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

# FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended June 30, 2021**
**Or**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from to**
**Commission File Number: 000-21088**

# BRICKELL BIOTECH, INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **93-0948554** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **5777 Central Avenue, Boulder, CO** | **80301** |
| **(Address of principal executive offices)** | **(Zip Code)** |

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

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

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

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| Emerging growth company | ☐ | | |

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

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

As of July 30, 2021, there were85,915,445 shares of the registrant's common stock outstanding.

**BRICKELL BIOTECH, INC.**
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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this Quarterly Report other than statements of historical fact, including statements relating to future financial, business, and/or research and clinical performance, conditions, plans, prospects, trends, or strategies and other such matters, including without limitation, our strategy, future operations, future financial position, future liquidity, future revenue, projected expenses, results of operations, the anticipated timing, scope, design, progress, results and/or reporting of data of ongoing and future non-clinical studies and clinical trials, intellectual property rights, including the validity, term, and enforceability of such, the expected timing and/or results of regulatory submissions and approvals, and prospects for commercializing any of Brickell's product candidates, or research collaborations with, or actions of, its partners, including in Japan, the United States ("U.S.") or any other country. The words "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," "looking forward" or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Unless otherwise mentioned or unless the context requires otherwise, all references in this Quarterly Report to "Brickell," "Brickell Subsidiary," "Company," "we," "us," and "our," or similar references, refer to Brickell Biotech, Inc. and its consolidated subsidiaries.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part II, Item 1A, "Risk Factors" in this Quarterly Report, in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, and in Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (the "SEC") in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and trends discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

You should read carefully the factors described in Part II, Item 1A, "Risk Factors" in this Quarterly Report to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised to consult any further disclosures we make on related subjects in our future public filings and on our website.

## RISK FACTORS SUMMARY

Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, let alone combined with any of the others, could materially and adversely affect our business, financial condition, results of operations, and stock price. We have provided a summary of some of these risks below, with a more detailed explanation of those and other risks applicable to the Company in Part II, Item 1A. "Risk Factors" in this Quarterly Report.

- Our business depends on the successful continued financing, clinical development, regulatory approval, and commercialization of sofpironium bromide.
- We previously have not conducted a pivotal Phase 3 clinical trial ourselves and may be unable to successfully do so for sofpironium bromide.
- Clinical drug development for sofpironium bromide is expensive, time-consuming, and uncertain.
- Use of patient-reported outcome ("PRO") assessments 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.
- 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.
- Kaken Pharmaceutical Co., Ltd. ("Kaken") substantially controls the development and commercialization 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 secure an appropriate local business partner (if desirable) and/or obtain approval of the drug in the ex-Japan Asian markets over which it has rights.
- If we or any partners with which we may collaborate to market and sell sofpironium bromide are unable to achieve and maintain medical insurance coverage and adequate levels of reimbursement for this compound following regulatory approval and usage by patients, our commercial success may be hindered severely.
- Even if sofpironium bromide obtains regulatory approval outside Japan, and despite our partner Kaken launching the drug as ECCLOCK® in Japan in 2020, it may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.
- Sofpironium bromide, where approved, will face significant competition and its failure to compete effectively may prevent it from achieving significant market penetration.
- We may face generic competition for sofpironium bromide, which could expose us to litigation or adversely affect our business, financial condition, operating results, and prospects.
- If clinical research organizations ("CROs") and other third parties do not meet our requirements or otherwise conduct our sofpironium bromide clinical trials as required or are unable to staff or supply our trials, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, sofpironium bromide at all or in the time frames currently planned for.
- 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 meaningful product revenue.
- 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.
- 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.

- We may never obtain regulatory approval to commercialize any of our product candidates in the U.S., or anywhere else in the world other than Japan, and any products approved for sale will be subject to continued regulatory review and compliance obligations and there could be further restrictions on post-approval activities, including commercialization efforts. In obtaining regulatory approval, we will need to negotiate an appropriate product label (aka package insert) with the regulators, which will determine the extent of our allowed promotional activities, and this label could be restrictive or prohibitory with regard to subject matter we believe is necessary to maximize the commercial success of sofpironium bromide.
- Major public health issues, and specifically the pandemic caused by the spread of COVID-19 and COVID-19 variants, and the impact as certain markets emerge from the pandemic, especially in terms of constraints on supply chains and human resource availability, and different degrees of success various countries experience in rolling out their vaccine campaigns, could have an adverse impact on our financial condition and results of operations and other aspects of our business and that of our suppliers, contractors, and business partners.
- We have sponsored or supported and may in the future sponsor or support clinical trials for our product candidates outside the U.S. and Japan, and the Food and Drug Administration ("FDA"), Japan's Pharmaceuticals and Medical Devices Agency ("PMDA"), and applicable foreign regulatory authorities may not accept data from such trials; in addition, we may not be allowed alone or with local country business partners to obtain regulatory approval for our product candidates without first conducting clinical trials in each of these other countries.
- 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 may be subject to risks related to pre-approval promotion or off-label use, or unauthorized direct-to-consumer advertising, of our product candidates.
- Healthcare reform measures, including price controls or restricted access, could hinder or prevent the commercial success of our product candidates in any country.
- We are and 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.
- We rely completely on third-party contractors to supply, manufacture, and distribute clinical drug supplies and to help prepare for a possible launch for our product candidates, including certain sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing, and distribution, and possibly sales and promotion, 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, and possibly sales and promotion, of any future product candidates.
- Manufacturing and supply of the active pharmaceutical ingredients ("API") 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.
- We may not be able to finance or acquire additional pipeline or marketed assets to grow or sustain our company business.
- We may not be able to obtain, afford, maintain, or enforce global patent rights or other intellectual property rights that cover sofpironium bromide and related technologies (and any other product candidates) that are of sufficient type, breadth, and term.
- We may not be able to protect our intellectual property rights meaningfully throughout the world.
- 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 other key aspects of product development and/or commercialization, or increase our financial or other obligations to our licensors.

## PART I. FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

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

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 24,408 | $ 30,115 |
| Prepaid expenses and other current assets | 4,507 | 3,415 |
| Total current assets | 28,915 | 33,530 |
| Property and equipment, net | 72 | 30 |
| Operating lease right-of-use asset | 86 | 74 |
| Total assets | $ 29,073 | $ 33,634 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,514 | $ 568 |
| Accrued liabilities | 4,120 | 5,420 |
| Lease liability, current portion | 50 | 74 |
| Note payable, current portion | — | 291 |
| Total current liabilities | 6,684 | 6,353 |
| Lease liability, net of current portion | 36 | — |
| Note payable, net of current portion | — | 146 |
| Total liabilities | 6,720 | 6,499 |
| Commitments and contingencies (Note 5) | | |
| Stockholders' equity: | | |
| Common stock, $0.01 par value, 300,000,000 and 100,000,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 71,945,222 and 53,551,461 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively | 719 | 536 |
| Additional paid-in capital | 147,681 | 132,492 |
| Accumulated deficit | (126,047) | (105,893) |
| Total stockholders' equity | 22,353 | 27,135 |
| Total liabilities and stockholders' equity | $ 29,073 | $ 33,634 |

*See accompanying notes to these condensed consolidated financial statements.*

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Revenue | | | | |
| Collaboration revenue | $ — | $ 607 | $ — | $ 1,653 |
| Royalty revenue | 151 | — | 168 | — |
| Total revenue | 151 | 607 | 168 | 1,653 |
| Operating expenses: | | | | |
| Research and development | 8,838 | 2,712 | 14,890 | 5,376 |
| General and administrative | 2,891 | 3,021 | 5,858 | 5,502 |
| Total operating expenses | 11,729 | 5,733 | 20,748 | 10,878 |
| Loss from operations | (11,578) | (5,126) | (20,580) | (9,225) |
| Investment and other income, net | 459 | 7 | 490 | 3 |
| Interest expense | (30) | — | (64) | — |
| Net loss | $ (11,149) | $ (5,119) | $ (20,154) | $ (9,222) |
| Net loss per common share attributable to common stockholders, basic and diluted | $ (0.16) | $ (0.43) | $ (0.31) | $ (0.87) |
| Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted | 68,856,370 | 11,819,152 | 64,646,565 | 10,595,960 |

*See accompanying notes to these condensed consolidated financial statements.*

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Net loss | $ (11,149) | $ (5,119) | $ (20,154) | $ (9,222) |
| Other comprehensive income: | | | | |
| Unrealized gain on available-for-sale marketable securities arising during holding period, net of tax benefit of $0 | — | — | — | 28 |
| Total comprehensive loss | $ (11,149) | $ (5,119) | $ (20,154) | $ (9,194) |

*See accompanying notes to these condensed consolidated financial statements.*

**BRICKELL BIOTECH, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**
**(in thousands, except share data)**
**(unaudited)**

| | Common Stock | | Additional Paid-In-Capital | Accumulated Other Comprehensive Gain (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Par Value | | | | |
| Balance, December 31, 2020 | 53,551,461 | $ 536 | $ 132,492 | $ — | $ (105,893) | $ 27,135 |
| Issuance of common stock upon exercise of warrants | 12,444,887 | 124 | 8,845 | — | — | 8,969 |
| Issuance of common stock, net of issuance costs of $50 | 1,083,548 | 11 | 1,617 | — | — | 1,628 |
| Issuance of common stock upon restricted stock unit settlement, net of shares withheld for taxes | 96,350 | 1 | (53) | — | — | (52) |
| Stock-based compensation | — | — | 469 | — | — | 469 |
| Net loss | — | — | — | — | (9,005) | (9,005) |
| Balance, March 31, 2021 | 67,176,246 | 672 | 143,370 | — | (114,898) | 29,144 |
| Common stock issued, net of issuance costs of $259 | 4,768,976 | 47 | 3,890 | — | — | 3,937 |
| Stock-based compensation | — | — | 421 | — | — | 421 |
| Net loss | — | — | — | — | (11,149) | (11,149) |
| Balance, June 30, 2021 | 71,945,222 | $ 719 | $ 147,681 | $ — | $ (126,047) | $ 22,353 |

| | Common Stock | | Additional Paid-In-Capital | Accumulated Other Comprehensive Gain (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Par Value | | | | |
| Balance, December 31, 2019 | 8,480,968 | $ 85 | $ 92,497 | $ (28) | $ (84,980) | $ 7,574 |
| Issuance of common stock and common stock purchase warrants, net of offering costs of $10 | 950,000 | 10 | 1,980 | — | — | 1,990 |
| Issuance of common stock upon exercise of warrants | 221,293 | 2 | 13 | — | — | 15 |
| Issuance of common stock upon restricted stock unit settlement, net of shares withheld for taxes | 19,643 | — | (13) | — | — | (13) |
| Stock-based compensation | — | — | 403 | — | — | 403 |
| Unrealized gain on available-for-sale marketable securities | — | — | — | 28 | — | 28 |
| Net loss | — | — | — | — | (4,103) | (4,103) |
| Balance, March 31, 2020 | 9,671,904 | 97 | 94,880 | — | (89,083) | 5,894 |
| Issuance of common stock upon exercise of warrants | 2,202,863 | 22 | (15) | — | — | 7 |
| Issuance of common stock upon restricted stock unit settlement, net of shares withheld for taxes | 6,673 | — | (4) | — | — | (4) |
| Common stock and warrants issued, net of issuance costs of $1,443 | 14,790,133 | 148 | 18,531 | — | — | 18,679 |
| Stock-based compensation | — | — | 453 | — | — | 453 |
| Net loss | — | — | — | — | (5,119) | (5,119) |
| Balance, June 30, 2020 | 26,671,573 | $ 267 | $ 113,845 | $ — | $ (94,202) | $ 19,910 |

*See accompanying notes to these condensed consolidated financial statements.*

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| **CASH FLOWS FROM OPERATING ACTIVITIES:** | | |
| Net loss | $ (20,154) | $ (9,222) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 890 | 856 |
| Gain on loan extinguishment | (437) | — |
| Depreciation | 8 | 6 |
| Reduction of discount on marketable securities | — | 25 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (1,092) | 512 |
| Accounts payable | 1,932 | (1,679) |
| Accrued liabilities | (1,352) | (135) |
| Deferred revenue | — | (1,653) |
| Net cash used in operating activities | (20,205) | (11,290) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Capital expenditures, net | (36) | — |
| Maturities of marketable securities | — | 4,500 |
| Net cash provided by (used in) investing activities | (36) | 4,500 |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Proceeds from the exercise of warrants | 8,969 | 22 |
| Proceeds from the issuance of common stock and warrants, net of offering costs | 5,565 | 20,669 |
| Proceeds from the issuance of note payable | — | 437 |
| Net cash provided by financing activities | 14,534 | 21,128 |
| **NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS** | (5,707) | 14,338 |
| **CASH AND CASH EQUIVALENTS—BEGINNING** | 30,115 | 7,232 |
| **CASH AND CASH EQUIVALENTS—ENDING** | $ 24,408 | $ 21,570 |
| | | |
| **Supplemental Disclosure of Non-Cash Investing and Financing Activities:** | | |
| Forgiveness of Paycheck Protection Program loan | $ 437 | $ — |

*See accompanying notes to these condensed consolidated financial statements.*

**BRICKELL BIOTECH, INC.**
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**(unaudited)**

## NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

Brickell Biotech, Inc. (the "Company" or "Brickell") is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated prescription therapeutics for debilitating skin diseases with a focus on its lead asset for the treatment of hyperhidrosis. The Company's pivotal Phase 3 clinical-stage investigational product candidate, sofpironium bromide, is a new chemical entity that belongs to a class of medications called anticholinergics. The Company intends to develop sofpironium bromide as a potential best-in-class, self-administered, once daily, topical therapy for the treatment of primary axillary hyperhidrosis. The Company's operations to date have been limited to business planning, raising capital, developing its pipeline assets (in particular sofpironium bromide), identifying product candidates, conducting clinical trials, and other research and development.

***Liquidity and Capital Resources***

The Company has incurred significant operating losses and has an accumulated deficit as a result of ongoing efforts to develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the six months ended June 30, 2021, the Company had a net loss of $20.2 million and net cash used in operating activities of $20.2 million. As of June 30, 2021, the Company had cash and cash equivalents of $24.4 million and an accumulated deficit of $126.0 million.

The Company believes that its cash and cash equivalents as of June 30, 2021, combined with the net proceeds received from the subsequent sales of the Company's common stock (see Note 8. "Subsequent Events"), are sufficient to fund its operations for at least the next 12 months from the issuance of these condensed consolidated financial statements. The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Additional funding will be required in the future to continue with the Company's planned development and commercial-related activities.

## NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

***Basis of Presentation***

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Brickell Subsidiary, Inc., and are presented in United States ("U.S.") dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the SEC for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company's financial information. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected for the full year ending December 31, 2021, for any other interim period, or for any other future period. The condensed consolidated balance sheet as of December 31, 2020 has been derived from audited financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. All intercompany balances and transactions have been eliminated in consolidation. The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein. The Company's management performed an evaluation of its activities through the date of filing of these financial statements and concluded that there are no subsequent events requiring disclosure, other than as disclosed.

***Use of Estimates***

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

***Risks and Uncertainties***

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

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

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to develop and, if successful, commercialize its product candidates. There can be no assurance that such financing will be available or will be at terms acceptable to the Company.

***Fair Value Measurements***

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

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

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

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

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

| | Level 1 (1) | |
|---|---|---|
| | June 30, 2021 | December 31, 2020 |
| Assets: | | |
| Money market funds | $ 23,202 | $ 29,182 |

(1) No assets as of each respective date were identified as Level 2 or 3 based on the three-tier fair value hierarchy. The Company had no financial liabilities measured at fair value on a recurring basis as of each respective date.

***Fair Value of Financial Instruments***

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

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

***Revenue Recognition***

The Company currently recognizes revenue primarily from licensing and royalty fees received under the Kaken Agreement described below, of which the terms of the agreement include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of milestones, and royalties on net product sales.

In March 2015, the Company entered into a license, development, and commercialization agreement (as amended, the "Kaken Agreement") with Kaken Pharmaceutical Co., Ltd. ("Kaken"). Under the Kaken Agreement, the Company granted to Kaken an exclusive right to develop, manufacture, and commercialize the Company's sofpironium bromide compound in Japan and certain other Asian countries (the "Territory"). In exchange, Kaken paid the Company an upfront, non-refundable payment of $11.0 million (the "upfront fee"). In addition, the Company was entitled to receive aggregate payments of up to $10.0 million upon the achievement of specified development milestones, and $30.0 million upon the achievement of commercial milestones, as well as tiered royalties based on a percentage of net sales of licensed products in the Territory. The Kaken Agreement further provides that Kaken will be responsible for funding all development and commercial costs for the program in the Territory. Kaken was also required to enter into negotiations with the Company, to supply the Company, at cost, with clinical supplies to perform Phase 3 clinical trials in the U.S.

In May 2018, the Company entered into an amendment to the Kaken Agreement, pursuant to which the Company received an upfront non-refundable fee of $15.6 million (the "Kaken R&D Payment"), which was initially recorded as deferred revenue, to provide the Company with research and development funds for the sole purpose of conducting certain clinical trials and other such research and development activities required to support the submission of a new drug application for sofpironium bromide. Upon receipt of the Kaken R&D Payment on May 31, 2018, a milestone payment originally due upon the first commercial sale in Japan was removed from the Kaken Agreement and all future royalties to the Company under the Kaken Agreement were reduced by 150 basis points. During the three and six months ended June 30, 2020, the Company recognized revenue of $0.6 million and $1.7 million, respectively, related to the Kaken R&D Payment. The Kaken R&D Payment was recognized in full by the end of the third quarter of 2020.

The Company recognizes revenue upon the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that it determines are within the scope of Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including the constraint on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the performance obligations. At contract inception, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. To date, the Company has not received approval for any drug candidates from the FDA.

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

*Licenses of Intellectual Property*

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

*Milestones*

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission) is included in the transaction price. Milestone payments that are not within the Company or the Company's collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration, and other revenues and earnings in the period of adjustment and future periods through the end of the performance obligation period. To date, Kaken has paid the Company $10.0 million in milestone payments under the Kaken Agreement.

*Royalties*

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to

which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Prior to 2020, the Company had not recognized any royalty revenue from any collaboration arrangement. In September 2020, Kaken received regulatory approval in Japan to manufacture and market sofpironium bromide gel, 5% (ECCLOCK®) for the treatment of primary axillary (underarm) hyperhidrosis. During the three and six months ended June 30, 2021, the Company recognized royalty revenue earned on a percentage of net sales of ECCLOCK in Japan of approximately $0.2 million.

***Research and Development***

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

***Clinical Trial Accruals***

Expense accruals related to clinical trials are based on the Company's estimates of services received and efforts expended pursuant to contracts with multiple research institutions and third-party clinical research organizations that conduct and manage clinical trials on the Company's behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing costs, the Company estimates the period over which services will be performed and the level of effort to be expended in each period based upon patient enrollment, clinical site activations, or information provided to the Company by its vendors on their actual costs incurred. Any estimates of the level of services performed or the costs of these services could differ from actual results.

***Net Income (Loss) per Common Share***

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

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

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

| | Three and Six Months Ended June 30, | |
|---|---|---|
| | 2021 | 2020 |
| Outstanding warrants | 27,944,544 | 19,556,108 |
| Outstanding options | 6,716,167 | 1,578,231 |
| Unvested restricted stock units | 47,435 | 253,045 |
| Total | 34,708,146 | 21,387,384 |

***Leases***

The Company accounts for leases under the Financial Accounting Standards Board ("FASB") Accounting Standards Codification Topic 842 ("ASC 842"). Under ASC 842, the Company determines if an arrangement is a lease at inception. Operating leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company does not currently hold any financing leases. The Company has elected the practical expedient not to recognize on the balance sheet leases with terms of one year or less and not to separate lease components and non-lease components for long-term real estate leases. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company estimates the incremental borrowing rate based on industry peers in determining the present value of lease payments. Industry peers consist of several public companies in the biotechnology industry with comparable characteristics. The Company's facility operating lease has one single component. The lease component results in a right-of-use asset being recorded on the balance sheet, which is amortized as lease expense on a straight-line basis in the Company's condensed consolidated statements of operations.

***New Accounting Pronouncements***

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company does not believe that the adoption of recently issued standards has had or may have a material impact on the Company's condensed consolidated financial statements or disclosures.

**NOTE 3. ACCRUED LIABILITIES**

Accrued liabilities consisted of the following (in thousands):

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| Accrued contracted research and development services | $ 2,922 | $ 3,733 |
| Accrued compensation | 978 | 1,369 |
| Accrued professional fees | 220 | 318 |
| Total | $ 4,120 | $ 5,420 |

**NOTE 4. NOTE PAYABLE**

On April 15, 2020, the Company executed an unsecured promissory note to IberiaBank (the "PPP Loan") pursuant to the U.S. Small Business Administration's Paycheck Protection Program (the "PPP") under Division A, Title I of the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The Company used the PPP Loan proceeds in the principal amount of $0.4 million and bearing interest at a fixed rate of1.00% per

annum to cover payroll costs and certain other permitted costs in accordance with the relevant terms and conditions of the CARES Act. In January 2021, the Company applied for forgiveness of the full amount of the PPP Loan, which was forgiven in full in June 2021. As a result, during the three months ended June 30, 2021, the Company recognized a gain on extinguishment of debt of approximately $0.4 million in the condensed consolidated statements of operations within the line "Investment and other income, net."

**NOTE 5. COMMITMENTS AND CONTINGENCIES**

***Operating Lease***

In August 2016, the Company entered into a five-year lease for office space in Boulder, Colorado that was scheduled to expire on October 31, 2021 (the "Boulder Lease"), subject to the Company's option to renew the Boulder Lease for two additional terms of three years each. Pursuant to the Boulder Lease, the Company leases 3,038 square feet of space in a multi-suite building. Base rental payments under the Boulder Lease were $4,430 per month during the first year of the Boulder Lease with an annual increase of 3.5% through October 31, 2021. In addition to base rental payments included in the contractual obligations table below, the Company is responsible for its pro rata share of the operating expenses for the building, which includes common area maintenance, utilities, property taxes, and insurance. Upon adoption of ASC 842, on January 1, 2019, the Company recognized a lease liability and corresponding right-of-use asset for the lease agreement by calculating the present value of lease payments, discounted at the Company's estimated incremental borrowing rate of 12.0%, over the expected remaining term of 2.8 years.

Effective June 17, 2021, the Boulder Lease was amended. The amendment extends the lease term to December 31, 2022. Base rent through October 31, 2021, was unchanged. The amendment provides for two months free rent and a fixed rate of $6,076 per month thereafter. The amendment also provides for an option to extend the lease for two additional terms of three years each with monthly rent payments determined at the time of renewal at the lower of $6,076 per month or current market rental rates. In accordance with ASC 842, upon modification of the Boulder Lease, the Company reassessed classification of the lease and determined that the lease still met the criteria to be classified as an operating lease. Furthermore, the Company remeasured the lease liability as of the effective date by calculating the present value of the new lease payments, discounted at the Company's updated incremental borrowing rate of 11.0%, over the extended term of 18 months. Because the Company was not reasonably certain to exercise the renewal option, the option was not considered in determining the lease term, and associated potential additional payments were excluded from lease payments.

Operating lease cost for the three months ended June 30, 2021 and 2020 was $23 thousand and $22 thousand, respectively. Lease expense for each of the six months ended June 30, 2021 and 2020 was less than $0.1 million.

The following is a summary of the contractual obligations related to operating lease commitments as of June 30, 2021, and the effect such obligations are expected to have on the Company's liquidity and cash flows in future periods (in thousands):

| | |
|---|---|
| 2021 (remaining six months) | $ 57 |
| 2022 | 36 |
| Total maturities | 93 |
| Less imputed interest | (7) |
| Present value of lease liability | $ 86 |

***Amended and Restated License Agreement with Bodor***

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

The Amended and Restated License Agreement retains with the Company a worldwide, exclusive license to develop, manufacture, market, sell, and sublicense products containing the proprietary compound sofpironium bromide based upon the patents referenced in the Amended and Restated License Agreement for a defined field of use. As of June 30, 2021, under the original License Agreement and the Amended and Restated License Agreement, the Company had remaining obligations to pay Bodor (i) a royalty on sales of product outside Kaken's territory, including a low single-digit royalty on sales of certain product not covered by the patent estate licensed from Bodor; (ii) approximately 50 to 55% of all royalties the Company receives from Kaken for sales of product within its territory; (iii) a percentage of non-royalty sublicensing income the Company receives from Kaken or other sublicensees; and (iv) up to an aggregate of $0.8 million (plus an additional $0.1 million for approvals of additional products) in cash payments and $1.0 million of shares of the Company's common stock upon the achievement of certain regulatory and other milestones.

During the three and six months ended June 30, 2020, under the terms of the Amended and Restated License Agreement, the Company made a $0.5 million milestone payment to Bodor following the closing of a public offering in June 2020 and accrued an additional $1.0 million related to its plan to initiate its U.S. Phase 3 pivotal program in the fourth quarter of 2020. As a result, the Company recorded $1.5 million as research and development expense in the condensed consolidated statements of operations during the three and six months ended June 30, 2020. No similar or associated research and development expense was incurred in the three or six months ended June 30, 2021, but the Company paid Bodor the applicable amount with respect to the royalties it received from Kaken for sales of product in Japan during those periods.

**NOTE 6. CAPITAL STOCK**

***Common Stock***

On April 19, 2021, following approval by the Company's stockholders, the Company filed an amendment to its amended and restated certificate of incorporation with the Secretary of State of the State of Delaware that increased the number of the Company's authorized shares of common stock, par value $0.01 per share, from 100,000,000 to 300,000,000. Each share of the Company's common stock is entitled to one vote, and the holders of the Company's common stock are entitled to receive dividends when and as declared or paid by its board of directors. The Company had reserved authorized shares of common stock for future issuance at June 30, 2021 as follows:

| | June 30, 2021 |
|---|---|
| Common stock warrants | 27,944,544 |
| Common stock options outstanding | 6,716,167 |
| Shares available for grant under the Omnibus Plan | 3,988,558 |
| Unvested restricted stock units | 47,435 |
| Shares available for grant under the Employee Stock Purchase Plan | 2,600,000 |
| Total | 41,296,704 |

***Public Offerings of Common Stock and Warrants***

In October 2020, the Company completed a sale of 19,003,510 shares of its common stock, and, to certain investors, pre-funded warrants to purchase 1,829,812 shares of its common stock, and accompanying common stock warrants to purchase up to an aggregate of 20,833,322 shares of its common stock (the "October 2020 Offering"). Each share of common stock and pre-funded warrant to purchase one share of the Company's common stock was sold together with a common warrant to purchase one share of the Company's common stock. The public offering price of each share of the Company's common stock and accompanying common warrant was $ 0.72 and $0.719 for each pre-funded warrant and accompanying common warrant, respectively. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The common warrants are exercisable at a price of $0.72 per share of the Company's common stock and will expire five years from the date of issuance. The pre-funded warrants were exercised in October 2020 at an exercise price of $0.001 per share of the Company's common stock. The October 2020 Offering resulted in net proceeds of approximately $13.7 million to the Company after deducting underwriting commissions and discounts and other offering expenses of $1.3 million and excluding the proceeds from the exercise of the warrants. During the six months ended June 30, 2021, 12,427,387 common warrants associated with the October 2020 Offering were exercised at a weighted-average exercise price of $0.72 per share, resulting in aggregate proceeds of approximately $8.9 million.

In June 2020, the Company completed a sale of 14,790,133 shares of its common stock, and, to certain investors, pre-funded warrants to purchase 2,709,867 shares of its common stock, and accompanying common stock warrants to purchase up to an aggregate of 17,500,000 shares of its common stock (the "June 2020 Offering") (and together with the October 2020 Offering, the "2020 Offerings"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $1.15 and $1.149 for each pre-funded warrant and accompanying common warrant, respectively. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The pre-funded warrants were exercised in the third quarter of 2020 at an exercise price of $0.001 per share of common stock. The common warrants were immediately exercisable at a price of $1.25 per share of common stock and will expirefive years from the date of issuance. The June 2020 Offering resulted in approximately $18.7 million of net proceeds to the Company after deducting underwriting commissions and discounts and other offering expenses of $1.4 million and excluding the proceeds from the exercise of the warrants. Certain officers of the Company participated in the June 2020 Offering by purchasing an aggregate purchase price of $0.2 million of the Company's common stock and warrants. During the six months ended June 30, 2021, 17,500 common warrants associated with the June 2020 Offering were exercised at a weighted-average exercise price of $1.25 per share, resulting in aggregate proceeds of approximately $22 thousand.

The Company is using the net proceeds from the 2020 Offerings for research and development, including clinical trials, working capital, and general corporate purposes.

***At Market Issuance Sales Agreements***

In April 2020, the Company entered into an At Market Issuance Sales Agreement (the "2020 ATM Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer") as the Company's sales agent. Pursuant to the terms of the 2020 ATM Agreement, the Company may sell from time to time through Oppenheimer shares of its common stock having an aggregate offering price of up to $8.0 million. Such shares are issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by the Company and Oppenheimer. Under the terms of the 2020 ATM Agreement, the Company may also sell the shares from time to time to Oppenheimer as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to Oppenheimer as principal would be pursuant to

the terms of a separate placement notice between the Company and Oppenheimer. During the three months ended June 30, 2021, the Company sold 5,500 shares under the 2020 ATM Agreement at a weighted-average price of $1.16 per share, for aggregate net proceeds of $6 thousand, after giving effect to a 3% commission to Oppenheimer as agent. During the six months ended June 30, 2021, the Company sold 1,089,048 shares under the 2020 ATM Agreement at a weighted-average price of $1.55 per share, for aggregate net proceeds of approximately $1.6 million, after giving effect to a 3% commission to Oppenheimer as agent. As of June 30, 2021, approximately $2.6 million of shares of common stock were remaining, but had not yet been sold by the Company under the 2020 ATM Agreement.

In March 2021, the Company entered into an At Market Issuance Sales Agreement (the "2021 ATM Agreement") with Oppenheimer and William Blair & Company, L.L.C. as the Company's sales agents (the "Agents"). Pursuant to the terms of the 2021 ATM Agreement, the Company may sell from time to time through the Agents shares of its common stock having an aggregate offering price of up to $50.0 million. Such shares are issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-254037). Sales of the shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by the Company and the Agents. Under the terms of the 2021 ATM Agreement, the Company may also sell the shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to an Agent as principal would be pursuant to the terms of a separate placement notice between the Company and such Agent. During the three and six months ended June 30, 2021, the Company sold 3,963,476 shares under the 2021 ATM Agreement at a weighted-average price of $0.89 per share, for aggregate net proceeds of $3.4 million, after giving effect to a 3% commission to the Agents. As of June 30, 2021, approximately $46.5 million of shares of common stock were remaining, but had not yet been sold by the Company under the 2021 ATM Agreement.

***Private Placement Offerings***

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

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $28.0 million in the aggregate of shares of common stock. In order to retain maximum flexibility to issue and sell up to the maximum of $28.0 million of the Company's common stock under the Purchase Agreement, the Company sought and, at its annual meeting on April 19, 2021, received, stockholder approval for the sale and issuance of common stock in connection with the Purchase Agreement under Nasdaq Listing Rule 5635(d). Sales of common stock by the Company will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on August 14, 2020 (the "Commencement Date").

Following the Commencement Date, under the Purchase Agreement, on any business day selected by the Company, the Company may direct Lincoln Park to purchase up to 100,000 shares of common stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 125,000 shares, provided that the closing sale price of the common stock is not below $3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below $5.00 on the purchase date. In each case, Lincoln Park's maximum

commitment in any single Regular Purchase may not exceed $1,000,000. The purchase price per share for each such Regular Purchase will be based on prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, the Company may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of common stock. During the three and six months ended June 30, 2021, the Company sold to Lincoln Park800,000 shares under the Purchase Agreement at a weighted-average price of $0.81 per share, for aggregate net proceeds of $0.6 million. As of June 30, 2021, approximately $27.3 million of shares of common stock were remaining, but had not yet been sold by the Company under the Purchase Agreement.

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

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

***Preferred Stock***

Under the Company's amended and restated certificate of incorporation, the Company's board of directors has the authority to issue up to5,000,000 shares of preferred stock with a par value of $0.01 per share, at its discretion, in one or more classes or series and to fix the powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, without further vote or action by the Company's stockholders. As of June 30, 2021, the Company had no shares of preferred stock outstanding and had not designated the rights, preferences, or privileges of any class or series of preferred stock.

**NOTE 7. STOCK-BASED COMPENSATION**

***Equity Incentive Plans***

*2020 Omnibus Plan*

On April 20, 2020, the Company's stockholders approved the 2020 Omnibus Long-Term Incentive Plan (the "Omnibus Plan"), which replaced, with respect to new award grants, the Company's 2009 Equity Incentive Plan, as amended and restated (the "2009 Plan"), and the Vical Equity Incentive Plan (the "Vical Plan") (collectively, the "Prior Plans") that were previously in effect. Following the approval of the Omnibus Plan on April 20, 2020, no additional grants will be made pursuant to the Prior Plans, but awards outstanding under those plans as of that date remain outstanding in accordance with their terms. On August 31, 2020 and April 19, 2021, the Company's stockholders approved increases in the number of shares of common stock authorized for issuance under the Omnibus Plan by 4,500,000 and 4,000,000 shares, respectively, and as of June 30, 2021, 9,125,000 shares were authorized and 5,379,767 shares were subject to outstanding awards under the Omnibus Plan. As of June 30, 2021,3,988,558 shares remained available for grant under the Omnibus Plan.

*2009 Equity Incentive Plan*

The 2009 Plan was replaced by the Omnibus Plan on April 20, 2020, and as a result, as of June 30, 2021, there wereno remaining shares available for new grants under the 2009 Plan. However, as of June 30, 2021,

1,266,655 shares were subject to outstanding awards under the 2009 Plan, which awards remain outstanding in accordance with their terms.

*Vical Equity Incentive Plan*

In connection with the merger in 2019, the Company adopted the Vical Plan, which was replaced by the Omnibus Plan on April 20, 2020. As a result, as of June 30, 2021, there were no remaining shares available for new grants under the Vical Plan. However, as of June 30, 2021, 117,180 shares were subject to outstanding awards under the Vical Plan, which awards remain outstanding in accordance with their terms.

***Employee Stock Purchase Plan***

On April 19, 2021, the Company's stockholders approved the Brickell Biotech, Inc. Employee Stock Purchase Plan (the "ESPP"), which had a first eligible purchase period commencing on July 1, 2021. The ESPP allows qualified employees to purchase shares of the Company's common stock at a price per share equal to 85% of the lower of: (i) the closing price of the Company's common stock on the first trading day of the applicable purchase period or (ii) the closing price of the Company's common stock on the last trading day of the applicable purchase period. New six-month purchase periods begin each January 1 and July 1. As of June 30, 2021, the Company had2,600,000 shares available for issuance under the ESPP.

***Stock-Based Compensation Expense***

Total stock-based compensation expense reported in the condensed consolidated statements of operations was allocated as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Research and development | $ 88 | $ 68 | $ 197 | $ 172 |
| General and administrative | 333 | 385 | 693 | 684 |
| Total stock-based compensation expense | $ 421 | $ 453 | $ 890 | $ 856 |

**NOTE 8. SUBSEQUENT EVENTS**

***Public Offering of Common Stock***

In July 2021, the Company entered into an amended and restated underwriting agreement (as amended, the "Underwriting Agreement") with H.C. Wainwright & Co., LLC (the "Underwriter"), pursuant to which the Company issued and sold, in an underwritten public offering (the "July 2021 Offering"), 11,290,323 shares (the "Base Shares") of the Company's common stock. In addition, the Underwriter fully exercised its option to purchase 1,693,548 additional shares of common stock (the "Option Shares," and together with the Base Shares, the "Shares"). The offering price to the public in the July 2021 Public Offering was $0.62 per Share, and the Underwriter agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of $0.5828 per Share, representing an underwriting discount of six percent (6.0%). The July 2021 Offering resulted in net proceeds of approximately $7.3 million, after deducting underwriting discounts and commissions and offering expenses. The Company anticipates using the net proceeds from the July 2021 Offering for research and development, including clinical trials, working capital, and general corporate purposes.

The Underwriting Agreement also contains representations, warranties, indemnification, and other provisions customary for transactions of this nature. Pursuant to the Underwriting Agreement, the Company and its directors and officers agreed, for a period of 45 days, subject to certain exceptions, not to offer, sell, pledge, or otherwise dispose of the Company's common stock and other of the Company's securities that they beneficially

own, including securities that are convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock, without the prior written consent of the Underwriter.

***Lincoln Park Purchase Agreement***

Subsequent to June 30, 2021, and through August 12, 2021, the Company sold to Lincoln Park500,000 shares of common stock under the Purchase Agreement at a weighted-average price of $0.81 per share, for aggregate net proceeds of approximately $0.4 million.

***At Market Issuance Sales Agreements***

Subsequent to June 30, 2021, and through August 12, 2021, the Company sold486,352 shares of common stock under the 2021 ATM Agreement at a weighted-average price of $0.86 per share, for aggregate net proceeds of approximately $0.4 million.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

We are a clinical-stage pharmaceutical company focused on the development of innovative and differentiated prescription therapeutics for debilitating skin diseases with a focus on our lead asset for the treatment of hyperhidrosis. Our executive management team and board of directors bring extensive experience in product development and global commercialization, having served in leadership roles at large global pharmaceutical companies and biotechs that have developed and/or launched successful products, including several that were first-in-class and/or achieved iconic status, such as Cialis®, Taltz®, Gemzar®, Prozac®, Cymbalta®, and Juvederm®.

Our pivotal Phase 3 clinical-stage investigational product candidate, sofpironium bromide, is a new chemical entity that belongs to a class of medications called anticholinergics. Anticholinergics block the action of acetylcholine, a chemical that transmits signals within the nervous system that are responsible for a range of bodily functions, including activation of the sweat glands. Sofpironium bromide was retrometabolically designed. Retrometabolic drugs are designed to exert their action locally and are potentially rapidly metabolized to a less active form once absorbed into the blood. This proposed mechanism of action may potentially allow for highly effective doses to be used while limiting systemic side effects. We intend to develop sofpironium bromide as a potential best-in-class, self-administered, once daily, topical therapy for the treatment of primary axillary (underarm) hyperhidrosis.

Hyperhidrosis is a life-altering condition of sweating beyond what is physiologically necessary for thermoregulation of the body. It is believed to be caused by an overactive cholinergic response of the sweat glands and affects an estimated 15.3 million, or 4.8%, of the U.S. population, and 12.76% of the population in Japan. According to a 2016 update on the prevalence and severity of hyperhidrosis in the U.S., axillary hyperhidrosis, which is the targeted first potential indication for sofpironium bromide, is the most common occurrence of hyperhidrosis, affecting approximately 65% of patients, or an estimated 10 million individuals, in the U.S.

**Our Clinical Programs**

***U.S. Pivotal Phase 3 Cardigan I and II Clinical Studies***

Based on the positive results in the clinical trials for sofpironium bromide gel conducted globally to date by us and Kaken, our development partner in Asia, we initiated during the fourth quarter of 2020 two U.S. pivotal Phase 3 clinical trials (also referred to as our "Phase 3 Program" or "Cardigan Studies").

In October 2020, we initiated our first of two U.S. pivotal Phase 3 clinical studies (the "Cardigan I Study"), and in December 2020 we initiated the second U.S. pivotal Phase 3 clinical study (the "Cardigan II Study" and, together with the Cardigan I Study, the "Cardigan Studies"), both evaluating the efficacy and safety of topically applied sofpironium bromide gel, 15% for the treatment for primary axillary hyperhidrosis. The Cardigan Studies are multicenter, randomized, double-blinded, vehicle (placebo)-controlled Phase 3 clinical studies that each have enrolled approximately 350 subjects ages nine years and older with primary axillary hyperhidrosis. Subjects apply sofpironium bromide or vehicle once daily at bedtime to their underarms for six consecutive weeks, with a two-week post-treatment follow-up. The co-primary efficacy endpoints of the Cardigan Studies include the proportion of subjects achieving at least a 2-point improvement on the Hyperhidrosis Disease Severity Measure-Axillary© scale, a proprietary and validated PRO measure, and change in gravimetric sweat production ("GSP"), each from baseline to end of treatment. In addition, safety and tolerability assessments are being performed throughout the Cardigan Studies.

As of the date of filing of this Quarterly Report, the final patient has completed the Cardigan I Study. Enrollment is completed in the Cardigan II Study, and the final patient is expected to complete the Cardigan II Study in the third quarter of 2021. We expect to concurrently report topline results from the Cardigan Studies in the fourth quarter of 2021. If successful, those results are expected to form the basis of a prospective new drug application ("NDA") submission in the U.S., anticipated in mid-2022, for sofpironium bromide gel, 15% for the treatment of primary axillary hyperhidrosis.

***U.S. Phase 3 Open-Label Long-Term Safety Study***

In July 2020, we completed our U.S. Phase 3 open-label long-term safety study ("LTSS") evaluating the safety and efficacy of sofpironium bromide gel, 5% and 15% for 48 weeks of treatment in 300 patients aged nine years or older with primary axillary hyperhidrosis. Patients were randomized to receive either sofpironium bromide gel, 5% or 15% in a 1:2 ratio. Subjects applied the assigned investigational product once daily at bedtime to both axillae for 48 weeks, followed by a four-week post-treatment visit. A total of 190 patients completed the full study duration of 52 weeks.

Overall, the safety, tolerability, and efficacy results for sofpironium bromide gel, 5% and 15% in the LTSS were consistent with prior clinical experience and no unexpected safety findings were observed. There were no clinically significant changes in laboratory parameters or vital signs over 48 weeks of treatment.

**Collaboration with Kaken in Asia**

Under our License, Development and Commercialization Agreement with Kaken, dated March 31, 2015 (as amended, the "Kaken Agreement"), we and Kaken have completed multiple clinical trials of sofpironium bromide gel that encompass over 1,300 subjects in the U.S. and Japan. These trials evaluated the potential safety, tolerability, pharmacokinetics, and efficacy of sofpironium bromide gel in adult and pediatric patients with primary axillary hyperhidrosis and healthy adult subjects. We expect that the sofpironium bromide total exposure for the potential U.S. NDA submission would be in excess of 1,600 subjects, including those in the U.S. Phase 3 pivotal studies.

In September 2020, Kaken received regulatory approval in Japan to manufacture and market sofpironium bromide gel, 5% under the brand name ECCLOCK for the once-daily treatment of primary axillary hyperhidrosis. Japan is the first country to approve sofpironium bromide, which also marks the first approval of a topical prescription product for the treatment of primary axillary hyperhidrosis in Japan. This approval was based on the results of Kaken's Japanese pivotal Phase 3 registration study of sofpironium bromide gel, 5% in 281 patients with primary axillary hyperhidrosis.

In November 2020, Kaken launched commercial sales of ECCLOCK in Japan. This marked the first commercialization of sofpironium bromide for any indication worldwide. Under the Kaken Agreement, we are entitled to receive commercial milestone payments, as well as tiered royalties based on a percentage of net sales of ECCLOCK in Japan. As a result, beginning in the fourth quarter of 2020, we have recognized royalty revenue earned on a percentage of net sales of ECCLOCK in Japan. To help ensure patient safety, Japanese law generally restricts new pharmaceutical products to 14-day prescriptions for one year from the first day of the month that a government-approved pricing for the product to be launched is listed. This means that in the first year of launch, patients must return to see their prescribing physician in person to obtain a refill lasting another two weeks in duration.

In June 2021, Kaken initiated a Japanese Phase 1 clinical study to assess the pharmacokinetics, safety and efficacy of sofpironium bromide gel in patients with primary palmoplantar hyperhidrosis, or excessive sweating from the palms and soles, for which there are currently no approved topical prescription treatment options in Japan.

In addition, Kaken has rights to develop and commercialize sofpironium bromide in South Korea, China, and certain other Asian countries, and we are entitled to receive royalties based on a percentage of Kaken's net sales in these countries.

Together with Kaken, we were granted by the Japanese Patent Office a composition of matter patent with claims directed to the novel polymorphic, or crystalline, forms of sofpironium bromide that are being commercialized by Kaken in Japan and would be by us in the U.S. subject to our own ongoing development efforts. This patent is expected to provide additional protection for these newly developed and distinct forms in certain countries around the world, including Japan, potentially through 2040.

**AnGes Collaboration Agreement**

In September 2020, we entered into a collaboration agreement with AnGes, Inc. ("AnGes") relating to the development and potential commercialization of AnGes' proprietary investigational adjuvanted plasmid DNA vaccine intended to prevent COVID-19. Under the terms of the collaboration agreement, AnGes will continue to lead the development of its vaccine candidate in Japan, and we will provide information and know-how that could be relevant to such development efforts. If AnGes obtains positive results from its clinical studies in Japan and we are able to satisfy certain conditions, including raising the required development funding, we would have the right to lead the development efforts in the U.S. and certain emerging markets. If ultimately approved for sale in the applicable jurisdictions, AnGes would have commercial rights to the vaccine in Japan and we would have commercial rights in the U.S. and certain emerging markets on terms and conditions to be agreed with AnGes prior to any launch of a vaccine product. AnGes has completed a Phase 1/2 study and a Phase 2/3 clinical study with its vaccine candidate in Japan. It is currently analyzing the results of both clinical trials in accordance with the international standards recommended by the World Health Organization and estimates it will be later this year before the results become publicly available. Depending on the study results, AnGes may meet with the PMDA to discuss design of a larger Phase 3 registration trial.

**Significant Financing and Licensing Arrangements**

***Public Offerings of Common Stock and Warrants***

In July 2021, we completed the sale of 12,983,871 shares of our common stock (the "July 2021 Offering"). The July 2021 Offering resulted in net proceeds of approximately $7.3 million, after deducting underwriting discounts and commissions and offering expenses. We anticipate using the net proceeds from the July 2021 Offering for research and development, including clinical trials, working capital, and general corporate purposes.

In October 2020, we completed the sale of 19,003,510 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 1,829,812 shares of our common stock, and accompanying common stock warrants to purchase up to an aggregate of 20,833,322 shares of our common stock (the "October 2020 Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of our common stock. The public offering price of each share of common stock and accompanying common warrant was $0.72 and $0.719 for each pre-funded warrant and accompanying common warrant, respectively. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The common warrants are exercisable at a price of $0.72 per share of our common stock and will expire five years from the date of issuance. The pre-funded warrants were exercised in October 2020 at an exercise price of $0.001 per share of our common stock. The October 2020 Offering resulted in net proceeds of approximately $13.7 million to us after deducting underwriting commissions and discounts and other offering expenses of $1.3 million and excluding the proceeds from the exercise of the warrants. During the six months ended June 30, 2021, 12,427,387 common warrants associated with the October 2020 Offering were exercised at a weighted-average exercise price of $0.72 per share, resulting in aggregate proceeds of approximately $8.9 million.

In June 2020, we completed the sale of 14,790,133 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 2,709,867 shares of our common stock, and accompanying common warrants to purchase up to an aggregate of 17,500,000 shares of our common stock (the "June 2020 Offering") (and together with the October 2020 Offering, the "2020 Offerings"). Each share of common stock and pre-funded warrant to purchase one share of our common stock was sold together with a common warrant to purchase one share of our common stock. The public offering price of each share of common stock and accompanying common warrant was $1.15 and $1.149 for each pre-funded warrant and accompanying common warrant, respectively. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The pre-funded warrants were exercised in the third quarter of 2020 at an exercise price of $0.001 per share of our common stock. The common warrants were immediately exercisable at a price of $1.25 per share of our common stock and will expire five years from the date of issuance. The June 2020 Offering resulted in approximately $18.7 million of net proceeds after deducting underwriting commissions and discounts and other offering expenses of $1.4 million and excluding the proceeds from the exercise of the warrants. During the six months ended June 30, 2021, 17,500 common warrants associated with the June 2020 Offering were exercised at a weighted-average exercise price of $1.25 per share, resulting in aggregate proceeds of approximately $22 thousand.

We are using the proceeds from the 2020 Offerings for research and development, including clinical trials, working capital, and general corporate purposes.

***At Market Issuance Sales Agreements***

In April 2020, we entered into an At Market Issuance Sales Agreement (the "2020 ATM Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer") as our sales agent. Pursuant to the terms of the ATM Agreement, we may sell from time to time through Oppenheimer shares of our common stock having an aggregate offering

price of up to $8.0 million. Such shares are issued pursuant to our shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by us and Oppenheimer. Under the terms of the 2020 ATM Agreement, we may also sell the shares from time to time to Oppenheimer as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to Oppenheimer as principal would be pursuant to the terms of a separate placement notice between us and Oppenheimer. During the six months ended June 30, 2021, we sold 1,089,048 shares under the 2020 ATM Agreement at a weighted-average price of $1.55 per share, for aggregate net proceeds of approximately $1.6 million, after giving effect to a 3% commission to Oppenheimer as agent. As of June 30, 2021, approximately $2.6 million of shares of common stock were remaining, but had not yet been sold under the 2020 ATM Agreement.

In March 2021, we entered into an At Market Issuance Sales Agreement (the "2021 ATM Agreement" and, together with the 2020 ATM Agreement, the "ATM Agreements") with Oppenheimer and William Blair & Company, L.L.C. as our sales agents (the "Agents"). Pursuant to the terms of the 2021 ATM Agreement, we may sell from time to time through the Agents shares of our common stock having an aggregate offering price of up to $50.0 million. Such shares are issued pursuant to our shelf registration statement on Form S-3 (Registration No. 333-254037). Sales of shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by us and the Agents. Under the terms of the 2021 ATM Agreement, we may also sell the shares from time to time to an Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the shares to an Agent as principal would be pursuant to the terms of a separate placement notice between us and such Agent. During the six months ended June 30, 2021, we sold 3,963,476 shares under the 2021 ATM Agreement at a weighted-average price of $0.89 per share, for aggregate net proceeds of $3.4 million, after giving effect to a 3% commission to the Agents. As of June 30, 2021, approximately $46.5 million of shares of common stock were remaining, but had not yet been sold under the 2021 ATM Agreement. Subsequent to June 30, 2021, and through the date of filing of this Quarterly Report, we sold 486,352 shares of common stock under the 2021 ATM Agreement at a weighted-average price of $0.86 per share, for aggregate net proceeds of approximately $0.4 million.

***Private Placement Offerings***

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

Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $28.0 million in the aggregate of shares of our common stock. In order to retain maximum flexibility to issue and sell up to the maximum of $28.0 million of our common stock under the Purchase Agreement, we sought and, at our annual meeting on April 19, 2021, received, stockholder approval for the sale and issuance of common stock in connection with the Purchase Agreement under Nasdaq Listing Rule 5635(d). Sales of common stock by us will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on August 14, 2020 (the "Commencement Date").

Following the Commencement Date, under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 100,000 shares of our common stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 125,000

shares, provided that the closing sale price of the common stock is not below $3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below $5.00 on the purchase date. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The purchase price per share for each such Regular Purchase will be based on prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, we may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, we may not sell shares of our common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of our common stock. During the three and six months ended June 30, 2021, we sold to Lincoln Park 800,000 shares under the Purchase Agreement at a weighted-average price of $0.81 per share, for aggregate net proceeds of $0.6 million. As of June 30, 2021, approximately $27.3 million of shares of common stock were remaining, but had not yet been sold under the Purchase Agreement. Subsequent to June 30, 2021, and through August 12, 2021, we sold to Lincoln Park 500,000 shares of common stock under the Purchase Agreement at a weighted-average price of $0.81 per share, for aggregate net proceeds of approximately $0.4 million.

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

***Amended and Restated License Agreement with Bodor***

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

The Amended and Restated License Agreement retains with us a worldwide, exclusive license to develop, manufacture, market, sell and sublicense products containing the proprietary compound sofpironium bromide based upon the patents referenced in the Amended and Restated License Agreement for a defined field of use. As of June 30, 2021, under the original License Agreement and the Amended and Restated License Agreement, we had remaining obligations to pay Bodor (i) a royalty on sales of product outside Kaken's territory, including a low single-digit royalty on sales of certain product not covered by the patent estate licensed from Bodor; (ii) approximately 50 to 55% of all royalties we receive from Kaken for sales of product within its territory; (iii) a percentage of non-royalty sublicensing income we receive from Kaken or other sublicensees; and (iv) up to an aggregate of $0.8 million (plus an additional $0.1 million for approvals of additional products) in cash payments and $1.0 million of shares of our common stock upon the achievement of certain regulatory and other milestones.

During the three and six months ended June 30, 2020, under the terms of the Amended and Restated License Agreement, we made a $0.5 million milestone payment to Bodor following the closing of a public offering in June 2020 and accrued an additional $1.0 million related to our plan to initiate our U.S. Phase 3 pivotal program in the fourth quarter of 2020. As a result, we recorded $1.5 million as research and development expense in the condensed consolidated statements of operations during the three and six months ended June 30, 2020. No similar or associated research and development expense was incurred in the three or six months ended June 30, 2021, but we paid Bodor the applicable amount with respect to the royalties we received from Kaken for sales of product in Japan during those periods.

**Financial Overview**

Our operations to date have been limited to business planning, raising capital, developing our pipeline assets (in particular sofpironium bromide), identifying product candidates, conducting clinical trials, and other research and development.

To date, we have financed operations primarily through funds received from the sale of common stock and warrants, convertible preferred stock, debt and convertible notes, payments received under license and collaboration agreements, and cash and investments acquired in connection with the merger pursuant to which Private Brickell became a wholly-owned subsidiary of Brickell Biotech, Inc. (formerly Vical Incorporated) in 2019 (the "Merger"). We do not have any products approved for sale and have not generated any product sales. Since inception, we have incurred operating losses. We recorded a net loss of $20.2 million and $9.2 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of $126.0 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

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

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

**Key Components of Operations**

***Revenue***

Revenue generally consists of revenue recognized under our strategic collaboration agreements for the development and commercialization of our product candidates. Our strategic collaboration agreements generally outline overall development plans and include payments we receive at signing, payments for the achievement of certain milestones, and royalties. For these activities and payments, we utilize judgment to assess the nature of the performance obligations to determine whether the performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. Prior to 2020, we had not recognized any royalty revenue from any collaboration arrangement. Beginning during the three months ended December 31, 2020, and continuing in the six months ended June 30, 2021, pursuant to the Kaken Agreement, we recognized royalty revenue earned on a percentage of net sales of ECCLOCK in Japan, and we expect to continue to recognize such royalties going forward. Other than the revenue we may generate in connection with this agreement, we do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaboration agreements with third parties.

***Research and Development Expenses***

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

Below is a summary of our research and development expenses related to sofpironium bromide by categories of costs for the periods presented. The other expenses category includes travel, lab and office supplies, clinical trial management software, license fees, and other miscellaneous expenses. We expect our research and development expenses to decrease in future periods as we complete our Phase 3 clinical trials for sofpironium bromide.

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | (in thousands) | | | |
| Direct program expenses related to sofpironium bromide | $ 8,114 | $ 1,964 | $ 13,550 | $ 3,731 |
| Personnel and other expenses | | | | |
| Salaries, benefits, and stock-based compensation | 460 | 712 | 936 | 1,475 |
| Regulatory and compliance | 244 | 4 | 371 | 58 |
| Other expenses | 20 | 32 | 33 | 112 |
| Total research and development expenses | $ 8,838 | $ 2,712 | $ 14,890 | $ 5,376 |

***General and Administrative Expenses***

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

***Other Income, Net***

Other income, net consists primarily of a gain on extinguishment of debt recognized in June 2021 as a result of the forgiveness of an outstanding loan that we received under the Paycheck Protection Program (the "PPP Loan"). Other income, net also consists of interest income, interest expense, and various income or expense items of a non-recurring nature. We earn interest income from interest-bearing accounts and money market funds. Interest expense is comprised of interest incurred related to a note payable. Our interest income varies each reporting period depending on our average cash balances during the period and market interest rates. We expect interest income to fluctuate in the future with changes in average cash balances and market interest rates.

**Critical Accounting Policies and Estimates**

We have prepared the condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, management evaluates its critical estimates, including those related to revenue

recognition, accrued research and development expenses, warrants, and stock-based compensation. We base our estimates on our historical experience and on assumptions that we believe are reasonable; however, actual results may differ materially from these estimates under different assumptions or conditions.

There were no changes during the six months ended June 30, 2021 to our critical accounting policies as disclosed in the 2020 Form 10-K. For information on our significant accounting policies, please refer to Note 2 of the notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report.

**Recent Accounting Pronouncements**

Unless otherwise discussed elsewhere in this Quarterly Report, we believe that the impact of recently issued guidance to be adopted in the future is not expected to have a material impact on our condensed consolidated financial statements upon adoption.

**Results of Operations**

**Comparison of the Three Months Ended June 30, 2021 and 2020**

| | Three Months Ended June 30, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Revenue | $ 151 | $ 607 |
| Research and development expenses | (8,838) | (2,712) |
| General and administrative expenses | (2,891) | (3,021) |
| Total other income, net | 429 | 7 |
| Net loss | $ (11,149) | $ (5,119) |

***Revenue***

Revenue decreased by $0.5 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. Revenue in 2021 consisted of royalty revenue recognized related to sales of ECCLOCK in Japan by Kaken, while revenue in 2020 was driven by collaboration revenue recognized for research and development activities under the Kaken Agreement pursuant to which Kaken provided research and development funding to us. The decrease in revenue recognized was primarily attributable to our Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were concluded or winding down by the end of the first quarter of 2020. Conducting these studies was the basis for revenue recognition over time, through the third quarter of 2020, of a $15.6 million research and development payment received from Kaken in the second quarter of 2018. Beginning during the three months ended December 31, 2020, and continuing in 2021, pursuant to the Kaken Agreement, we recognized royalty revenue earned on a percentage of net sales of ECCLOCK in Japan, and we expect to continue to recognize such royalties on Kaken's net sales going forward. Despite recognizing such royalty revenue, we did not receive any cash related to such royalties because Kaken instead offset amounts we owed it under the Clinical Supply Agreement we entered into with Kaken on July 30, 2019 (the "Clinical Supply Agreement").

***Research and Development***

Research and development expense increased by $6.1 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020, which was primarily due to an increase in clinical costs related to sofpironium bromide. We began incurring greater research and development costs upon the initiation of our Phase 3 Cardigan Studies in the fourth quarter of 2020. Our Phase 3 open-label, long-term safety study of

sofpironium bromide gel and other ancillary clinical studies were concluded or winding down by the end of the first quarter of 2020.

***General and Administrative Expenses***

General and administrative expenses decreased by $0.1 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. This decrease was primarily due to lower costs for professional-related fees that were associated with capital raising activities that occurred in the second quarter of 2020.

***Total Other Income, Net***

Total other income, net increased by $0.4 million for the three months ended June 30, 2021 compared to the three months ended June 30, 2020. The increase was primarily due to a gain on extinguishment of debt of approximately $0.4 million that resulted from the forgiveness of the PPP Loan in June 2021.

**Comparison of the Six Months Ended June 30, 2021 and 2020**

| | Six Months Ended June 30, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Revenue | $ 168 | $ 1,653 |
| Research and development expenses | (14,890) | (5,376) |
| General and administrative expenses | (5,858) | (5,502) |
| Total other income, net | 426 | 3 |
| Net loss | $ (20,154) | $ (9,222) |

***Revenue***

Revenue decreased by $1.5 million for the six months ended June 30, 2021, compared to the six months ended June 30, 2020. Revenue in 2021 consisted of royalty revenue recognized related to sales of ECCLOCK in Japan by Kaken, while revenue in 2020 was driven by collaboration revenue recognized for research and development activities under the Kaken Agreement pursuant to which Kaken provided research and development funding to us. The decrease in revenue recognized was primarily attributable to our Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were concluded or winding down by the end of the first quarter of 2020. Conducting these studies was the basis for revenue recognition over time, through the third quarter of 2020, of a $15.6 million research and development payment received from Kaken in the second quarter of 2018. Beginning in late 2020, and continuing in the six months ended June 30, 2021, pursuant to the Kaken Agreement, we recognized royalty revenue earned on a percentage of net sales of ECCLOCK in Japan, and we expect to continue to recognize such royalties on Kaken's net sales going forward. Despite recognizing such royalty revenue, we did not receive any cash related to such royalties because Kaken instead offset amounts we owed it under the Clinical Supply Agreement.

***Research and Development Expenses***

Research and development expenses increased by $9.5 million for the six months ended June 30, 2021, compared to the six months ended June 30, 2020, which was primarily due to an increase in clinical costs related to sofpironium bromide. We began incurring greater research and development costs upon the initiation of our Phase 3 Cardigan Studies in the fourth quarter of 2020. Our Phase 3 open-label, long-term safety study of

sofpironium bromide gel and other ancillary clinical studies were concluded or winding down by the end of the first quarter of 2020.

***General and Administrative Expenses***

General and administrative expenses increased by $0.4 million for the six months ended June 30, 2021, compared to the six months ended June 30, 2020. The increase was primarily due to increased compensation and other miscellaneous expenses, partially offset by reduced professional fees.

***Total Other Income, Net***

Total other income, net increased by $0.4 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020. The increase was primarily due to a gain on extinguishment of debt of approximately $0.4 million that resulted from the forgiveness of the PPP Loan in June 2021.

**Liquidity and Capital Resources**

We have incurred significant operating losses and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the six months ended June 30, 2021 and 2020, we had a net loss of $20.2 million and $9.2 million, respectively. As of June 30, 2021, we had an accumulated deficit of $126.0 million. As of June 30, 2021, we had cash and cash equivalents of $24.4 million compared to $30.1 million as of December 31, 2020. Since inception, we have financed our operations primarily through funds received from the sale of common stock and warrants, convertible preferred stock, debt, and convertible notes, payments received under license and collaboration agreements, and cash and investments acquired in the Merger.

We believe that our cash and cash equivalents as of June 30, 2021, combined with the net proceeds received from the sale of our common stock in the July 2021 Offering, are sufficient to fund our operations for at least the next 12 months from the issuance of this Quarterly Report. We expect to continue to incur additional substantial losses in the foreseeable future as a result of our research and development activities. Additional funding will be required in the future to continue with our planned development and commercial-related activities.

**Cash Flows**

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2021 | 2020 |
| | (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ (20,205) | $ (11,290) |
| Investing activities | (36) | 4,500 |
| Financing activities | 14,534 | 21,128 |
| Total | $ (5,707) | $ 14,338 |

***Operating Activities***

Net cash used in operating activities of $20.2 million during the six months ended June 30, 2021 increased compared to $11.3 million during the six months ended June 30, 2020, which was primarily attributable to an increase in cash used to support our operating activities, including but not limited to, our clinical trials, an increase in research and development activities, and general working capital requirements. The increase was impacted by an increase in net loss of $10.9 million and an increase of $0.4 million in non-cash operating expenses, partially offset by the effect of changes in working capital of $2.4 million.

***Investing Activities***

Net cash used in investing activities of $36 thousand during the six months ended June 30, 2021 decreased compared to net cash provided by investing activities of $4.5 million during the six months ended June 30, 2020. The $4.5 million decrease in net cash provided by investing activities was primarily the result of a $4.5 million reduction in maturities of marketable securities.

***Financing Activities***

Net cash provided by financing activities of $14.5 million during the six months ended June 30, 2021 decreased compared to $21.1 million during the six months ended June 30, 2020. The decrease was primarily related to net proceeds received during the six months ended June 30, 2020 of $18.7 million associated with the June 2020 Offering and $0.4 million from proceeds of the PPP Loan, which was partially offset by higher net proceeds received during the six months ended June 30, 2021 of $8.9 million from the exercise of warrants and $3.6 million in sales of our common stock under the ATM Agreements and the Purchase Agreement.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are not required to provide the information under this item.

## ITEM 4. CONTROLS AND PROCEDURES

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act, as of the end of the period covered by this Quarterly Report. Based on this evaluation, our

principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of June 30, 2021.

**Changes in Internal Control over Financial Reporting**

Management has determined that there were no significant changes in our internal control over financial reporting that occurred during the three months ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our Company, nor is any such litigation threatened as of the date of this filing.

### ITEM 1A. RISK FACTORS

*Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price. The following information should be read in conjunction with Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the condensed consolidated financial statements and related notes in Part I, Item 1, "Financial Statements (Unaudited)" of this Quarterly Report.*

**Risks Related to Our Business Operations**

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

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

- timely and successful completion of Phase 3 clinical trials in the U.S., which may be significantly costlier than we currently anticipate, especially in a pandemic, and/or produce results that do not achieve the endpoints of the trials or which are ultimately deemed not to be clinically meaningful;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials beyond those currently planned to support the approval and commercialization of sofpironium bromide;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our and their contractual obligations and with all regulatory and legal requirements applicable to them and 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, and the product's package insert, to hire and retain a sufficient and qualified workforce, and to manage their own supply chain to comply with their contractual obligations to us, which supply chains and workforce availability have been constrained in recent months;
- a continued acceptable safety and tolerability profile during clinical development and following any 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 U.S. and outside Japan, if approved for marketing, sale, and distribution in such countries and territories, whether alone or in collaboration with Kaken or others;

- ability of Kaken to commercialize sofpironium bromide successfully in Japan now that it has been approved and is being marketed;

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

- existence of a regulatory, pricing and reimbursement, 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, regulatory exclusivity rights, 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 that we will be able to generate sufficient revenue through the sale of sofpironium bromide, or any other asset, to continue our business.

***We previously have not conducted a pivotal Phase 3 clinical trial ourselves and may be unable to successfully do so for sofpironium bromide.***

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

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

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

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

***Use of 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 GSP has the potential for significant variability and uncertain outcomes. This potential for variability and uncertain outcomes may adversely impact our ability to achieve statistical significance on our primary and secondary endpoints or may provide us with initial or subsequent results that are ultimately deemed not to be clinically meaningful or that do not result in regulatory approval.

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

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

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

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by sofpironium bromide after obtaining U.S. or foreign regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining regulatory approval and/or market acceptance of sofpironium bromide and could substantially increase the costs (and extent) of commercializing sofpironium bromide, potentially even leading to withdrawal of the drug.

***Under our Clinical Supply Agreement with Kaken, our inability to obtain such API from Kaken on a timely basis could have a material adverse impact on our business.***

On July 30, 2019, we entered into the Clinical Supply Agreement with Kaken under which we made various purchase orders for certain amounts of drug substance and product components for use in non-clinical and clinical studies, as well as for scale-up validation activities. Failure to receive such API from Kaken on a timely basis could have a material impact on our business. Furthermore, at this time, we do not have a commercial supply agreement with Kaken or other suppliers. Our inability to enter into an adequate commercial supply agreement at the right time for sofpironium bromide for the U.S. and other markets outside of Japan and certain other Asian countries would materially impact our business.

***Kaken substantially controls the development and commercialization 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 secure an appropriate local business partner (if desirable) and/or obtain approval of the drug in the ex-Japan Asian markets over which it has rights.***

The Kaken Agreement granted Kaken an exclusive license in Japan and certain rights to additional Asian countries to develop and commercialize sofpironium bromide. Under the terms of the Kaken Agreement, as amended, we received an up-front payment, development milestones, and research and development payments and have received and are eligible to receive future milestones and royalties 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 U.S. and the other territories where we maintain exclusive rights. Additionally, Kaken is responsible for conducting certain nonclinical and API-related activities (chemistry, manufacturing, and controls) that will be required for FDA approval in the U.S., and as a result, we are reliant on Kaken to execute successfully, in a timely, compliant, and efficient manner, such activities on our behalf. To the extent Kaken experiences delays and/or difficulties in performing its development activities, this could prevent or cause substantial delays in our ability to seek approval for sofpironium bromide gel in the U.S. and other territories in which we maintain exclusive rights.

In September 2020, Kaken received approval of an NDA in Japan for the manufacturing and marketing of sofpironium bromide gel, 5% under the brand name ECCLOCK for the treatment of primary axillary hyperhidrosis, and in November 2020, Kaken launched commercial sales of ECCLOCK in Japan. Beginning in January 2021, Kaken would have paid us a royalty on sales during the previous quarter, but instead offset amounts we owe Kaken under the Clinical Supply Agreement, which offsets were completed in the second quarter of 2021. Despite receiving regulatory approval and commencing these commercial activities in Japan, we cannot provide any assurance that an NDA in any other Asian markets will be approved or that regulatory approvals in other Asian countries will occur. We will not receive additional milestone or other payments from Kaken if Kaken does not continue to be successful in its development, regulatory, or commercial activities, or if the approval is withdrawn for any reason.

***If we or any partners with which we may collaborate to market and sell sofpironium bromide are unable to achieve and maintain medical 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 managed care approvals and the availability of 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 are denied. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the U.S., and private third-party payors is often critical to new product acceptance regardless of how well the product works. Coverage decisions may depend on clinical and economic standards that disfavor new drug products when more established or lower-cost therapeutic alternatives are already available or subsequently become available, even if these alternatives are not as safe and effective or may be affected by the budgets and demands on the various entities responsible for providing health insurance to patients who will use 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 the U.S., although private third-party payors tend to follow Medicare and Medicaid practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as state to state. Consequently, the coverage determination process is often uncertain and a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require us to provide scientific, clinical, and health economics support for the use of 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 U.S. and in international markets, potentially based on changes in law and/or payor practices. Third-party coverage and reimbursement for sofpironium bromide may not be available or adequate in either the U.S. or international markets, which could harm our business, financial condition, operating results, and prospects.

After receiving regulatory approval in 2020 for ECCLOCK from Japanese regulators, Kaken applied for and received pricing approval in Japan, which is required by law to do before selling. On November 18, 2020, ECCLOCK was placed on Japan's National Health Insurance drug reimbursement price list. Kaken will likely face pricing pressures in Japan as it continues to commercialize ECCLOCK, and if it is unable to maintain this

current price, or is unable to increase the price in future years, this could have a negative impact on sales in Japan.

***Even if sofpironium bromide obtains regulatory approval outside Japan, and despite our partner Kaken launching the drug as ECCLOCK in Japan in 2020, 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 and as 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 U.S., will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat hyperhidrosis;
- our ability to market and sell the drug, including through direct-to-consumer advertising and non-traditional sales strategies;
- our ability to manage the COVID-19 pandemic to complete necessary clinical trials, supply/manufacture sofpironium bromide for such trials and commercially, and otherwise market and sell sofpironium bromide while the pandemic continues in effect, and the short- and long-term consequences of such pandemic if and as certain markets improve;
- 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, or, if limited or no reimbursement is available, the degree to which patients will be willing to purchase sofpironium bromide treatment out-of-pocket;
- 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, or results from any post-marketing surveillance studies that FDA may require as a condition of product approval;

- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, legal, medical, public relations, compliance, chemistry, manufacturing and controls, 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.

***Major public health issues, and specifically the pandemic caused by the spread of COVID-19 and COVID-19 variants, and the impact as certain markets emerge from the pandemic, especially in terms of constraints on supply chains and human resource availability, and different degrees of success various countries experience in rolling out their vaccine campaigns, could have an adverse impact on our financial condition and results of operations and other aspects of our business and that of our suppliers, contractors, and business partners.***

The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 variants and the actions to contain COVID-19 or treat its impact, among others, and even as or after the pandemic subsides, how long it takes for global supply chains to handle the pent-up demand for goods and services and the shutdowns associated around the world with those supply chains, and worker eagerness to return to the workforce and/or change employment patterns.

The effects of the COVID-19 pandemic could delay or interrupt our business operations. For instance, our clinical trials may be affected by the continuing pandemic. Ongoing clinical trial participant dosing, manufacturing, supply, and distribution of clinical trial materials and materials required for an eventual NDA for submission to the FDA, study monitoring, and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state, or local regulations, prioritization of hospital resources toward pandemic efforts, worker and supplier patterns, or other reasons related to, or as a consequence of, the pandemic. Some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to complete our clinical trials. Further, if our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance. Infections and deaths related to the pandemic may disrupt the U.S.' and other countries' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA or other regulatory review and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

We currently rely on third parties, such as contract laboratories, contract research organizations, medical institutions, and clinical investigators to conduct these studies and clinical trials. If these third parties themselves are adversely impacted by restrictions or disruptions resulting from the COVID-19 pandemic, we will likely experience delays, and/or realize additional costs. As a result, our efforts to obtain regulatory approvals for, and to commercialize, our therapeutic candidates may be delayed or otherwise adversely impacted.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, negative supply chain impacts, and worker unavailability, may have a material economic effect on our business. While the potential economic impact brought by, and the duration of, the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial and distribution markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression, or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

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

***Sofpironium bromide, where 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, where approved, may compete with other dermatological products, including over-the-counter ("OTC") treatments, for a share of some patients', or payors', discretionary budgets and for physicians' attention within their clinical practices.

We anticipate that 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 cloth. Oral and compounded topical anticholinergics also may be used off-label.

- Non-Surgical Office-Based Procedures. Office-based procedures have been approved by the FDA for certain uses and which may be used, on-or off-label, to treat hyperhidrosis, including intradermal injections of BOTOX®, marketed by Allergan plc, and MiraDry®, a microwave-based treatment marketed by Miramar Labs, Inc.

- Surgical Treatments. Surgical treatments include techniques for the removal of sweat glands, such as excision, curettage, and liposuction. Surgical procedures, such as endoscopic thoracic sympathectomy, are also used to destroy nerves that transmit activating signals to sweat glands.

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

In some international markets, due to different regulatory requirements than in the U.S., there may be more dermatological products available for use than in the U.S., and there may be 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 could face more competition in these markets than in the U.S.

***We may 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 U.S. (and any other countries where patent coverage exists, such as Japan) 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 would reduce existing sales and could expose us to litigation, adversely affecting our business, financial condition, operating results, and prospects. Further, other therapies used for hyperhidrosis that would compete with sofpironium bromide could lose their patent protection at any time, increasing the risk of generic competition, which could reduce existing sales and adversely affect our business, financial condition, operating results, and prospects.

***If CROs and other third parties do not meet our requirements or otherwise conduct our sofpironium bromide clinical trials as required or are unable to staff or supply our trials, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, sofpironium bromide at all or in the time frames currently planned for.***

We have in the past relied, and expect to continue to rely, on third-party 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 current 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 Current Good Manufacturing Practice ("cGMP") regulations. Our failure to comply with these regulations and policies, or to obtain supply of key items in

sufficient quantities, in a timely manner or at all, may require us to extend or repeat clinical trials, which would delay or halt the regulatory approval process.

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

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

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

To commercialize sofpironium bromide in the rest of the world, we may be able to leverage the current (and only) regulatory approval in Japan and/or commercial infrastructure of our partner, Kaken, which will provide us with resources and expertise in certain areas that are greater than we could initially provide ourselves. We may choose to collaborate with additional third parties in various countries that have direct sales forces, commercial and regulatory capacities, 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.

***Our collaboration with AnGes may prove to be unsuccessful, either because AnGes is unable to timely develop its COVID-19 vaccine candidate, or because we are not able to continue with this alliance for a variety of business, financial, or other reasons, or the results of AnGes' clinical trials are not supportive, or AnGes decides for its own business reasons to pursue different priorities.***

The COVID-19 vaccine candidate that is the subject of our collaboration agreement with AnGes, Inc. is in a data review stage just prior to AnGes making a decision on whether it can pursue Phase 3 registration trials in Japan, and this research program may not result in a safe and effective product candidate in a timely manner, or at all. The investigational vaccine candidate may not be deemed attractive by consumers given other COVID-19 vaccines that are now in the market and available earlier, there could be supply chain issues for both clinical and commercial contexts, we may not be able to proceed with related development and commercialization activities, or emerging COVID-19 variants could disrupt AnGes' current development efforts. Our contractual relationship with AnGes may end in a variety of ways or we may be unable to negotiate additional acceptable terms with AnGes. Further, any attention and resources we devote to this vaccine candidate could negatively impact our development program related to sofpironium bromide.

In September 2020, we entered into a collaboration agreement with AnGes relating to the development and potential commercialization of AnGes' proprietary investigational adjuvanted plasmid DNA vaccine intended to prevent COVID-19. Under the terms of the collaboration agreement, AnGes will continue to lead the development of its vaccine candidate in Japan, and we will provide information and know-how that could be relevant to such development efforts. If AnGes obtains positive results from its clinical studies in Japan and we are able to satisfy certain conditions, including raising the required development funding, we would have the right to lead the development efforts in the U.S. and certain emerging markets. If ultimately approved for sale in the applicable jurisdictions, AnGes would have commercial rights to the vaccine in Japan and we would have commercial rights in the U.S. and certain emerging markets on terms and conditions to be agreed with AnGes prior to any launch of a vaccine product.

AnGes has completed a Phase 1/2 study and a Phase 2/3 clinical study with its vaccine candidate in Japan. It is currently analyzing the results of both clinical trials in accordance with the international standards recommended by the World Health Organization and estimates it will be later this year before the results become publicly available. Depending on the study results, AnGes may meet with the PMDA to discuss design of a larger Phase 3 registration trial. The results from these studies will guide any further development efforts of this novel vaccine candidate. Because the AnGes vaccine candidate is later in its development than other vaccine options for COVID-19, its potential for commercial success could be adversely affected, even if regulatory approval is obtained. The work on the AnGes vaccine candidate is still in preliminary stages prior to registration-ready trials, and it may not develop into an effective and safe vaccine in a timely manner, or at all. All product candidates are prone to significant risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by one or more regulatory authorities, or that another vaccine option is deemed to be safer, better, more easily obtained, or cheaper. Some regulatory authorities may approve a product candidate while others do not or may provide approval on different terms or with additional conditions or limitations, or may issue any regulatory approval decisions at very different times. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, costly, and inherently unpredictable, especially for early-stage product candidates. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The development of any early-stage product candidates may be discontinued at any time for a variety of reasons, including but not limited to safety and efficacy concerns, the appearance of new technologies that make the product obsolete, competition from a competing product, supply chain considerations, intellectual property right impacts, ability to price or changes in or failure to comply with applicable regulatory requirements, or constraints on us or our product sponsor in obtaining additional financing and capital.

In addition, a substantial number of companies, individuals, and institutions are working to develop, or have developed or received regulatory approval, and are now distributing, a COVID-19 vaccine. Many of them commenced studies and launched products much earlier than the studies commenced by AnGes, and many of them have substantially greater financial, scientific, and other resources than AnGes and us, and another party may be successful in producing a safer or more efficacious vaccine or other treatment for COVID-19 and its

variants, or a less costly treatment, which may also lead to the diversion of governmental and quasi-governmental funding toward other companies and better insurance coverage for other COVID-19 preventative measures or treatments, and lead to demand being driven away from any product developed by AnGes or us, or cause AnGes and/or us to cancel or significantly scale back the introduction of a vaccine candidate based on the other available patient options or AnGes' own assessment of its priorities. The current market entry of certain COVID-19 vaccines and rapid expansion of other development programs directed at COVID-19 may also generate a scarcity of manufacturing capacity among contract research organizations that provide cGMP materials for development and commercialization of biopharmaceutical products, and/or could make it difficult for those conducting clinical studies to recruit in a timely manner an adequate number of trial participants, especially for companies like AnGes and us which started these studies much later than other companies.

We do not have expertise in the development of vaccine candidates in infectious disease applications. While we remain focused on our U.S. Phase 3 pivotal program for sofpironium bromide for the treatment of primary axillary hyperhidrosis, the collaboration agreement with AnGes, including actions taken following the receipt of results from AnGes' clinical studies of the vaccine candidate in Japan, could divert our management's attention and other of our resources, which could cause delays in or otherwise negatively impact our sofpironium bromide development program. As a result, we cannot provide assurance that any attention we provide to the development of a vaccine candidate against COVID-19 will not adversely impact the timing and development of our other product candidates, and we may decide not to proceed with this collaboration depending on many still evolving factors.

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

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants, and even the regulators who we rely on to advance our business, are vulnerable to damage from computer viruses, unauthorized access, computer hacking or breaches, natural disasters, epidemics and pandemics, terrorism, war, labor unrest, and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, and probably exacerbated by the COVID-19 pandemic and increased remote working arrangements, malicious cyber actors may increase malware and ransom campaigns and phishing emails targeting teleworkers as well as company systems, preying on the uncertainties surrounding COVID-19 or other world trends and events, which exposes us to additional cybersecurity risks. While we have not experienced any such material system failure, accident, security breach, or ransom demand/threat 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, thereby 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, ongoing, 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.

***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 and in an area prone to wildfires. If a disaster, power outage, or other event occurred that prevented us from using all or a significant

portion of our office, that damaged critical infrastructure, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a 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, 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. 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.

**Risks Related to Our Liquidity, Financial Matters and Our Common Stock**

***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.***

We will require substantial additional funds to develop and, if successful, commercialize our product candidates. Our future capital requirements will depend upon a number of factors, including but not limited to: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; compliance with our material contracts including the licensing agreement for sofpironium bromide; the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance for such product candidates; and overall stock market and global business conditions and trends.

Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit our ability to achieve our business objectives. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interests in our company will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us in one or more countries.

Our ability to raise additional funds is uncertain and is limited given our small market capitalization. Even if sufficient funding is available, 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 downturns.***

Our operating results and liquidity could be affected negatively by global economic conditions generally, both in the U.S. and elsewhere around the world, including but not limited to that related to the ongoing COVID-19 pandemic, and global information technology ("IT") threats. The market for discretionary pharmaceutical products, medical devices, and procedures may be particularly vulnerable to unfavorable economic or other 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 in the future 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 again become volatile, or a bear market ensues in the U.S. stock market, including as a result of the COVID-19 pandemic or other stimulus, 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 and volume of shares traded have been and may continue to be highly volatile, and our common stock may continue to be illiquid.***

The market price of our common stock 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 of our operating as a publicly-traded company, to $0.69 per share as of July 30, 2021. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. In addition, there has been limited liquidity in the trading market for our securities, which may adversely affect stockholders. Some of the factors that may cause the market price of our common stock to continue to fluctuate include, but are not limited to:

- material developments in, or the conclusion of, any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- our inability to increase our share price to at least $1.00 per share for the frequency and duration required by The Nasdaq Capital Market to stay listed on this stock exchange and the impact that this lower price may have on investors, including our inability to address the remedial conditions laid out by Nasdaq in our current notice of non-compliance in this regard;
- the entry into, or termination of, or breach by us or our partners of material agreements, including key commercial partner or licensing agreements, including the Kaken Agreement;
- our ability to obtain timely regulatory approvals for 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 or the supply chain for 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 and/or inability to recruit the necessary talent for new positions or to replace exiting employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment, such as the ongoing reaction of global markets to the COVID-19 pandemic and the impacts of the pandemic as markets reopen. 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 and 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. Consequently, any predictions 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, the achievement of sales milestones and royalties under the Kaken Agreement, 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. These up-front and milestone payments may vary significantly from period to period, and country to country, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict.

***We 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 Exchange Act. As a smaller reporting company, we are entitled to rely on certain exemptions and reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements, in our SEC filings. These exemptions and decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock price may be more volatile.

***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.***

If the holders of our outstanding stock options and warrants exercise their rights to acquire our common stock and service conditions related to restricted stock units are met, the percentage ownership of our stockholders existing prior to the exercise of such rights will be diluted. As of June 30, 2021, we had outstanding warrants to purchase (i) one share of our common stock at an exercise price of $0.07 per share; (ii) 490,683 shares of our

common stock at an exercise price of $10.36 per share; (iii) 9,005 shares of our common stock at an exercise price of $33.31 per share; (iv) 1,556,420 shares of our common stock at an exercise price of $1.16 per share; (v) 17,482,500 shares of our common stock at an exercise price of $1.25 per share; and (vi) 8,405,935 shares of our common stock at an exercise price of $0.72 per share. As of June 30, 2021, we also had 6,716,167 options issued and outstanding to purchase our common stock at a weighted-average exercise price of $3.08 per share and 47,435 shares of common stock underlying unvested restricted stock units outstanding.

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

On February 17, 2020, we entered into the Purchase Agreement with Lincoln Park pursuant to which Lincoln Park agreed to purchase from us up to an aggregate of $28.0 million of our common stock (subject to certain limitations) from time to time over the 36-month period commencing on August 14, 2020. As of June 30, 2021, approximately $27.3 million of shares of common stock were remaining, but had not yet been sold, under the Purchase Agreement. All remaining funds available under the Purchase Agreement are subject to the satisfaction of certain conditions specified in the Purchase Agreement, including that our common stock remains listed on The Nasdaq Capital Market, the effectiveness of a registration statement relating to the resale of the shares to be sold to Lincoln Park under the Purchase Agreement and that no event of default has occurred under the Purchase Agreement. Additionally, depending upon the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park if such a sale would result in us issuing to Lincoln Park more than 9.99% of our shares outstanding prior to entering into the Purchase Agreement. In the event that we are unable to satisfy the conditions specified, the purchase commitment made by Lincoln Park will be unavailable to us and Lincoln Park will not be required to purchase any shares of our common stock. If obtaining funding from Lincoln Park were to prove unavailable, we will need to secure other sources of funding in order to continue with our proposed development activities and launch and commercialize any product candidates for which we receive regulatory approval. Additionally, even if we are able to sell all shares under the Purchase Agreement, we will still need additional capital to fully implement our business, operating, and development plans.

***Our failure to maintain compliance with The Nasdaq Stock Market LLC's ("Nasdaq") continued listing requirements could result in the delisting of our common stock.***

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On June 17, 2021, we received a notice from the Listing Qualifications Department of the Nasdaq informing us that because the closing bid price for our common stock listed on Nasdaq was below $1.00 per share for 30 consecutive business days, we were not in compliance with the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2) (the "Rule"). In accordance with Nasdaq's listing rules, we have a period of 180 calendar days, or until December 13, 2021, to regain compliance with the Rule. If at any time during this 180-day period, the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written confirmation that we have achieved compliance with the Rule.

The notice also disclosed that in the event we do not regain compliance with the Rule by December 13, 2021, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we meet these requirements, Nasdaq will inform us that we have been granted an additional 180 calendar days. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting. We

intend to continue to monitor the bid price for our common stock between now and December 13, 2021, and will consider available options to resolve the deficiency and regain compliance with the Rule, including seeking stockholder approval of a reverse split of our common stock in order to increase the trading price of our common stock in compliance with The Nasdaq Capital Market rules. There is no assurance, however, that we will be eligible for an additional compliance period or that our common stock will not be delisted from Nasdaq.

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

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

Our current expectation is that we will retain any 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.

***Our ability to use our net operating loss carryforwards and other tax assets to offset future taxable income may be subject to certain limitations.***

As of December 31, 2020, we had approximately $420.8 million of federal and $382.7 million of state net operating loss ("NOL") carryforwards available to offset future taxable income, of which $91.8 million will carryforward indefinitely and the remainder expiring in varying amounts beginning in 2021 for federal and state purposes if unused. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Under the U.S. Tax Cuts and Jobs Acts ("Tax Act"), U.S. federal NOLs incurred in 2018 and later years may be carried forward indefinitely, but our ability to utilize such U.S. federal NOLs to offset taxable income is limited to 80% of the current-year taxable income. It is uncertain if and to what extent various states within the U.S. will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986 and corresponding provisions of state law, if a corporation undergoes an "ownership change" (which is generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not determined whether we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is therefore subject to an annual limitation under Section 382. Therefore, we cannot provide any assurance that a change in ownership within the meaning of the Internal Revenue Code of 1986 and corresponding provisions of state law has not occurred in the past, and there is a risk that changes in ownership could have occurred. We may experience ownership changes as a result of subsequent changes in our stock ownership, as a result of offerings of our stock or subsequent shifts in our stock ownership, some of which may be outside of our control. In that case, the ability to use NOL carryforwards to offset future taxable income will be limited following any such ownership change and could be eliminated. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance on our financial statements.

**Risks Related to Legal, Regulatory, and Compliance Matters**

***We may never obtain regulatory approval to commercialize any of our product candidates in the U.S., or anywhere else in the world other than Japan, and any products approved for sale will be subject to continued***

***regulatory review and compliance obligations and there could be further restrictions on post-approval activities, including commercialization efforts. In obtaining regulatory approval, we will need to negotiate an appropriate product label (aka package insert) with the regulators, which will determine the extent of our allowed promotional activities, and this label could be restrictive or prohibitory with regard to subject matter we believe is necessary to maximize the commercial success of sofpironium bromide.***

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

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

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

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

- impose restrictions on the sale, marketing, advertising, or manufacturing of the product, or amend, suspend, or withdraw product approvals, or revoke necessary licenses;

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

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

***We have sponsored or supported and may in the future sponsor or support clinical trials for our product candidates outside the U.S. and Japan, and the FDA, PMDA, and applicable foreign regulatory authorities***

***may not accept data from such trials; in addition, we may not be allowed alone or with local country business partners to obtain regulatory approval for our product candidates without first conducting clinical trials in each of these other countries.***

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

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

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

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies, or others selling or otherwise coming into contact with our product candidates, among others, and under some circumstances even government agencies. If we cannot successfully defend against product liability or similar claims, we will incur substantial liabilities, reputational harm, and possibly injunctions and punitive actions. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize, or restrictions on commercializing, our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;

- product recall or withdrawal from the market or labeling, marketing, or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- significant delay in product launch;
- debarment of our clinical trial investigators or other related healthcare practitioners working with our Company;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

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

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

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

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

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

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

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

***Healthcare reform measures, including price controls or restricted access, could hinder or prevent the commercial success of our product candidates in any country.***

A new presidential administration recently took office. The enactment of any new healthcare initiatives or pharmaceutical industry regulations could have significant impacts on our ability to advance development of sofpironium bromide or other product candidates and eventually to commercialize them, if at all. In particular, the current President and Vice President during their successful campaign proposed to lower Medicare Part B drug prices, in addition to contemplating other measures to lower or prescribe certain mandatory prescription drug prices or drug substitution policies. While these proposals have not yet been enacted, we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

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

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

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

***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 to operate as a public company, including costs associated with public company reporting and other SEC requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. These rules and regulations have, and are expected to continue to, increase our legal and financial compliance costs and to make some activities more time-consuming and costly. These rules and regulations may also make it expensive for us to operate our business.

**Risks Related to Strategic Matters**

***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, royalty monetization, 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 cause us to grow and expand rapidly, putting pressure on current resources and capabilities, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Further, any such transaction(s) may require us to obtain additional financing, which may not be available to us on favorable terms or at all. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could expose us to liability, delays, and implementation obstacles that could harm our business, financial condition, operating results, and prospects. We have no current commitment or obligation to enter into any transaction described above other than ones to which we are already committed.

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

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

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

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

***Other than our focus on sofpironium bromide, we are not currently developing other product candidates, but continue to assess opportunities to in-license or acquire assets that would fit well with our strategic vision.***

We are only developing sofpironium bromide at this time. From time to time, we may evaluate the potential clinical development of various clinical stage product candidates that become available for partnering. The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming, and costly, and inherently unpredictable, especially for early-stage product candidates. Government policies, regulations, or the type and amount of clinical data necessary to gain approval for pharmaceutical assets may change during the course of a product candidate's clinical development, and most product candidates never make it entirely through approval. Accordingly, we cannot provide assurance that we will acquire and/or develop any other clinical-stage product candidates, or if we do, that we would be able to seek or obtain regulatory approval for any such product candidates.

***We may choose not to continue developing or commercializing any of our early-stage product candidates, or to pursue the AnGes collaboration regarding a COVID-19 vaccine, 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 or licensed rights to product candidates for a variety of reasons, including the appearance of new technologies that make our product obsolete or significantly impact the ability to commercialize the affected product successfully, competition from a competing product including entry of generics, supply chain considerations, intellectual property right impacts, ability to price or changes in or failure to comply with applicable regulatory requirements, or constraints on obtaining additional financing and capital. If we terminate or exit 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.

**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 and to maintain their supply chain systems and safeguard their IT operations and their and our data;
- reduced control over supply, delivery, and manufacturing schedules;
- price increases and product reliability;
- manufacturing deviations from internal or regulatory specifications;
- quality or integrity incidents;
- the failure of partners to perform their obligations for technical, market, legal, or other reasons;
- misappropriation of our current or future product candidates; and
- other risks in potentially meeting our current and future product commercialization schedule or satisfying the requirements of our end-users.

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

***We rely completely on third-party contractors to supply, manufacture, and distribute clinical drug supplies and to help prepare for a possible launch for our product candidates, including certain sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing, and distribution, and possibly sales and promotion, 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, and possibly sales and promotion, of any future product candidates.***

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

We do not have direct control over whether our contract suppliers and manufacturers will maintain current pricing terms, be willing (or able) 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, destruction of, or threats to our third-party manufacturers' or suppliers' facilities, equipment, or systems, even by force majeure or by criminal acts, 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 and systems, will have access to and may misappropriate our trade secrets, clinical trial and other research data, or other proprietary information. In addition, the manufacturing facilities of certain of our suppliers may be located outside of the U.S. This may give rise to difficulties in importing our products or product candidates or their components into the U.S. or other countries, or otherwise protecting these assets.

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

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

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

**Risks Related to Our Intellectual Property**

***We may not be able to obtain, afford, maintain, or enforce global patent rights or other intellectual property rights that cover sofpironium bromide and related technologies (and any other product candidates) that are of sufficient type, breadth, and term.***

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 U.S. and other countries, to preserve our trade secrets, and to prevent third parties from infringing on our proprietary rights. Our ability to prevent unauthorized or infringing use of 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. Our partners or licensees may inappropriately take or use our intellectual property and/or confidential information to infringe our patents or otherwise violate their contractual obligations as to us related to protection of our intellectual property. Any of these outcomes could impair our ability to enforce the exclusivity of our patents effectively, which may have an adverse impact on our business, financial condition, operating results, and prospects.

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

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

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

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

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

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

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

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

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

grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the U.S. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. For example, in Brazil, pharmaceutical patents require prior initial approval from 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 noncompliance with these requirements.***

Periodic maintenance, validation, 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. Noncompliance 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 other key aspects of product development and/or commercialization, or increase our financial or other obligations to our licensors.***

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

Our commercial success depends on our ability to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties and do this in one or more countries. We cannot assure that marketing and selling such product candidates and using

such technologies will not infringe existing or future patents or other intellectual property rights. Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents and other intellectual property rights are issued, the risk increases that others may assert that our product candidates, technologies, or methods of delivery or use(s) infringe their patent or other intellectual property rights. Moreover, it is not always clear to industry participants, including us, which patents and other intellectual property rights cover various drugs, biologics, drug delivery systems and formulations, manufacturing processes, or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent or other rights encompassing our product candidates, technologies, or methods.

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

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

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

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

**General Risk Factors**

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

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

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

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

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

Our ability to compete in the highly competitive pharmaceuticals industry depends on our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel, and directors of our board of directors. We are highly dependent on our management, scientific personnel, and our directors. The loss of the services of any of these individuals could impede, delay, or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could impact negatively our ability to implement successfully our business plan and in a way that complies with all applicable laws. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We might not be able to attract or retain qualified management and other key personnel or directors in the future due to the intense competition for qualified individuals among biotechnology, pharmaceutical, and other businesses. This risk is heightened recently for most employers by the global reaction to emergence from the COVID-19 pandemic and its impact on worker availability.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

**EXHIBIT INDEX**

| Exhibit Number | Description of Exhibit | Form | Date of Filing | Exhibit Number | Filed Herewith |
|---|---|---|---|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation, as amended through April 19, 2021 | 8-K | 4/19/2021 | 3.2 | |
| 3.2 | Amended and Restated Bylaws, as currently in effect | 10-Q | 5/14/2020 | 3.2 | |
| 10.1 | Fourth Amendment to Lease Agreement, dated as of June 17, 2021, by and between Brickell Biotech, Inc. and GPIF 5777 Flatiron LLC (f/k/a BMC Properties, LLC) | | | | × |
| 10.2 | Brickell Biotech, Inc. 2020 Omnibus Long-Term Incentive Plan, as amended through April 19, 2021 | 8-K | 4/19/2021 | 10.1 | |
| 10.3 | Brickell Biotech, Inc. Employee Stock Purchase Plan | 8-K | 4/19/2021 | 10.2 | |
| 10.4† | Brickell-Kaken Amendment to Clinical Supply Agreement and License, Development and Commercialization Agreement, dated as of May 14, 2021, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. | | | | × |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended | | | | × |
| 31.2 | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended | | | | × |
| 32.1* | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | × |
| 101.INS | Inline XBRL Instance Document | | | | × |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document | | | | × |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document | | | | × |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document | | | | × |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document | | | | × |

| | | |
|---|---|---|
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document | × |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | × |

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× Filed herewith.

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

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

**SIGNATURES**

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

Brickell Biotech, Inc.

Date: August 12, 2021

By: /s/ Robert. B. Brown

Robert B. Brown
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Albert N. Marchio, II

Albert N. Marchio, II
Chief Financial Officer
(Principal Financial Officer)

**Exhibit 10.1**

**FOURTH AMENDMENT TO LEASE**

THIS FOURTH AMENDMENT TO LEASE ("Amendment"), dated as of June 17, 2021, is entered into by and between GPIF 5777 FLATIRON LLC, a Delaware limited liability company ("Landlord"), and BRICKELL BIOTECH, INC., a Delaware corporation ("Tenant").

Recitals:

A. Landlord's predecessor in interest and Tenant entered into a written lease agreement ("Base Lease") dated August 4, 2016, as amended by that certain First Amendment to Lease ("First Amendment") dated August 26, 2016, that certain Second Amendment to Lease ("Second Amendment") dated January 19, 2017, and that certain Third Amendment to Lease ("Third Amendment") dated January 1, 2018. The Base Lease as amended by the First Amendment, the Second Amendment and the Third Amendment is referred to herein as the "Lease" which Lease pertains to approximately 3,038 rentable square feet of space known as Suite 102 (the "Premises") located in the building having an address of 5777 Central Avenue, Boulder, Colorado 80301 ("Building"). Initially capitalized terms not otherwise defined herein have the same meaning as in the Lease.

B. The Primary Lease Term is scheduled to expire on October 31, 2021.

C. Landlord and Tenant desire to extend the Primary Lease Term and otherwise amend the Lease in the manner and form set forth herein.

NOW, THEREFORE, for good and valuable consideration, Landlord and Tenant hereby agree as follows:

1. The Primary Lease Term is hereby extended for a period of 14 months (the "Extension Term"), commencing on November 1, 2021 ("Extension Commencement Date"), and expiring at 12:00 noon on December 31, 2022 ("Expiration Date"). Except as expressly set forth in Section 4 of this Amendment, Tenant has no other rights to extend or renew the Term of the Lease, and any such rights set forth in the Lease are hereby deleted in their entirety. The Primary Lease Term and any extension thereof is referred to herein as the "Term".

2. Notwithstanding anything to the contrary set forth in the Lease, commencing on the Extension Commencement Date, Tenant shall pay monthly Base Rent for the Premises at the times and in the manner provided in the Lease in accordance with the following schedule:

| **Period** | **Monthly Base Rent** |
|---|---|
| 11/1/2021 – 12/31/2022 | $6,076.00 |

*Notwithstanding anything to the contrary, Tenant may occupy the Premises and monthly Base Rent (but not any other charges payable by Tenant under the Lease, as hereby amended) will be abated ("Abated Base Rent") for the months of November 2021 and December 2021 ("Abatement Period"). The Abated Base Rent is allocable to, and will be accrued by the parties during, their fiscal periods in which the same is actually paid. No portion of the Base Rent paid by Tenant during periods after the expiration of the Abatement Period will be allocated to such Abatement Period, nor is such Base Rent intended to be allocable to the Abatement Period. In the event of a default by Tenant under the Lease, which default is not cured within the applicable notice and cure period, the full amount of the Abated Base Rent shall be due and payable and Tenant shall immediately pay to Landlord the full amount of the Abated Base Rent.

3. Throughout the Primary Lease Term, as herein extended for the Extension Term (as extended, the "Term"), including during the Abatement Period, Tenant shall, subject to Section 2 above, be obligated to pay Additional Rent and all other sums payable by Tenant in accordance with the Lease applicable to the Premises, including, without limitation, payment of Tenant's Pro Rata Share of Operating Expenses.

4. Section 31 of the Base Lease is hereby deleted in its entirety, and replaced with the following in lieu thereof:

Option to Extend. (a) Tenant may, at its option ("Option to Extend"), extend the Term of the Lease for all, but not a portion, of the Premises for two renewal periods of three years each (each, a "Renewal Period") by written notice to Landlord (the "Renewal Notice") given for each Renewal Period no earlier than 12 months nor later than six months prior to the then expiration of the Term, provided that at the time of such Renewal Notice as well as at the time the applicable Renewal Period is scheduled to commence, (i) Tenant remains in occupancy of the Premises, and (ii) no uncured Tenant default exists under the Lease. The Rent payable during the Renewal Period (including Base Rent and parking charges) shall be at the Market Rental Rate (as defined below) for the Premises. However, in no event shall the Base Rent for the Renewal Period be less than the Base Rent during the last year of the Extension Term or first Renewal Period, as appropriate. Except as provided in this Section, all terms and conditions of the Lease shall continue to apply during the Renewal Period.

(b) Within 30 days of the Renewal Notice, Landlord shall notify Tenant of the Market Rental Rate for such Renewal Period (the "Rental Notice"). Tenant may accept or object to the terms set forth in the Rental Notice by written notice (the "Tenant's Notice") to Landlord given within 15 days after receipt of the Rental Notice. If Tenant timely delivers the Tenant's Notice and accepts the terms set forth in the Rental Notice, Landlord and Tenant shall, within 15 days after receipt, execute a lease amendment confirming the Base Rent and such other non-material terms of the Lease during the Renewal Period. If Tenant fails timely to deliver the Tenant's Notice, then this Option to Extend shall automatically expire and be of no further force or effect. If Tenant timely delivers the Tenant's Notice and objects to the Market Rental Rate set forth in the Rental Notice, Landlord and Tenant shall endeavor for a period of 30 days after Landlord's receipt of the Tenant's Notice (the "Negotiation Period") to reach an agreement on the Market Rental Rate for the Renewal Period. If, at the end of the Negotiation Period, Landlord and Tenant are unable to agree on the Market Rental Rate, Landlord shall deliver to Tenant Landlord's proposal for such terms (the "Landlord's Proposal") and Tenant shall deliver to Landlord Tenant's proposal for such terms (the "Tenant's Proposal"). Tenant shall have a period of 10 days after receipt of the Landlord's Proposal (the "Tenant's Decision Period") to elect to (i) accept the terms set forth in Landlord's Proposal by written notice (the "Acceptance Notice") to Landlord, (ii) withdraw its Renewal Notice by written notice to Landlord (the "Withdrawal Notice"), or
(iii) notify Landlord that it has elected to renew the term of this Lease and elected to have the Market Rental Rate determined in accordance with Section (d) below (the "Arbitration Notice"). If Tenant timely delivers its Acceptance Notice (or is deemed to have accepted the Rental Notice, as such deemed acceptance is described below), Landlord and Tenant shall, within 15 days after receipt, execute a lease amendment reasonably satisfactory to Landlord and Tenant confirming the Base Rent and such other non-material terms of the Lease during the Renewal Period. If Tenant delivers a

Withdrawal Notice, then the Option to Extend shall automatically expire and be of no further force or effect. If Tenant fails timely to deliver its Acceptance Notice, Withdrawal Notice or its Arbitration Notice (as applicable), then Tenant shall be deemed to have accepted the terms set forth in the Rental Notice. The Option to Extend shall not be assignable, except to assignees of Tenant in connection with an assignment permitted without Landlord's consent pursuant to Section 12.b of the Lease, and the rights pursuant to the Option to Extend shall extend to such permitted assignees. Furthermore, this Option to Extend shall be voidable at Landlord's election if (a) Tenant fails timely to execute and return the required lease amendment, (b) [intentionally deleted] or (c) Tenant fails to occupy the entire Premises at the commencement of the Renewal Period, subject to instances of casualty, applicable laws to the contrary, and reasonable periods of time required for completion of tenant improvements.

(c) The "Market Rental Rate" is the rate (or rates) a willing tenant would pay and a willing landlord would accept for a comparable transaction (e.g., renewal, expansion, relocation, etc., as applicable, in comparable space and in a comparable building) as of the commencement date of the applicable term, neither being under any compulsion to lease and both having reasonable knowledge of the relevant facts, considering the highest and most profitable use if offered for lease in the open market with a reasonable period of time in which to consummate a transaction. In calculating the Market Rental Rate, all relevant factors will be taken into account, including the location and quality of the Building, lease term, parking charges, amenities of the Property, condition of the space and any concessions and allowances commonly being offered by Landlord for comparable transactions in the Property. The parties agree that the best evidence of the Market Rental Rate will be the rate then charged for comparable transactions in the Property, taking into account the factors mentioned above. Although the determination of Market Rental Rate shall be made at a point in time prior to the commencement date for the Renewal Period, such determination is to be made based on Landlord's reasonable opinion of what the Market Rental Rate should be at the time the rate being determined will go into effect.

(d) If Tenant delivers an Arbitration Notice to Landlord prior to the expiration of Tenant's Decision Period, then the Term of the Lease shall be renewed, and Landlord and Tenant shall proceed to arbitration in accordance with the procedure set forth below. Landlord and Tenant shall commence arbitration proceedings in accordance with the Commercial Arbitration Rules of the American Arbitration Association and Landlord shall submit Landlord's Proposal and Tenant shall submit Tenant's Proposal, together with the supporting data that was used to calculate such proposals, to a panel of 3 qualified independent licensed commercial real estate brokers who (i) are licensed under the laws of the State of Colorado, (ii) have been active over the 5-year period ending on the date of appointment to the panel in the leasing of office buildings in the Boulder, Colorado area, (iii) are recognized as a market expert in office leasing of office buildings, (iv) have not represented either Landlord or Tenant during the preceding 5 years or in connection with the Lease, and (v) have general experience and competence in determining market rates for office space comparable to the Premises, and being familiar with the Commercial Arbitration Rules of the American Arbitration Association (a "Qualified Panel"). The Qualified Panel shall be selected as follows: Tenant shall select 1 panel member, Landlord shall select 1 panel member, and the 2 panel members so selected shall select a third panel member within 10 days after Tenant delivers the Arbitration Notice. If either Landlord or Tenant fails to select its panel member within

such 10-day period, then the panel member selected by the other party shall select the other 2 panel members. Within 20 days after the proposals are submitted, the Qualified Panel shall hold a hearing during which Landlord and Tenant may present evidence in support of their respective proposals. Within 3 days after the date of the hearing, the Qualified Panel will determine the Market Rental Rate provided the Qualified Panel may select only Landlord's Proposal or Tenant's Proposal (and no other amount) as the Market Rental Rate, which proposal so selected shall be the Market Rental Rate for the applicable Renewal Period. The Qualified Panel's determination shall be binding on Landlord and Tenant and may be enforced by a court of competent jurisdiction. The cost of such arbitration shall be paid by the party whose proposal was not selected. Within 15 days after the Qualified Panel's determination of the Market Rental Rate, Landlord and Tenant shall execute a mutually acceptable amendment to the Lease specifying that the Lease has been extended at a rate equal to the determined Market Rental Rate. If the foregoing arbitration process is not completed prior to the commencement of the applicable Renewal Period, Tenant shall continue to pay Base Rent and parking charges at the rates in effect prior to such Renewal Period until such time as the arbitration process is complete, at which time Tenant will pay Landlord, or Landlord will pay Tenant, the amounts necessary to adjust the payments made prior to such date to be equal to the Market Rental Rate determined by such arbitration process.

(e) After exercise of the Option to Extend for the second Renewal Period or failure to exercise the Option to Extend for a Renewal Period, the Option to Extend shall terminate and be of no further force and effect.

5. At any time after January 1, 2023, Landlord, upon 150 days' written notice (the "Trigger Notice") to Tenant, may relocate the Premises to any other comparably sized premises within a building owned by Landlord or its affiliate in the Flatiron Business Park, Boulder, Colorado ("Relocated Premises") on a date of relocation (the "Relocation Date") specified therein. The Relocated Premises shall in all respects be substantially the same or better than the Premises, as reasonably determined by Landlord and Tenant, in area, finish, and appropriateness for the Permitted Use. In such event, all reasonable expenses of moving Tenant and decorating the Relocated Premises with substantially the same leasehold improvements shall be at the expense of Landlord, including the physical move, relocating Tenant's existing telephone equipment and other costs set forth below. All moving costs (including the cost to relocate phones, computers and other systems of similar nature), all costs of reprinting stationery, cards and other printed material bearing Tenant's address at the Premises if such address changes due to the relocation (but only the quantity existing immediately prior to the relocation) and all other out-of- pocket costs directly incurred by Tenant in connection with relocation to the Relocated Premises, including, without limitation, reasonable decorating and design costs, shall be paid by Landlord within 30 days after receipt of third-party invoices therefor. Tenant shall, within 30 days following the date of the Trigger Notice, enter into an appropriate amendment to the Lease reflecting relocation of the Premises to the Relocated Premises. Landlord shall have the option to tender the Relocated Premises to Tenant on any date within a 30-day period after the Relocation Date, in which event the date of tender of possession of the Relocated Premises shall become the Relocation Date. From the Relocation Date through the Expiration Date, the aggregate Rent for the Relocated Premises shall be the same as for the original Premises. Tenant's failure to vacate the Premises and move into the Relocated Premises on or before five
(5) business days after the Relocation Date shall constitute a default under the Lease without the need for additional notice or cure periods.

6. Section 32.b of the Base Lease is hereby deleted in its entirety and replaced with the following in lieu thereof:

Provided this Lease is then in full force and effect and Tenant is not then in default beyond all applicable notice and cure periods under this Lease, Tenant shall have the right of first refusal as hereinafter described to lease that portion of the space to be leased to a prospective tenant (the "Offered Space") which is all or part of the space (the "Right of First Refusal Space") located on the same floor as the Premises and contiguous to the Premises at such time as Landlord engages in negotiations with a prospective tenant, exercisable at the following times and upon the following conditions:

(a) If Landlord enters into negotiations with a prospective tenant to lease the Offered Space, Landlord shall notify Tenant of such fact and shall include in such notice the rent, term, and other terms (including, but not limited to, finish out, moving allowances and design fees) at which Landlord is prepared to offer such Offered Space to such prospective tenant. Tenant shall have a period of five (5) Business Days from the date of delivery of the notice to notify Landlord whether Tenant elects to exercise the right granted hereby to lease the Offered Space. If Tenant fails to give any notice to Landlord within the required five (5) business day period, Tenant shall be deemed to have waived its right to lease the Offered Space.

(b) If Tenant so waives its right to lease the Offered Space (either by giving written notice thereof or by failing to give any notice), Landlord shall have the right to lease the Offered Space to the prospective tenant and upon the execution of such lease between Landlord and the prospective tenant this Right of First Refusal as to the Offered Space shall thereafter be null, void and of no further force or effect.

(c) If Landlord does not enter into a lease with such prospective tenant covering the Offered Space, Landlord shall not thereafter engage in other lease negotiations with respect to the Right of First Refusal Space without first complying with the provisions of this paragraph.

(d) Upon the exercise by Tenant of its right of first refusal as provided in this Section 6, Landlord and Tenant shall, within fifteen (15) days after Tenant delivers to Landlord notice of its election, enter into an amendment to the Lease incorporating the Offered Space into the Premises for the rent, for the term, and containing such other terms and conditions as Landlord notified Tenant pursuant to Section 6(a) above.

(e) The right of first refusal of Tenant contained herein shall not be assignable, except to assignees of Tenant in connection with an assignment permitted without Landlord's consent pursuant to Section 12.b of the Lease, and the rights pursuant to such right of first refusal shall extend to such permitted assignees.

(f) The right of first refusal of Tenant contained herein shall be subject and subordinate to any rights of renewal, expansion or extension existing under any other tenant leases for the Building as of the date of the Fourth Amendment to Lease between Landlord and Tenant.

7. From and after the date hereof, subsections e. and f. of Section 32 of the Base Lease are hereby deleted in their entirety.

8. Landlord and Tenant each hereby represents and warrants to the other that it has not engaged any broker in connection with the negotiation and/or execution of this Amendment, other than

Chad Henry with WWR Real Estate Services, LLC ("Tenant's Agent"), who has acted as Tenant's agent, and Crescent Real Estate, LLC ("Landlord's Agent"), who has acted as Landlord's agent. Landlord and Tenant have no knowledge of any other broker's involvement in this transaction. Tenant will indemnify Landlord and Landlord's Agent, and Landlord will indemnify Tenant and Tenant's Agent, against any claim or expense (including, without limitation, attorneys' fees) paid or incurred by the other party (or Landlord's Agent, or Tenant's Agent, as appropriate) as a result of any claim for commissions or fees by any broker, finder, or agent, whether or not meritorious, employed by the indemnifying party or claiming by, through or under the indemnifying party, other than Tenant's Agent or Landlord's Agent, as appropriate.

9. If there is any conflict between the terms of this Amendment and the terms of the Lease, the terms of this Amendment govern. The Lease as hereby amended is in full force and effect, is hereby ratified and affirmed by the parties, and is binding upon the parties in accordance with its terms.

10. Time is of the essence herein.

11. This Amendment and the balance of the Lease shall be construed consistent with the laws of the State of Colorado without regard to its conflicts of laws principles. Any dispute resulting in litigation shall be resolved in court proceedings instituted in Boulder County and in no other jurisdiction. Landlord and Tenant hereby accept jurisdiction of such courts and waive any defense of improper venue, jurisdiction or forum *non conveniens* and irrevocably agree to be bound by any judgment rendered thereby in connection with the Lease, as amended hereby.

12. In the event any action is commenced to enforce the terms of this Amendment or the balance of the Lease, the prevailing party in any such action shall be awarded its costs and expenses, including reasonable attorneys' fees through all appeals, in addition to any other remedy awarded in such action.

13. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original with the same effect as if the signatures thereto and hereto were upon the same instrument. Facsimile and electronic signatures shall have the same force and effect as original signatures.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the day and year first above written and it is effective upon delivery of a fully executed copy to Tenant.

BRICKELL BIOTECH, INC., a Delaware corporation

By: /s/ Andrew Sklawer
Print Name: Andrew Sklawer
Print Title: COO

"Tenant"

GPIF 5777 FLATIRON LLC, a Delaware limited liability company

By: /s/ Ben Molk
Print Name: Ben Molk
Print Title: Vice President

"Landlord"

**CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED**

# BRICKELL-KAKEN
# AMENDMENT TO CLINICAL SUPPLY AGREEMENT AND LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Amendment to the Clinical Supply Agreement and License, Development, and Commercialization Agreement ("**Amendment**") is entered into between Brickell Biotech, Inc. ("**Brickell**") and Kaken Pharmaceutical Co., Ltd ("**Kaken**") as of this 14th day of May, 2021 ("**Effective Date**") and amends both (i) the Clinical Supply Agreement entered into between Brickell and Kaken dated July 30, 2019, as amended by the Letter Agreement for Supply of [***] of API dated June 8, 2020 ("**First API Payment Letter Agreement**") and the Letter Agreement – Payment for [***] of API dated December 8, 2020 ("**Second API Payment Letter Agreement**") (collectively, "**Clinical SA**") and (ii) the License, Development and Commercialization Agreement entered into between Brickell and Kaken as of March 31, 2015, as amended ("**LDCA**"). For purposes of this Amendment, Kaken and Brickell shall collectively be referred to as the "**Parties**".

**Section 1. Amendment to Clinical SA**

The Clinical SA shall be amended as set forth in Section 1 of this Amendment:

A. [***] Quantity of API

(1) Kaken will make available to Brickell [***] (Lot #[***]) of the remaining [***] of Drug Substance (as such term is defined in the Clinical SA) that Kaken previously manufactured for Brickell pursuant to the Clinical SA and for which Brickell has not yet paid for ("**[***] Quantity**"), and do so [***] Kaken's [***] facility (Incoterms® 2020) on or before [***] according to the additional terms described in Section 1 of this Amendment.

(2) On or before [***] Business Days (as the term "**Business Day**" is defined in the Clinical SA) after the date Brickell notifies Kaken in writing to prepare the [***] Quantity for pick-up by Brickell's designated carrier at Kaken's [***] facility ("**Brickell's Pick-up Notice**"), Brickell shall pay Kaken [***] ("**[***] Price**") by wire transfer to such bank account in Japan as specified by Kaken and without set-off, deduction or withholding for any purpose whatsoever unless required by applicable law.

(3) After Kaken confirms its receipt of the [***] Price in full, Kaken shall notify Brickell in writing and promptly make available the [***] Quantity to such carrier as set forth in Brickell's Pick-up Notice.

(4) Additionally, Brickell will pay Kaken via wire transfer to the same bank account as specified above by Kaken, and without set-off, deduction or withholding for any purpose whatsoever unless required by applicable law, the accrued interest expense with

respect to the unpaid Price (as such term is defined in the Clinical SA) for the [***] Quantity through the date that Kaken confirms receipt in full of the [***] Price. Brickell shall remit payment for such accrued interest expense within [***] Business Days of receiving an invoice from Kaken for that interest amount. Storage charges for the remaining Drug Substance from the [***] of Drug Substance shall continue to accrue at the rate set forth in the First API Payment Letter Agreement through [***] after Brickell's carrier takes delivery of [***] of Drug Substance manufactured by Kaken for Brickell pursuant to the Clinical SA.

B. Drug Substance Quantity Required for Process Validation

(1) Brickell shall purchase from Kaken [***] of Drug Substance (consisting of [***] of Drug Substance each from Lot #s [***]) that Brickell will use to manufacture Product for process validation ("**PV Quantity**") and for which Brickell shall pay Kaken [***] ("**PV Price**") no later than [***] by means of wire transfer to such bank account as specified by Kaken per above and without set-off, deduction or withholding for any purpose whatsoever. Kaken shall issue an invoice to Brickell for the PV Price by [***] for this purpose.

(2) After Kaken confirms its receipt of the PV Price in full, Kaken shall notify Brickell in writing and deliver the PV Quantity per [***] Kaken's [***] facility (Incoterms® 2020) between [***] by making the PV Quantity available to Brickell's designated carrier within [***] Business Days after receiving notice from Brickell that its carrier is ready and able to receive the PV Quantity in this time period.

(3) Kaken shall make available the PV Quantity to Brickell as set forth in Section 1(B)(1) of this Amendment; provided, however, that Kaken shall have no obligation to deliver the PV Quantity to Brickell if Brickell does not pay Kaken in full all amounts that Brickell owes Kaken pursuant to the Clinical SA, including the [***] Price and the PV Price ("**Clinical SA Balance**") by [***].

C. Additional Kaken Rights

(1) In addition to Kaken's other rights and remedies set forth in the Clinical SA (which for the avoidance of doubt apply with respect to the [***] Quantity and the PV Quantity) if: (a) Brickell fails to pay Kaken in full for the Clinical SA Balance by [***] then Kaken shall have the right commencing at midnight on [***] JST to take sole title to, interest in and possession of the PV Quantity and use the PV Quantity for its own purposes or (b) Brickell's carrier fails to pick up the PV Quantity and the remaining Drug Substance from the [***] of Drug Substance by [***], then Kaken shall have the right commencing at midnight on [***] JST to take sole title to, interest in and possession of the PV Quantity and use the PV Quantity for its own purposes, and in the case of both (a) and (b) above, without changing Brickell's obligation to pay Kaken for the full Clinical SA Balance, including the PV Price.

(2) Without limiting its rights set forth in the Clinical SA as further amended by this Amendment, Kaken shall continue to have the right to offset all amounts that Kaken owes Brickell pursuant to the LDCA against the Clinical SA Balance, including the PV Price, until all amounts that Brickell owes Kaken under the Clinical SA are fully paid, provided that Kaken will not reduce the amount of any royalty payment that would otherwise be due to Brickell under the LDCA by more than [***] so that Brickell would be able to pay Bodor Laboratories, Inc. ("**Bodor**") sublicense royalties that Brickell will owe to Bodor pursuant to the Amended and Restated License Agreement entered into between Brickell and Bodor dated February 17, 2020.

(3) Except as set forth in Section 1 of this Amendment, the terms of the Clinical SA shall remain in full force and effect.

**Section 2. Amendment to LDCA** – The LDCA shall be amended as follows:

The language in Section 7.2 of the LDCA that reads:

"As soon as practicable, but, in any event, promptly after execution of the Phase III Clinical Supply Agreement, the Parties shall enter into good faith negotiations regarding [***]. If, despite [***], the Parties are unable to execute [***] within [***] of the Effective Date…"

shall be revised to read:

"As soon as practicable, but, in any event, no later than [***] after [***], the Parties shall enter into good faith negotiations regarding [***]. If, despite [***], the Parties are unable to execute [***] within such [***] period…."

Except as set forth in Section 2 of this Amendment the terms of the LDCA shall remain in full force and effect.

This Amendment shall be effective and legally binding on the Parties as of the Effective Date.

Kaken Pharmaceutical Co., Ltd.

/s/ [***]
Name: [***]
Title: [***]
Date: 5/24/2021

Brickell Biotech, Inc.

/s/ Andrew Sklawer
Name: Andrew Sklawer
Title: COO
Date: 5/14/2021

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a)**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Robert. B. Brown, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Brickell Biotech, Inc., a Delaware corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2021

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

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR RULE 15d-14(a)**
**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Albert N. Marchio, II, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Brickell Biotech, Inc., a Delaware corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2021

By: /s/ Albert N. Marchio, II
Albert N. Marchio, II
Chief Financial Officer
(Principal Financial Officer)

**Exhibit 32.1**

**SECTION 1350 CERTIFICATION**

Each of the undersigned, Robert. B. Brown, Chief Executive Officer of Brickell Biotech, Inc., a Delaware corporation (the "Company"), and Albert N. Marchio, II, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Robert. B. Brown

Robert B. Brown
Chief Executive Officer
(Principal Executive Officer)
Date: August 12, 2021

/s/ Albert N. Marchio, II

Albert N. Marchio, II
Chief Financial Officer
(Principal Financial Officer)
Date: August 12, 2021

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