compensatory plan.

* This certification is being furnished pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof.

** In accordance with Rule 406T of Regulation S-T, the Interactive Data Files in Exhibit 101 are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and otherwise are not subject to liability under these sections.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Brickell Biotech, Inc.

Date: March 18, 2020

By: /s/ Robert B. Brown
Robert B. Brown
Chief Executive Officer
(Principal Executive Officer)

By: /s/ R. Michael Carruthers
R. Michael Carruthers
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Robert B. Brown</u> Robert B. Brown	Chief Executive Officer and Director (Principal Executive Officer)	March 18, 2020
<u>/s/ R. Michael Carruthers</u> R. Michael Carruthers	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2020
<u>/s/ Reginald L. Hardy</u> Reginald L. Hardy	Co-Founder and Chairman of the Board of Directors	March 18, 2020
<u>/s/ George Abercrombie</u> George Abercrombie	Director	March 18, 2020
<u>/s/ Dennison T. Veru</u> Dennison T. Veru	Director	March 18, 2020
<u>/s/ Vijay B. Samant</u> Vijay B. Samant	Director	March 18, 2020
<u>/s/ Gary A. Lyons</u> Gary A. Lyons	Director	March 18, 2020

**Subsidiaries of the Registrant
(as of March 18, 2020)**

Name of Subsidiary	Jurisdiction of Incorporation
Brickell Subsidiary, Inc.	Delaware

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-8 No. 333-30181) pertaining to the 1992 Stock Plan of Vical Incorporated,
- (2) Registration Statement (Form S-8 No. 333-80681) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (3) Registration Statement (Form S-8 No. 333-60293) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (4) Registration Statement (Form S-8 No. 333-66254) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (5) Registration Statement (Form S-8 No. 333-97019) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (6) Registration Statement (Form S-8 No. 333-107581) pertaining to the Stock Incentive Plan of Vical Incorporated,
- (7) Registration Statement (Form S-8 No. 333-116951) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (8) Registration Statement (Form S-8 No. 333-135266) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (9) Registration Statement (Form S-8 No. 333-143885) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (10) Registration Statement (Form S-8 No. 333-169344) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (11) Registration Statement (Form S-8 No. 333-183215) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (12) Registration Statement (Form S-8 No. 333-190343) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (13) Registration Statement (Form S-8 No. 333-213034) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (14) Registration Statement (Form S-8 No. 333-219804) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated,
- (15) Registration Statement (Form S-3 No. 333-225208) of Vical Incorporated,
- (16) Registration Statement (Form S-8 No. 333-233698) pertaining to the Amended and Restated Stock Incentive Plan of Vical Incorporated and the Equity Incentive Plan of Brickell Biotech, Inc.,
- (17) Registration Statement (Form S-3 No. 333-236353) of Brickell Biotech, Inc.,
and
- (18) Registration Statement (Form S-3 No. 333-236757) of Brickell Biotech, Inc.

of our report dated March 18, 2020, with respect to the consolidated financial statements of Brickell Biotech, Inc., included in this Annual Report (Form 10-K) of Brickell Biotech, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Denver, Colorado
March 18, 2020

CERTIFICATION

I, Robert. B. Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K, or this report, of Brickell Biotech, Inc., a Delaware corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2020

By: /s/ Robert. B. Brown
Robert. B. Brown
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, R. Michael Carruthers, certify that:

1. I have reviewed this Annual Report on Form 10-K, or this report, of Brickell Biotech, Inc., a Delaware corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 18, 2020

By: /s/ R. Michael Carruthers
R. Michael Carruthers
Chief Financial Officer
(Principal Financial Officer)

SECTION 1350 CERTIFICATION

Each of the undersigned, Robert. B. Brown Chief Executive Officer of Brickell Biotech, Inc., a Delaware corporation (the "Company"), and R. Michael Carruthers, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Brickell Biotech, Inc.

By: /s/ Robert. B. Brown
Robert B. Brown
Chief Executive Officer
(Principal Executive Officer)
Date: March 18, 2020

By: /s/ R. Michael Carruthers
R. Michael Carruthers
Chief Financial Officer
(Principal Financial Officer)
Date: March 18, 2020

This certification accompanies and is being "furnished" with this Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.