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

FORM 8-K

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

Date of report (Date of earliest reported) February 10, 2020

BRICKELL BIOTECH, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**000-21088**	**93-0948554**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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

Registrant's telephone number, including area code: (720) 505-4755

(Former name or former address, if changed since last report.)

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

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

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

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

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

Emerging growth company ☐

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

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On February 10, 2020, Brickell Biotech Inc. (the "Company") announced that Dr. Sanjeev Ahuja notified the Company of his resignation from his position as the Company's Chief Medical Officer to pursue other opportunities. Dr. Ahuja will remain as the Company's Chief Medical Officer until February 29, 2020, and thereafter, plans to continue to work with the Company in a consulting capacity.

Item 8.01. Other Events.

The Company is filing the risk factors attached hereto as Exhibit 99.1 for the purpose of supplementing and updating the risk factor disclosure contained in its Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2019 as filed with the Securities and Exchange Commission on November 14, 2019. The updated risk factors are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1Risk Factors

SIGNATURE

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

Date: February 10, 2020

Brickell Biotech, Inc.

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

Exhibit 99.1

RISK FACTORS

*An investment in our securities involves risks. We urge you to carefully consider all of the risks described below and all other information contained in or incorporated by reference in our filings with the Securities and Exchange Commission ("**SEC**"). We expect to update these Risk Factors from time to time in the periodic and current reports that we file with the SEC. These Risk Factors also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of certain factors, including the risks described below. If any of these risks occur, this could expose us to liability, and our business, financial condition or results of operation could be adversely affected. As a result, you could lose all or part of your investment.*

Unless otherwise noted or unless the context requires otherwise, the terms "Brickell," the "Company," "we," "us" and "our" refer to Brickell Biotech, Inc. and its consolidated subsidiaries.

As used herein, "Merger" refers to the reverse merger transaction completed on August 31, 2019, pursuant to the Agreement and Plan of Merger and Reorganization dated as of June 2, 2019, as amended by Amendment No. 1 to the Agreement and Plan of Merger and Reorganization, dated August 20, 2019, and as further amended on August 30, 2019, by and among Vical Incorporated ("Vical"), Brickell and Victory Subsidiary, Inc., a wholly-owned subsidiary of Vical formed in connection with the merger (the "Merger Sub"), pursuant to which the Merger Sub merged with and into Brickell, with Brickell surviving the merger as a wholly-owned subsidiary of Vical.

Risks Related to the Development, Commercialization and Regulatory Approval of Our Investigational Drug, Sofpironium Bromide

We are currently involved in litigation with the Bodor Plaintiffs relating to our right to continue to develop sofpironium bromide.

On October 23, 2019, Bodor Laboratories, Inc. ("**Bodor**") notified us of its purported termination of the license agreement we entered into with Bodor, dated December 15, 2012, as amended by Amendment No. 1 to the License Agreement, effective as of October 21, 2013, and Amendment No. 2 to the License Agreement, effective as of March 31, 2015 (the "**License Agreement**"). Bodor alleges that we materially breached the License Agreement resulting in its termination. In connection with this purported termination, on October 23, 2019, Bodor and Dr. Nicholas S. Bodor (collectively, the "**Bodor Plaintiffs**") filed a complaint (the "**Bodor Complaint**") against us in the United States District Court for the Southern District of Florida. The Bodor Complaint alleges damages incurred by the Bodor Plaintiffs in connection with our alleged material breach of the License Agreement. The Bodor Complaint seeks: (i) a declaratory judgment that the termination of the License Agreement by the Bodor Plaintiffs was valid and enforceable; (ii) an injunction requiring us to cease and desist use of the Bodor Plaintiffs' intellectual property; and (iii) damages for breach of contract and breach of the covenant of good faith and fair dealing.

On October 30, 2019, we initiated an arbitration proceeding pursuant to Article 9 of the License Agreement with the American Arbitration Association ("**AAA**"), in Florida against the Bodor Plaintiffs. This arbitration seeks a declaratory judgment that the purported termination of the License Agreement by the Bodor Plaintiffs was invalid and unenforceable and asserts (i) a claim for breach of the License Agreement against the Bodor Plaintiffs, and (ii) a claim against the Bodor Plaintiffs for tortious interference with our business relations. On October 30, 2019, we concurrently filed with the United States District Court for the Southern District of Florida a motion to dismiss (or stay) the complaint brought against us by the Bodor Plaintiffs described above.

In its response to our motion to dismiss or, alternatively, stay the litigation, Bodor agreed to comply with the License Agreement terms, which require mediation and, if necessary, arbitration to resolve the dispute. Bodor also asked the court to stay the federal judicial proceedings against us pending mediation, and, if necessary, final, conclusive and binding arbitration. We proceeded with mediation on December 10, 2019, which was unsuccessful. As a result, we recommenced the arbitration proceeding with the Bodor Plaintiffs to conclude the dispute. In December 2019, we recorded an estimated loss contingency of $1.0 million for this matter and will continue to evaluate the adequacy of this estimate as the matter develops.

As a result of these matters, the timeline and funding for our Phase 3 clinical trials in subjects with primary axillary hyperhidrosis in the United States has been negatively impacted. In addition, we have been required to devote substantial financial resources to address the Bodor Complaint. Arbitration and litigation are expensive and may likely be time-consuming and divert management's attention and our resources away from other clinical development activities. The outcome of arbitration or litigation is inherently uncertain. If one or more of the legal claims made by the Bodor Plaintiffs were resolved against us, we may become subject to additional litigation claims, and/or our ability to continue to develop sofpironium bromide and our financial condition and operating results could be materially adversely affected. While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise.

Unless we are able to negotiate an acceptable settlement with the Bodor Plaintiffs in the near future, we may have difficulty retaining our key employees who have extensive knowledge and experience in developing and commercializing pharmaceutical products. We may be required to undertake a reduction in personnel and to minimize our expenses until such time as we prevail in our arbitration with the Bodor Plaintiffs. To the extent that our cash resources are depleted as a result of the mediation and arbitration-related expenses, we may be required to consider other measures. Even if we reach a favorable settlement with the Bodor Plaintiffs, there is no assurance that we will be able to raise the capital necessary to advance sofpironium bromide through the Phase 3 clinical trials on the timetable we contemplated. To the extent that we are unable to raise capital sufficient to fund our clinical development, there may be substantial doubt regarding our ability to remain a going concern.

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

The success of our business, including our prospective ability to finance our operations and generate revenue, primarily depends on the successful development, regulatory approval and commercialization of sofpironium bromide, at least in the United States. The clinical and commercial success of sofpironium bromide 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 delayed particularly in light of the Bodor Complaint, or costlier than we currently anticipate and/or produce results that do not achieve the endpoints of the trials or which are ultimately deemed not to be clinically meaningful;

- whether we are required by the U.S. Food and Drug Administration ("**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 sofpironium bromide;

- ability of third parties with which we contract to manufacture consistently adequate clinical trial and commercial supplies of sofpironium 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 sofpironium bromide;

- ability to obtain favorable labeling for sofpironium bromide through regulators that allows for successful commercialization, given the drug may be marketed only to the extent approved by these regulatory authorities (unlike with most other industries);

- ability to commercialize sofpironium bromide successfully in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with Kaken Pharmaceutical Co. Ltd. ("**Kaken**") or others;

- acceptance by physicians, insurers and payors, and patients of the quality, benefits, safety and efficacy of sofpironium bromide, if approved, including relative to alternative and competing treatments and the next best standard of care;

- existence of a regulatory and legal environment conducive to the success of sofpironium bromide;

- ability to price sofpironium bromide to recover our development costs and generate a satisfactory profit margin; and

- our ability and our partners' ability to establish and enforce intellectual property rights in and to sofpironium bromide, including but not limited to patents and licenses.

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

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

The conduct of a Phase 3 clinical trial is a long, expensive, complicated, uncertain and highly regulated process. Although our employees have conducted successful Phase 2 and Phase 3 clinical trials in the past across many therapeutic areas while employed at other companies, we as a company have not conducted a Phase 3 pivotal clinical trial, and as a result, we may require more time and incur greater costs than we anticipate. We commenced a Phase 3 long-term safety study for sofpironium bromide gel in the third quarter of 2018 and intend to initiate two pivotal Phase 3 clinical trials in subjects with primary axillary hyperhidrosis in the United States, subject to the successful resolution of our dispute with the Bodor Plaintiffs and 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 sofpironium bromide and could prevent us from, or delay us in, receiving development- or regulatory-based milestone payments and commercializing sofpironium bromide gel for the treatment of hyperhidrosis, which would adversely impact our financial performance, as well as put us in potential breach of material contracts for the licensing and development of sofpironium bromide, subjecting us to significant contract liabilities, including but not limited to loss of rights in and to sofpironium bromide.

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

Clinical development for sofpironium bromide is very expensive, time-consuming, difficult to design and implement, and its outcome is inherently uncertain. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization and of those that are approved many do not cover their costs of development or ever generate a profit. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, a local or central institutional review board ("**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 hyperhidrosis. The topical route of administration may involve new dosage forms, which can be difficult to develop and manufacture and may raise

novel regulatory issues and result in development or review delays or inability to get the investigational drug approved for use.

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

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

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

Unforeseen side effects from sofpironium bromide could arise either during clinical development or, if approved, after it has been marketed. Undesirable side effects caused by sofpironium bromide could cause us, any partners with which we may collaborate, or regulatory authorities to interrupt, extend, modify, delay or halt clinical trials 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.

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 of commercializing sofpironium bromide, potentially even leading to recall 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.

Under our License, Development and Commercialization Agreement with Kaken, dated March 31, 2015 (the "**Kaken Agreement**"), we 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 sofpironium 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 sofpironium bromide, which may delay or prevent achieving regulatory approval for sofpironium 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 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 sofpironium 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 sofpironium 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 sofpironium 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 sofpironium 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 sofpironium bromide may be denied, or at least severely restricted. In this case, patients would be forced to pay for sofpironium bromide out-of-pocket for cash, which they may not be willing or able to do. Even if we obtain coverage for sofpironium bromide, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients may not use sofpironium bromide unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of sofpironium bromide.

In addition, the market for sofpironium 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 sofpironium bromide in their formularies or otherwise restrict patient access to sofpironium 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 addition, 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 sofpironium 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. Third-party coverage and reimbursement for sofpironium 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 sofpironium 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 sofpironium 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 sofpironium 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 sofpironium 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 sofpironium bromide;
- the cost of treatment with sofpironium bromide in relation to alternative hyperhidrosis treatments and willingness to pay for sofpironium 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 sofpironium 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 sofpironium bromide;
- patient satisfaction with the results and administration of sofpironium 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 sofpironium bromide;
- any FDA requirement to undertake a risk evaluation and mitigation strategy;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, legal, medical and distribution efforts;

- adverse publicity about sofpironium 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 sofpironium bromide.

If sofpironium 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 sofpironium 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, sofpironium bromide, if approved, may compete with other dermatological products, including over-the-counter treatments, for a share of some patients', or payors', discretionary budgets and for physicians' attention within their clinical practices.

We anticipate that sofpironium 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 cloths. 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 alternative to these existing and other new therapies. Such competition could lead to reduced market share for sofpironium bromide and contribute to downward pressure on the pricing of sofpironium 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 sofpironium 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 sofpironium bromide, we could lose a significant portion of then-existing sales of sofpironium bromide in a short period of time from generic competition, which could expose us to litigation and would adversely affect our business, financial condition, operating results and prospects.

We have in the past relied, and expect to continue to rely, on third-party CROs and other third parties to conduct and oversee our sofpironium 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, sofpironium bromide.

We have in the past relied, and expect to continue to rely, on third-party contract research organizations ("**CROs**") to conduct and oversee our sofpironium 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 sofpironium 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, or are unable to continue to support us due to delay in implementation of the clinical trials due to the Bodor Complaint, 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. In addition, 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. Any failure or delay in the development of our internal sales, marketing, distribution and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products.

To commercialize sofpironium bromide in Asia, we also 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 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 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 U.S. 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, 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 ("**OPDP**") regulation of promotional activities, 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 (i.e., prohibition on direct-to-consumer advertising that does 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 or manufacturing of the product, 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; 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 regulations may be enacted, including at the state and local levels, 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, either in the United States or abroad. If we are not able to achieve and maintain regulatory 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 authority 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 authority 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 authority 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 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 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 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 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, independent contractors, principal investigators, other clinical trial staff, consultants, 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.

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

We are evaluating the next clinical development steps for BBI-3000 and BBI-6000, as each is in an early stage of clinical (prior to Phase 3) and preclinical development. 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 assure you that we will be able to seek or obtain regulatory approval for any of our early stage product candidates.

Our clinical trials may fail to demonstrate the safety and efficacy of our other investigational agents BBI-3000 or BBI-6000, or serious adverse or unacceptable side effects may be identified during their development, which could prevent or delay marketing approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of BBI-3000 or BBI-6000.

Before obtaining marketing approvals for the commercial sale of BBI-3000 and BBI-6000, we must demonstrate through lengthy, complex, uncertain and expensive preclinical testing and clinical trials that BBI-3000 and BBI-6000 are both safe and effective for use in each targeted indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and are associated with side effects or have characteristics that are unexpected. Based on the safety profile seen in clinical testing, we may need to abandon development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more tolerable from a risk-benefit perspective. The FDA or an IRB also may require that we suspend, discontinue, or limit clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for BBI-3000 or BBI-6000. Many drug candidates that initially showed promise in early-stage testing and which were efficacious have later been found to cause side effects that prevented further development of the drug candidate and, in extreme cases, the side effects were not seen until after the drug was marketed and exposed to large populations, causing regulators to remove the drug from the market post-approval.

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. 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. At this time, the company is preserving its resources to resolve the Bodor dispute.

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 (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 inseverable 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, which would limit our ability to market our product candidates. The United States is already in a minority of jurisdictions that 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 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 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 and could harm our business, financial condition, operating results and prospects. We have no current plan, 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). 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, or achieve 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 delivery and manufacturing schedules;
- price increases and product reliability;
- manufacturing deviations from internal or regulatory specifications;
- quality 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 in order 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, 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 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, 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 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.

Pending successful resolution of the Bodor Complaint and obtaining substantial additional funding, we intend to conserve our resources. The advancement of the Phase 3 clinical trials for sofpironium bromide has been negatively impacted by the Bodor Complaint. As a result, 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. In December 2019, an estimated loss contingency of $1.0 million was recorded for the Bodor Complaint and we will continue to evaluate the adequacy of this estimate as the matter develops. Nonetheless, we will require substantial additional funds to conduct the costly and time-consuming clinical trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of sofpironium bromide in new indications or uses including commencing the Phase 3 clinical trials for sofpironium bromide. Our future capital requirements will depend upon a number of factors, including but not limited to: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; compliance with our material contracts including the licensing agreement for sofpironium bromide and resolution of the Bodor Complaint; the

time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance for such product candidates; and overall stock market 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.

As a result of the Bodor Complaint, Novaquest Co-Investment Fund X, L.P. terminated its Funding Agreement, dated as of June 2, 2019, with us and we have lost significant market capitalization. Our ability to raise the significant additional funds required to commence the Phase 3 clinical trials for sofpironium bromide is uncertain and is limited given our small market capitalization. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

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

Our operating results and liquidity could be affected negatively by global economic conditions generally, both in the 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 sofpironium bromide as discretionary, and if full reimbursement for the product is not available, demand for the product may be tied to the discretionary, out-of-pocket cash-spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, or a bear market ensues in the U.S. stock market given the current bull market is the longest on record, our operating results and liquidity could be affected adversely by those factors in many ways, including weakening demand for sofpironium 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 $1.53 per share as of February 7, 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 sofpironium bromide or future product candidates, and delays or failures to obtain such approvals;
- failure of sofpironium bromide, if approved, to achieve commercial success;
- issues in manufacturing sofpironium bromide or future product candidates;
- the results of current and any future clinical trials of sofpironium 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 sofpironium 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.

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. 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. In addition, 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 sofpironium bromide and undertaking preclinical studies and clinical trials of sofpironium bromide. We (and our partners) have not yet obtained regulatory approvals for sofpironium 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 sofpironium bromide, and the achievement of development and clinical milestones under an agreement with Kaken, as well as any potential future collaboration and license agreements and sales of sofpironium bromide or future products, if approved, and our ability to maintain the related license as part of the Bodor Complaint. 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 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. 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 February 7, 2020, we have (i) warrants issued and outstanding to purchase one share of our common stock at an exercise price of $0.07 per share, 490,683 shares of our common stock at an exercise price of $10.36 per share and 9,005 shares of our common stock at an exercise price of $33.31 per share; and (ii) we have 1,793,602 options issued and outstanding to purchase our common stock at a weighted average exercise price of $13.00 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 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 and 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, 2018, we had approximately $36.5 million of federal and $30.9 million of state operating loss carryforwards available to offset future taxable income, which expire in varying amounts beginning in 2030 for federal and state purposes if unused. It is possible that we will not generate taxable income in time to use these loss carryforwards before their expiration. Our net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership in connection with the Merger. In addition, we may experience ownership changes in the future as a result of offerings of our stock or subsequent shifts in our stock ownership, some of which are 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 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 sofpironium 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 are vulnerable to damage from computer viruses, unauthorized access, computer hacking or breaches, natural disasters, 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 Intellectual Property

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

Our success with respect to sofpironium 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 sofpironium 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. 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 over-the-counter 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 are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how by entering into confidentiality 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 and unpatented know-how 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 and/or unpatented know-how, we may not be allowed to retrieve the inadvertently disclosed trade secret and/or unpatented know-how 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 licenseholder receiving the compulsory license may not be calculated at fair market value and can be inconsequential, thereby disaffecting the patentholder's business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the 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 ("**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. 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 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 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 and partners and will continue to do so in the future, around the world, if one of our licensors 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 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 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 officers, directors, employees, 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 customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants 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 and consultants 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, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.