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, 2020

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 August 12, 2020, there were 27,787,081 shares of the registrant's common stock outstanding.

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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, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 21,570	$ 7,232
Marketable securities, available-for-sale	—	4,497
Prepaid expenses and other current assets	5,736	6,240
Total current assets	27,306	17,969
Property and equipment, net	10	16
Operating lease right-of-use asset	114	159
Total assets	$ 27,430	$ 18,144
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 566	$ 2,245
Accrued liabilities	6,261	6,379
Lease liability, current portion	83	78
Deferred revenue	142	1,795
Note payable, current portion	194	—
Total current liabilities	7,246	10,497
Lease liability, net of current portion	31	73
Note payable, net of current portion	243	—
Total liabilities	7,520	10,570
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.01 par value, 50,000,000 shares authorized at June 30, 2020 and December 31, 2019; 26,671,573 and 8,480,968 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	267	85
Additional paid-in capital	113,845	92,497
Accumulated other comprehensive gain	—	(28)
Accumulated deficit	(94,202)	(84,980)
Total stockholders' equity	19,910	7,574
Total liabilities and stockholders' equity	$ 27,430	$ 18,144

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,	
	2020	2019	2020	2019
Collaboration revenue	$ 607	$ 2,573	$ 1,653	$ 6,065
Operating expenses:				
Research and development	2,712	4,229	5,376	10,248
General and administrative	3,021	1,323	5,502	3,389
Total operating expenses	5,733	5,552	10,878	13,637
Loss from operations	(5,126)	(2,979)	(9,225)	(7,572)
Investment and other income, net	7	4	3	10
Interest expense	—	(660)	—	(884)
Change in fair value of derivative liability	—	(11)	—	(11)
Change in fair value of warrant liability	—	(8)	—	223
Net loss	(5,119)	(3,654)	(9,222)	(8,234)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	—	(163)	—	10,356
Net income (loss) attributable to common stockholders	$ (5,119)	$ (3,817)	$ (9,222)	$ 2,122
Net income (loss) per common share attributable to common stockholders, basic	$ (0.43)	$ (6.48)	$ (0.87)	$ 3.60
Net loss per common share attributable to common stockholders, diluted	$ (0.43)	$ (6.48)	$ (0.87)	$ (4.46)
Weighted-average shares used to compute net income (loss) per share attributable to common stockholders, basic	11,819,152	589,001	10,595,960	589,001
Weighted-average shares used to compute net loss per share attributable to common stockholders, diluted	11,819,152	589,001	10,595,960	1,845,467

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,	
	2020	2019	2020	2019
Net loss	$ (5,119)	$ (3,654)	$ (9,222)	$ (8,234)
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	$ (5,119)	$ (3,654)	$ (9,194)	$ (8,234)

See accompanying notes to these condensed consolidated financial statements.

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

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In-Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Carrying Value	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 issuance 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

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In-Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Carrying Value	Shares	Par Value				
Balance, December 31, 2018	1,256,466	$ 58,290	589,001	$ 6	$ —	$ —	$ (71,624)	$ (71,618)
Reduction of redeemable convertible preferred stock to redemption value	—	(10,519)	—	—	—	—	10,519	10,519
Stock-based compensation	—	—	—	—	384	—	—	384
Net loss	—	—	—	—	—	—	(4,580)	(4,580)
Balance, March 31, 2019	1,256,466	47,771	589,001	6	384	—	(65,685)	(65,295)
Stock based compensation	—	—	—	—	299	—	—	299
Accretion of redeemable convertible preferred stock to redemption value	—	163	—	—	(163)	—	—	(163)
Net loss	—	—	—	—	—	—	(3,654)	(3,654)
Balance, June 30, 2019	1,256,466	$ 47,934	589,001	$ 6	$ 520	$ —	$ (69,339)	$ (68,813)

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,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,222)	$ (8,234)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	6	21
Accretion of discount on marketable securities	25	—
Change in fair value of derivative liability	—	11
Change in fair value of warrant liability	—	(223)
Amortization of discounts and financing costs	—	551
Stock-based compensation	856	683
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	512	(165)
Accounts payable	(1,679)	3,053
Accrued liabilities	(135)	865
Deferred revenue	(1,653)	(6,064)
Net cash used in operating activities	(11,290)	(9,502)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturities of marketable securities	4,500	—
Capital expenditures	—	(4)
Net cash provided by (used in) investing activities	4,500	(4)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock and warrants, net of issuance costs	20,669	—
Proceeds from the issuance of note payable	437	—
Proceeds from the exercise of warrants	22	—
Proceeds from issuance of convertible promissory notes	—	5,127
Payments of principal of note payable	—	(1,609)
Net cash provided by financing activities	21,128	3,518
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	14,338	(5,988)
CASH AND CASH EQUIVALENTS—BEGINNING	7,232	8,067
CASH AND CASH EQUIVALENTS—ENDING	$ 21,570	$ 2,079
Supplement Disclosure of Cash Flow Information:		
Interest paid	$ —	$ 234
Supplement Disclosure of Non-Cash Investing and Financing Activities:		
Reduction of redeemable convertible preferred stock to redemption value	$ —	$ (10,376)
Warrants to purchase common stock issued with convertible promissory notes	$ —	$ 1,029
Derivative liability issued with convertible promissory notes	$ —	$ 996
Deferred financing costs included in accrued liabilities	$ —	$ 154
Accretion of redeemable convertible preferred stock issuance costs	$ —	$ 20

See accompanying notes to these condensed consolidated financial statements.

NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

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

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

The accompanying condensed consolidated financial statements and related notes reflect the historical results of Private Brickell prior to the Merger and of the combined company following the Merger, and do not include the historical results of Vical prior to the completion of the Merger. These financial statements and related notes should be read in conjunction with the audited financial statements for the year ended December 31, 2019, included in the Company's Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 18, 2020.

Liquidity and Capital Resources

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. The Company has incurred significant operating losses and has an accumulated deficit as a result of ongoing efforts to develop product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the six months ended June 30, 2020, the Company had a net loss of $9.2 million and net cash used in operating activities of $11.3 million. As of June 30, 2020, the Company had cash and cash equivalents of $21.6 million and an accumulated deficit of $94.2 million.

The Company believes that its cash and cash equivalents as of June 30, 2020 and periodic sales of the Company's common stock under the Purchase Agreement (see Note 7. "Capital Stock"), are sufficient to fund its operations for at least the next 12 months from the issuance of these condensed consolidated financial statements. However, in order to sell additional shares of common stock under the Purchase Agreement, Lincoln Park Capital Fund, LLC ("Lincoln Park") will need to purchase shares of common stock from the Company, subject to the conditions under the Purchase Agreement. Further, the Company will be significantly limited in its ability to sell shares of its common stock under the Purchase Agreement, or to utilize its common stock in any other capital raising transaction, if the Company's stockholders do not approve an increase in the number of authorized shares of common stock of the Company, as further described in Note 7. "Capital Stock" and in Note 9. "Subsequent Events." 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 proceed with the Company's current and proposed research activities, including completing both pivotal U.S. Phase 3 clinical trials of sofpironium bromide.

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 U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("US 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 US 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, 2020 are not necessarily indicative of the results to be expected for the full year ending December 31, 2020, for any other interim period, or for any other future period. The condensed consolidated balance sheet as of December 31, 2019 has been derived from audited financial statements at that date but does not include all of the information required by US 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 US GAAP, which requires it to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Although these estimates are based on the Company's knowledge of current events and actions it may take in the future, actual results may ultimately differ from these estimates and assumptions.

Risks and Uncertainties

The Company's business is subject to significant risks common to early-stage companies in the pharmaceutical industry including, but not limited to, the ability to develop appropriate formulations, scale up and 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 alliance management; and obtaining additional financing to fund the Company's efforts.

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

The Company expects to incur substantial operating losses for the next several years and will need to obtain additional financing in order to complete clinical studies and launch and commercialize any product candidates for which it receives regulatory approval. There can be no assurance that such financing will be available or will be at terms acceptable 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 is established to distinguish between (1) inputs that reflect the assumptions market participants would use in pricing an asset or liability developed based on market data obtained from sources independent of the reporting entity (observable inputs) and (2) inputs that reflect the reporting entity's own assumptions about the

assumptions market participants would use in pricing an asset or liability developed based on the best information available in the circumstances (unobservable inputs), and establishes a classification of fair value measurements for disclosure purposes.

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

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

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

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

The following 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, 2020	December 31, 2019
Assets:		
Money market funds	$ 21,570	$ 7,232
U.S. treasuries	—	4,497
Total	$ 21,570	$ 11,729

(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).

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

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

Leases

The Company accounts for leases under the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, Leases ("ASC 842"). Under ASC 842, the Company determines if an arrangement is a lease at inception. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected the practical expedient not to recognize on the balance

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

Revenue Recognition

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

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

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

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

Under Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("Topic 606"), the Company evaluated the terms of the Kaken Agreement, and the transfer of intellectual property and manufacturing rights (the "license") was identified as the only performance obligation as of the inception of the agreement. The Company concluded that the license for the intellectual property was distinct from its ongoing supply obligations. The Company further determined that the transaction price under the arrangement was comprised of the $11.0 million upfront payment, which was allocated to the license performance obligation. The future potential milestone amounts were not included in the transaction price, as they were all determined to be fully constrained. As part of its evaluation of the development and regulatory milestones constraint, the Company determined that the achievement of such milestones is contingent upon success in future clinical trials and regulatory approvals, each of which is uncertain at this time. The Company will re-evaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur. Future potential milestone amounts would be recognized as revenue from collaboration arrangements, if unconstrained. The remainder of the

arrangement, which largely consisted of both parties incurring costs in their respective territories, provides for the reimbursement of the ongoing supply costs. These costs were representative of a collaboration arrangement outside of the scope of Topic 606 as they do not have the characteristics of a vendor and customer relationship. Reimbursable program costs are recognized proportionately with the delivery of drug substance and are accounted for as reductions to research and development expense and are excluded from the transaction price.

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. These clinical trials have a benefit to Kaken and have the characteristics of a vendor and customer relationship. The Company has accounted for the Kaken R&D Payment under the provisions of Topic 606. This Kaken R&D Payment is being initially recognized using an input method over the average estimated performance period of 1.45 years in proportion to the cost incurred. Upon receipt of the Kaken R&D Payment, on May 31, 2018, a milestone payment originally due upon the first commercial sale in Japan was removed from the Kaken Agreement and all future royalties to the Company under the Kaken Agreement were reduced 150 basis points.

Consequently, during the three months ended June 30, 2020 and 2019, the Company recognized revenue of $0.6 million and $2.6 million, respectively, related to the Kaken R&D Payment. During the six months ended June 30, 2020 and 2019, the Company recognized revenue of $1.7 million and $6.1 million, respectively, related to the Kaken R&D Payment. As of June 30, 2020 and December 31, 2019, the Company had a deferred revenue balance related to the Kaken R&D Payment of $0.1 million and $1.8 million, respectively, which is recorded in deferred revenue on the accompanying condensed consolidated balance sheets.

Milestones

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

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). To date, the Company has not recognized any royalty revenue from any collaborative arrangement.

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 income (loss) per common share, because their inclusion would be anti-dilutive:

	Three and Six Months Ended June 30,	
	2020	2019
Outstanding warrants	19,556,108	349,074
Outstanding options	1,578,231	625,428
Unvested restricted stock units	253,045	—
Redeemable convertible preferred stock (as converted into common stock)	—	1,256,466
Promissory notes (as converted into common stock)	—	168,832
Total	21,387,384	2,399,800

Recent Accounting Pronouncements – Adopted

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"), which amends certain disclosure requirements over Level 1, Level 2, and Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. The Company adopted ASU 2018-13 during the three months ended March 31, 2020, however, the effect of adoption did not have a material impact on its disclosures.

NOTE 3. ACCRUED LIABILITIES

Accrued liabilities consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Accrued contracted research and development services	$ 4,443	$ 4,532
Accrued license fee	1,000	—
Accrued professional fees	365	1,788
Accrued compensation	453	59
Total	$ 6,261	$ 6,379

NOTE 4. CONVERTIBLE PROMISSORY NOTES

In March 2019, the Company initiated a convertible promissory notes offering pursuant to which the Company issued unsecured convertible promissory notes (the "Prom Notes"), bearing interest at 12.00% with a maturity of one year. Through August 31, 2019, the Company had raised an aggregate principal amount of $7.4 million in Prom Notes, including $1.7 million from certain of the Company's management and board of directors. On August 31, 2019, immediately prior to the Merger, the Prom Notes and related accrued interest converted into 1,069,740 shares of Private Brickell common stock at a conversion price of $7.54 per share (the "Conversion").

The Prom Notes also provided for the issuance of warrants at 50% coverage, to acquire 490,683 shares of common stock. The warrants are exercisable for a term of five years at an exercise price of $10.36. The Company evaluated the various financial instruments under ASC 480, "Distinguishing Liabilities from Equity," and ASC 815, "Derivatives and Hedging" ("ASC 815"), and determined the warrants required fair value accounting. The fair value of the warrants was recorded as a warrant liability upon issuance. The fair value of the warrants on the dates of issuance of $1.5 million was determined with the assistance of a third-party valuation firm. The fair value of the warrants was recorded as a debt discount upon issuance and was amortized to interest expense over the term of the Prom Notes based on the effective interest method.

At inception of the Prom Notes offering, the Company analyzed the conversion feature of the agreement for derivative accounting consideration under ASC 815 and determined that the embedded conversion features should be classified as a derivative, which was required to be bifurcated and recorded as a derivative liability.

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

During the three and six months ended June 30, 2019, the Company recognized $0.5 million of interest expense, including $0.4 million of accretion of discounts using an effective interest rate of 12.00%. During the three and six months ended June 30, 2020, no interest expense was recognized.

NOTE 5. NOTES PAYABLE

Loan Agreement with Hercules Capital, Inc.

On February 18, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. (the "Lender") under which the Company borrowed $7.5 million upon the execution of the Loan Agreement on February 18, 2016. The interest rate applicable to each tranche was variable based upon the greater of either (i) 9.2% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal minus 3.5%, plus (b) 9.2%. Payments under the Loan Agreement were interest only until June 1, 2017, followed by equal monthly payments of principal and interest through the maturity date of September 1, 2019. The Company paid the Lender aggregate facility fees of $0.2 million in connection with the Loan Agreement.

In connection with the Loan Agreement, the Company issued warrants to the Lender, which are exercisable for 9,005 shares of common stock at a per share exercise price of $33.31 (the "Hercules Capital Warrants"). The Hercules Capital Warrants will terminate, if not earlier exercised, on February 18, 2026. The fair value of the Hercules Capital Warrants was recorded at inception as a redeemable convertible preferred stock warrant liability upon issuance.

On September 3, 2019, the Company repaid the remaining outstanding loan balance of $2.6 million and an associated accrued interest and aggregate end-of-term payment of $0.6 million, and the Loan Agreement was terminated. At the effective time of the Merger, the warrant liability was reclassified to equity in the condensed consolidated balance sheets. As of June 30, 2020, there were no remaining unaccreted debt discounts and issuance costs.

Paycheck Protection Program

On April 15, 2020, the Company executed an unsecured promissory note (referred to in the condensed consolidated financial statements as of and for the six months ended June 30, 2020 as a "note payable") 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 federal Coronavirus Aid, Relief, and Economic Security ("CARES") Act. A PPP loan is for the purpose of helping businesses keep their workforce employed during the Coronavirus (COVID-19) crisis. The Company is using the PPP Loan proceeds for covered payroll costs and certain other permitted costs in accordance with the relevant terms and conditions of the CARES Act.

The PPP Loan is in the principal amount of $0.4 million, bears interest at a fixed rate of 1.00% per annum and matures on April 15, 2022. The PPP Loan requires equal monthly payments of principal and interest commencing on November 15, 2020. The PPP Loan may be prepaid by the Company at any time prior to maturity without penalty. Under the terms of the PPP Loan, the Company is evaluating whether it may apply for forgiveness of the amount due on the PPP Loan.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Operating Leases

In August 2016, the Company entered into a five-year lease for office space in Boulder, Colorado that expires on October 31, 2021 (the "Boulder Lease") subject to the Company's option to renew the Boulder Lease for two additional terms of three years each. Pursuant to the Boulder Lease, the Company leased 3,038 square feet of space in a multi-suite building. Rent payments under the Boulder Lease included base rent of $4,430 per month during the first year of the Boulder Lease with an annual increase of 3.5%, and additional monthly fees to cover the Company's share of certain facility expenses, including utilities, property taxes, insurance, and maintenance, which were $2,160 per month during the first year of the Boulder Lease.

The Company recognized a right-of-use asset and corresponding lease liability on January 1, 2019, by calculating the present value of lease payments, discounted at 12.0%, the Company's estimated incremental borrowing rate, over the 2.8 years expected remaining term. As the Company's lease does not provide an implicit rate, the Company estimated the incremental borrowing rate based on industry peers. Industry peers consist of several public companies in the biotechnology industry with comparable characteristics, including clinical trials progress and therapeutic indications. Amortization of the operating lease right-of-use asset for the Boulder Lease amounted to $19 thousand and $37 thousand for the three and six months ended June 30, 2020, respectively, which was included in operating expense. As of June 30, 2020, the remaining lease term was 1.3 years.

The terms of the Boulder Lease provide for rental payments on a monthly basis on a graduated scale. Lease expense for the three months ended June 30, 2020 and 2019 was $38 thousand and $32 thousand, respectively. Lease expense for the six months ended June 30, 2020 and 2019 was $41 thousand and $60 thousand, respectively.

The following is a summary of the contractual obligations related to operating lease commitments as of June 30, 2020 and the effect such obligations are expected to have on the Company's liquidity and cash flows in future periods (in thousands):

Less than 1 year	$	93
1-3 years		31
3-5 years		—
More than 5 years		—
Imputed interest		(10)
Total	$	114

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. In exchange for entering into the Amended and Restated License Agreement, settling the previously disclosed dispute, and resolving the associated litigation between the Company and Bodor, the Company made an upfront payment of $1.0 million in cash to Bodor following the execution of the Amended and Restated License Agreement and the settlement agreement by and among the Company, Brickell Subsidiary, Inc., and Bodor, dated February 17, 2020. Additionally, under the original License Agreement and the Amended and Restated License Agreement, the Company is required to pay Bodor (i) a royalty on sales of product outside Kaken's territory, including a low single-digit royalty on sales of certain product not covered by the patent estate licensed from Bodor; (ii) a specified percentage of all royalties 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 $1.8 million (plus an additional $0.1 million for approvals of additional products) in cash

payments and $1.5 million of shares of the Company's common stock upon the achievement of certain development, regulatory and other milestones, including the enrollment of the first patient in the U.S. Phase 3 trials. During the three months ended June 30, 2020, based on the foregoing, the Company made a $0.5 million milestone payment to Bodor following the closing of the public offering in June 2020 and accrued an additional $1.0 million related to 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 months ended June 30, 2020.

NOTE 7. CAPITAL STOCK

Common Stock

Each share of the Company's common stock is entitled to one vote, and the holders of the Company's common stock are entitled to receive dividends when and as declared or paid by its board of directors. The Company has reserved authorized shares of common stock for future issuance at June 30, 2020 as follows:

	June 30, 2020
Shares available for grant under the Omnibus Plan	—
Common stock warrants	20,669,533
Common stock options outstanding	1,578,231
Unvested restricted stock units	253,045
Total	22,500,809

While 694,162 shares of common stock remained available for grant under the 2020 Omnibus Long-Term Incentive Plan (the "Omnibus Plan") as of June 30, 2020, the Company's board of directors, in connection with the public offering in June 2020 described below, utilized shares that were previously reserved for issuance under the Omnibus Plan and not subject to outstanding awards, to instead be reserved for issuance under the warrants issued in the June 2020 offering. As a result, the number of shares reserved for issuance as of June 30, 2020 under the Omnibus Plan was zero.

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

Public Offering of Common Stock and Warrants

In June 2020, the Company entered into an underwriting agreement with Oppenheimer & Co. Inc. ("Oppenheimer"), as representative of several underwriters, relating to the public offering, issuance and sale of 14,790,133 shares of 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 "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 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 pre-funded warrants were immediately exercisable at a 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 expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The Offering resulted in approximately $18.7 million of net proceeds to the Company after deducting underwriting commissions and discounts and other offering expenses of $1.4 million and excluding the proceeds, if any, from the exercise of the warrants. The Company anticipates using the net proceeds from the Offering for research and development, including clinical trials, working capital, and general corporate purposes.

Certain officers of the Company participated in the Offering by purchasing an aggregate purchase price of $0.2 million of the Company's common stock and warrants.

At Market Issuance Sales Agreement

On April 14, 2020, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with Oppenheimer & Co. Inc. as the Company's sales agent (the "Agent"). Pursuant to the terms of the ATM Agreement, the Company may sell from time to time through the Agent shares of the Company's common stock having an aggregate offering price of up to $8.0 million (the "Shares"). Any Shares will be issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the Shares, if any, will be made by means of ordinary brokers' transactions on the Nasdaq Capital Market at market prices or as otherwise agreed by the Company and the Agent. Under the terms of the ATM Agreement, the Company may also sell the Shares from time to time to the Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the Shares to the Agent as principal would be pursuant to the terms of a separate placement notice between the Company and the Agent. As of June 30, 2020, the Company had not yet sold any Shares under the ATM Agreement.

Private Placement Offerings

On February 17, 2020, the Company and Lincoln Park entered into (i) a securities purchase agreement (the "Securities Purchase Agreement"); (ii) a purchase agreement (the "Purchase Agreement"); and (iii) a registration rights agreement (the "Registration Rights Agreement"). Pursuant to the Securities Purchase Agreement, Lincoln Park 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. Sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on the date the conditions set forth in the Purchase Agreement are satisfied (such date on which all of such conditions are satisfied, the "Commencement Date").

Following the Commencement Date, under the Purchase Agreement, on any business day 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 off of prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, the Company may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of common stock. As of June 30, 2020, the Company has not made any sales of its common stock 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

As of June 30, 2020, 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. Under the Company's restated certificate of incorporation, the Company's board of directors has the authority to issue up to 5,000,000 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.

NOTE 8. STOCK-BASED COMPENSATION

Equity Incentive Plans

2020 Omnibus Plan

On April 20, 2020, the Company's stockholders approved 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. The number of shares authorized for issuance under the Omnibus Plan includes 625,000 new shares and 54,389 shares that remained available for future grants pursuant to the Prior Plans, plus any shares that are forfeited pursuant to outstanding grants under the Prior Plans that would have again become available for grants pursuant to the terms of those plans. 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.

At June 30, 2020, 92,436 shares were subject to outstanding awards under the Omnibus Plan, and while 694,162 shares remained available for grant under the Omnibus Plan, those shares were no longer reserved for issuance, as described above in Note 7. "Capital Stock."

2009 Equity Incentive Plan

The 2009 Plan was replaced by the Omnibus Plan on April 20, 2020 and, as a result, at June 30, 2020, there were no remaining shares available for new grants under the 2009 Plan. However, at June 30, 2020, 1,351,974 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, the Company adopted the Vical Plan, which was replaced by the Omnibus Plan on April 20, 2020. As a result, at June 30, 2020, there were no remaining shares available for new grants under the Vical Plan. However, at June 30, 2020, 386,866 shares were subject to outstanding awards under the Vical Plan, which awards remain outstanding in accordance with their terms.

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,	
	2020	2019	2020	2019
Research and development	$ 68	$ 78	$ 172	$ 156
General and administrative	385	221	684	527
Total stock-based compensation expense	$ 453	$ 299	$ 856	$ 683

NOTE 9. SUBSEQUENT EVENTS

Proposed Amendment of Certificate of Incorporation and Omnibus Plan

On July 14, 2020, the Company's board of directors adopted, subject to stockholder approval, an amendment to Article IV, Section A of the Company's restated certificate of incorporation (the "Charter Amendment") to increase the number of authorized shares of the Company's common stock by 50,000,000 shares, or from 50,000,000 shares to 100,000,000 shares. Further, on July 14, 2020, the Company's board of directors approved the following amendments to the Omnibus Plan, subject to stockholder approval:

- an increase in the maximum number of shares that may be delivered under the Omnibus Plan by an additional 4,500,000 shares, from 679,389 shares to 5,179,389 shares (which amount is in addition to any shares granted previously under the Prior Plans that are forfeited, expire or are canceled after the effective date of the Omnibus Plan without delivery of shares or which result in the forfeiture of the shares back to the Company to the extent that such shares would have been added back to the reserve under the terms of the Prior Plans); and
- a corresponding increase in the maximum number of shares that may be delivered with respect to incentive stock options granted under the Omnibus Plan by an additional 4,500,000 shares, from 679,389 shares to 5,179,389 shares;

(collectively, the "Plan Amendments").

The Charter Amendment and the Plan Amendments are subject to stockholder approval. On July 27, 2020, the Company filed a definitive proxy statement with the SEC related to a special meeting of stockholders to be held on August 31, 2020, at which stockholders will be requested to approve the Charter Amendment and the Plan Amendments.

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 regarding our strategy, future operations, future financial position, liquidity, future revenue, projected expenses, results of operations, expectations concerning the timing and our ability to commence and subsequently report data from planned non-clinical studies and clinical trials, prospects, plans and objectives of management are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Unless otherwise mentioned or unless the context requires otherwise, all references in this Quarterly Report to "Brickell," "Brickell Subsidiary," "Company," "we," "us," and "our," or similar references, refer to Brickell Biotech, Inc., and our consolidated subsidiaries.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019, and in Part II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 and in this Quarterly Report, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (the "SEC"), in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this 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.

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 the treatment of debilitating skin diseases. Our pipeline consists of potential novel therapeutics for hyperhidrosis and other prevalent dermatological conditions. Our executive management team and board of directors bring extensive experience in product development and global commercialization, having served in leadership roles at large global pharmaceutical companies and biotechs that have developed and/or launched successful products, including several that were first-in-class and/or achieved iconic status, such as Cialis®, Taltz®, Gemzar®, Prozac®, Cymbalta® and Juvederm®.

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

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

sofpironium bromide, is the most common occurrence of hyperhidrosis, affecting approximately 65% of patients in the United States or an estimated 10 million individuals.

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

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

Recent Developments

Study Announcements

- In July 2020, we completed the analysis of our 12-month Phase 3 open-label long-term safety study, in 300 subjects 9 years and older with primary axillary hyperhidrosis, sofpironium bromide gel, 5% and 15%. The study results confirmed that sofpironium bromide gel, at both concentrations, was safe and generally well tolerated, which was consistent with the earlier Phase 2 clinical trial results. No treatment-related serious adverse events were observed. We expect to release additional details at an upcoming scientific forum.

- In June 2020, we announced positive Phase 3 pivotal study results in Japan from Kaken. All primary and secondary efficacy endpoints of the study were achieved and sofpironium bromide was safe and generally well tolerated. The study evaluated a total of 281 Japanese patients randomized 1:1 to apply sofpironium bromide gel, 5% (SB) or vehicle gel (placebo) to the axillae (i.e., underarm) for 42 days. These study results were presented as part of the Late-Breaking Research Program during the American Academy of Dermatology (AAD) Virtual Meeting Experience.

- In January 2020, Kaken announced submission of an NDA in Japan requesting approval to manufacture and market sofpironium bromide gel, 5% for primary axillary hyperhidrosis based on the positive Phase 3 data.

Upcoming Milestones

- Plan to initiate the U.S. Phase 3 pivotal program for sofpironium bromide gel, 15% in the fourth quarter of 2020. The planned program will be comprised of two pivotal Phase 3 trials to evaluate approximately 350 subjects per trial with primary axillary hyperhidrosis in the U.S. The first Phase 3 study is expected to begin in the fourth quarter of 2020.

- Expect Kaken to receive regulatory decision for sofpironium bromide gel, 5% in Japan, as early as the fourth quarter of 2020. Under the agreement with Kaken, we are entitled to receive commercial milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide in Japan.

Public Offering of Common Stock and Warrants

In June 2020, we entered into an underwriting agreement with Oppenheimer & Co. Inc. ("Oppenheimer"), as representative of several underwriters, relating to the public offering, issuance and sale of 14,790,133 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 2,709,867 shares of our common stock, and accompanying common warrants to purchase up to an aggregate of 17,500,000 shares of our common stock (the "Offering"). Each share of common stock and pre-funded warrant to purchase one share of our common stock was sold together with a common warrant to purchase one share of our common 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

pre-funded warrants were immediately exercisable at a price of $0.001 per share of our common stock. The common warrants were immediately exercisable at a price of $1.25 per share of our common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The Offering resulted in approximately $18.7 million of net proceeds after deducting underwriting commissions and discounts and other offering expenses of $1.4 million and excluding the proceeds, if any, from the exercise of the warrants. We anticipate using the proceeds from the Offering for research and development, including clinical trials, working capital, and general corporate purposes.

At Market Issuance Sales Agreement

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

Private Placement Offerings

In February 2020, we entered into (i) a securities purchase agreement (the "Securities Purchase Agreement"); (ii) a purchase agreement (the "Purchase Agreement"); and (iii) a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC, an Illinois limited liability company ("Lincoln Park"). Pursuant to the Securities Purchase Agreement, Lincoln Park 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. Sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on the date the conditions set forth in the Purchase Agreement are satisfied (such date on which all of such conditions are satisfied, the "Commencement Date").

Following the Commencement Date, under the Purchase Agreement, on any business day 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 off of prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, we may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, we may not sell shares of our common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of our common stock. As of June 30, 2020, we have not made any sales of our common stock under the Purchase Agreement.

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"). The Amended and Restated License Agreement supersedes the License Agreement, dated December 15, 2012, entered into between Brickell Subsidiary and Bodor, as amended by Amendment No. 1 to License Agreement, effective as of October 21, 2013, and Amendment No. 2 to License Agreement, effective as of March 31, 2015.

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

Corporate History

On August 31, 2019, the Delaware corporation formerly known as "Vical Incorporated" ("Vical"), completed a reverse merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated June 2, 2019, as further amended on August 20, 2019 and August 30, 2019, by and among Vical, Brickell Biotech, Inc., a then privately-held Delaware corporation that began activities in September 2009 ("Private Brickell") and Victory Subsidiary, Inc., a wholly-owned subsidiary of Vical ("Merger Sub"), pursuant to which Merger Sub merged with and into Private Brickell, with Private Brickell surviving the merger as a wholly-owned subsidiary of Vical (the "Merger"). Additionally, on August 31, 2019, immediately after the completion of the Merger, the Company changed its name from "Vical Incorporated" to "Brickell Biotech, Inc."

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, and other research and development. To date, we have financed operations primarily through funds received from license and collaboration agreements, cash and investments acquired in connection with the Merger, and funds received from the sale of convertible preferred stock, debt, convertible notes, common stock, and warrants. We do not have any products approved for sale and have not generated any product sales. Since inception and through June 30, 2020, we have raised or generated an aggregate of $146.7 million to fund our operations, of which $39.1 million was through license and collaboration agreements, $37.0 million was from cash and investments acquired in the Merger, $33.6 million was from the sale of convertible preferred stock, $22.1 million was from the sale of common stock and warrants, $7.5 million was from the sale of debt, and $7.4 million was from the sale of convertible notes. As of June 30, 2020, we had cash and cash equivalents of $21.6 million. In addition, we had approximately $4.6 million in prepaid expenses related to the Phase 3 program of sofpironium bromide.

Since inception, we have incurred operating losses. We recorded a net loss of $5.1 million and $3.7 million for the three months ended June 30, 2020 and 2019, respectively, and $9.2 million and $8.2 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $94.2 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

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

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

Key Components of Operations

Collaboration Revenue

Collaboration 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. We have not recognized any royalty revenue to date. Other than the revenue we may generate in connection with these agreements, we do not expect to generate any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our products or enter into other collaborative agreements with third parties.

Research and Development Expenses

Research and development expenses principally consist of payments to third parties known as Clinical Research Organizations ("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 increase in future periods following the initiation of the Phase 3 program for sofpironium bromide.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
Direct program expenses related to sofpironium bromide	$ 1,964	$ 3,392	$ 3,731	$ 8,419
Personnel and other expenses				
Salaries, benefits, and stock-based compensation	712	795	1,475	1,655
Regulatory and compliance	4	31	58	140
Other expenses	32	11	112	34
Total research and development expenses	$ 2,712	$ 4,229	$ 5,376	$ 10,248

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.

We expect our overall general and administrative expenses to continue to increase in the near term as we incur expenses associated with operating as a public company compared to prior periods, which may include increased insurance premiums, investor relations expenses, legal and accounting fees associated with the expansion of our business and corporate governance, financial reporting expenses, and expenses related to Sarbanes-Oxley and other regulatory compliance obligations.

Total Other Income (Expense)

Investment and Other Income, Net

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

Interest Expense

Interest expense historically consisted primarily of interest and amortization related to the issuance of $5.1 million of convertible promissory note principal during the six months ended June 30, 2019 and principal borrowings of $7.5 million provided by the loan and security agreement entered into with Hercules Capital, Inc. on February 18, 2016 (the "Loan Agreement"). In August 2019, the convertible promissory notes were converted and the Loan Agreement was repaid, and therefore, there was no interest expense thereafter related to these agreements.

Change in Fair Value of Warrant Liability

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

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

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 ("US 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, convertible promissory notes, redeemable convertible preferred stock, warrants, and stock-based compensation. We base our estimates on our historical experience and on assumptions that we believe are reasonable; however, actual results differ materially from these estimates under different assumptions or conditions.

For the six months ended June 30, 2020, there have been no material changes in our critical accounting policies and estimates as compared to those disclosed in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results

of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 18, 2020.

Recent Accounting Pronouncements

For information on the recent accounting pronouncements which may impact our business, see Note 2 of the notes to the condensed consolidated financial statements included elsewhere in this Quarterly Report.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

	Three Months Ended June 30,	
	2020	2019
	(in thousands)	
Collaboration revenue	$ 607	$ 2,573
Research and development expenses	(2,712)	(4,229)
General and administrative expenses	(3,021)	(1,323)
Total other income (expense), net	7	(675)
Net loss	$ (5,119)	$ (3,654)

Collaboration Revenue

Collaboration revenue decreased by $2.0 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019. Revenue in both periods was driven by research and development activities related to the Kaken Agreement for which Kaken provided research and development funding. The decrease in revenue recognized was attributable to our Phase 3 long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were ongoing in 2019 but were concluded or winding down by the end of the first quarter of 2020. Conducting these studies is the basis for revenue recognition of a $15.6 million research and development payment received from Kaken in the second quarter of 2018.

Research and Development

Research and development expense decreased by $1.5 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019, which was primarily due to reduced clinical and other related regulatory and administrative costs of the Phase 3 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. During the three months ended June 30, 2020, research and development expense of $1.5 million was recorded for paid or accrued milestone payments to Bodor, the licensor of sofpironium bromide.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019. This increase was primarily due to higher costs of $0.9 million for professional-related fees attributable to capital-raising activities and additional expenses associated with operating as a public company, $0.6 million for stock and other compensation expense that was driven by increased headcount, and $0.3 million for directors' and officers' liability insurance fees due to becoming a public company.

Total Other Income (Expense), Net

Total other income, net increased by $0.7 million for the three months ended June 30, 2020, compared to total other expense, net for the three months ended June 30, 2019. The change was primarily due to a decrease of $0.7 million in interest expense

related to the issuance of convertible promissory notes in 2019 and principal borrowings provided by the Loan Agreement with a former lender.

Comparison of the Six Months Ended June 30, 2020 and 2019

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Collaboration revenue	$ 1,653	$ 6,065
Research and development expenses	(5,376)	(10,248)
General and administrative expenses	(5,502)	(3,389)
Total other income (expense), net	3	(662)
Net loss	$ (9,222)	$ (8,234)

Collaboration Revenue

Collaboration revenue decreased by $4.4 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. Revenue in both periods was driven by research and development activities related to the Kaken Agreement for which Kaken provided research and development funding. The decrease in revenue recognized was attributable to our Phase 3 long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were ongoing in 2019 but were concluded or winding down by the end of the first quarter of 2020. Conducting these studies is the basis for revenue recognition of a $15.6 million research and development payment received from Kaken in the second quarter of 2018.

Research and Development

Research and development expenses decreased by $4.9 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, which was primarily due to a decrease in clinical and other related regulatory and administrative costs of the Phase 3 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. During the six months ended June 30, 2020, research and development expense of $1.5 million was recorded for paid or accrued milestone payments to Bodor.

General and Administrative Expenses

General and administrative expenses increased by $2.1 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. This increase was primarily due to higher costs of $0.8 million for professional-related fees attributable to capital-raising activities and additional expenses associated with operating as a public company, $0.8 million for stock and other compensation expense that was driven by increased headcount, and $0.6 million for directors' and officers' liability insurance fees due to becoming a public company, partially offset by lower costs of $0.1 million for other miscellaneous expenses.

Total Other Income (Expense), Net

Total other income, net increased by $0.7 million for the six months ended June 30, 2020 compared to total other expense, net for the six months ended June 30, 2019. The change was primarily due to a decrease of $0.9 million in interest expense related to the issuance of convertible promissory notes in 2019 and principal borrowings provided by the Loan Agreement with a former lender, partially offset by a $0.2 million gain resulting from fair value adjustments to warrant liabilities during the six months ended June 30, 2019 that did not recur in 2020.

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, 2020 and 2019, we had a net loss of $9.2 million and $8.2 million, respectively. As of June 30, 2020 and December 31, 2019, we had an accumulated deficit of $94.2 million and $85.0 million, respectively. As of June 30, 2020, we had cash and cash equivalents of $21.6 million. Since inception, we have financed

operations primarily through payments received under strategic license and collaboration agreements, cash and investments acquired in the Merger, and funds received from the sale of convertible preferred stock, common stock and warrants, debt, and convertible notes.

We believe that our cash and cash equivalents as of June 30, 2020 and periodic sales of our common stock under the Purchase Agreement, are sufficient to fund our operations for at least the next 12 months from the issuance of this Quarterly Report. However, in order to sell additional shares of common stock under the Purchase Agreement, Lincoln Park will need to purchase shares of common stock from us, subject to the conditions under the Purchase Agreement. Further, we will be significantly limited in our ability to sell shares of our common stock under the Purchase Agreement, or to utilize our common stock in any other capital raising transaction, if our stockholders do not approve an increase in the number of authorized shares of our common stock, as further described in 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 proceed with our current and proposed research activities, including completing the pivotal U.S. Phase 3 clinical trials of sofpironium bromide.

Cash Flows

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

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (11,290)	$ (9,502)
Net cash provided by (used in) investing activities	4,500	(4)
Net cash provided by financing activities	21,128	3,518
Net change in cash and cash equivalents	$ 14,338	$ (5,988)

Operating Activities

Net cash used in operating activities of $11.3 million during the six months ended June 30, 2020 increased compared to $9.5 million during the same period in the prior year primarily due to an increase in net loss of $1.0 million, a change in working capital of $0.6 million, and a decrease of other non-cash expenses of $0.2 million.

Investing Activities

Net cash provided by investing activities of $4.5 million during the six months ended June 30, 2020 increased compared to cash used in investing activities of $4 thousand during the same period in the prior year. The $4.5 million increase was primarily the result of maturities of marketable securities in the 2020 period.

Financing Activities

Net cash provided by financing activities of $21.1 million during the six months ended June 30, 2020 increased compared to $3.5 million during the same period in the prior year. The increase was primarily related to higher net proceeds received in the 2020 period from the issuance of common stock and warrants of $20.7 million and proceeds from the issuance of a note payable of $0.4 million, compared to net proceeds received in the 2019 period from the issuance of convertible promissory notes of $5.1 million, partially offset by the repayment of principal associated with the Loan Agreement in the 2019 period of $1.6 million.

Off-Balance Sheet Arrangements

As of June 30, 2020 and December 31, 2019, we had not been involved in any material off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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, 2020.

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, 2020 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

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

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

ITEM 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" of this Quarterly Report.

Risk factors below that have been modified from the version of that risk factor as it appeared in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (other than typographical or definitional modifications), or additional risk factors that did not appear in that Annual Report on Form 10-K, are noted with an "" preceding such risk factor.*

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

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

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

- ability to commercialize sofpironium bromide successfully in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with Kaken or others;

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

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

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

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

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

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

The conduct of a Phase 3 clinical trial is a long, expensive, complicated, uncertain, and highly regulated process. Although our employees have conducted successful Phase 2 and Phase 3 clinical trials in the past across many therapeutic areas while employed at other companies, we as a company have not conducted a pivotal Phase 3 clinical trial, and as a result, we may require more time and incur greater costs than we anticipate. We commenced a Phase 3 long-term safety study for sofpironium bromide gel in the third quarter of 2018 and intend to initiate two pivotal Phase 3 clinical trials in subjects with primary axillary hyperhidrosis in the United States. While we currently plan to initiate the U.S. Phase 3 pivotal program for sofpironium bromide gel, 15% in the fourth quarter of 2020, we may not be able to commence that program in that 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 loss of rights in and to sofpironium bromide.

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

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

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

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

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

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

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

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

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by sofpironium bromide after obtaining U.S. or foreign regulatory approval, a number of potentially negative consequences could result, which could prevent us or our potential partners from achieving or maintaining 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, we owe an outstanding sum for Active Pharmaceutical Ingredient ("API") for further development of sofpironium bromide, and our inability to obtain such API from Kaken on a timely basis, or Kaken's attempt to immediately collect the outstanding sum in full, could have a material adverse impact on our business.***

On July 30, 2019, we entered into a Clinical Supply Agreement with Kaken (the "Clinical Supply Agreement") under which we made various purchase orders for certain amounts of drug substance and product components for use in non-clinical and clinical studies, as well as for scale-up validation activities. As of June 30, 2020, we owed Kaken approximately $2.7 million. As a result of our non-payment, Kaken could assert a breach or default under the Clinical Supply Agreement and seek damages and/or termination of the Clinical Supply Agreement, among other available remedies. We have entered into a letter agreement with Kaken specifying the terms under which Kaken will ship to us, and we will pay for, a portion of the API, but that letter agreement does not include a waiver of Kaken's rights in respect of our non-payment. If Kaken were to seek the immediate payment of all amounts owed under the Clinical Supply Agreement, and we are unable to secure additional resources, our liquidity and cash position would be impaired, and our ability to meet our other financial obligations as they come due could be materially adversely affected.

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

The Kaken Agreement granted Kaken an exclusive Japan license and certain rights to additional Asian countries to develop and commercialize sofpironium bromide. Under the terms of the Kaken Agreement, as amended, we received an up-front

payment, development milestones and research and development payments and are eligible to receive future milestones and a royalty on net sales.

Kaken has final decision-making authority for the overall regulatory, development and commercialization strategy for sofpironium bromide, market access activities, pricing and reimbursement activities, promotion, distribution, packaging, sales and safety and pharmacovigilance in Japan and certain other Asian countries. In exercising its final decision-making authority in such territories, Kaken may make decisions regarding product development or regulatory strategy based on its determination of how best to preserve and extend regulatory approvals in these territories for sofpironium bromide, which may delay or prevent achieving regulatory approval for sofpironium bromide in Kaken's territories, as well as by us in the United States and the other territories where we maintain exclusive rights. Additionally, Kaken is responsible for conducting certain nonclinical and API (chemistry, manufacturing, and controls)-related activities that will be required for FDA approval in the United States, and as a result, we are reliant on Kaken to execute successfully, in a timely, 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 United States and other territories in which we maintain exclusive rights.

In early 2020, Kaken announced submission of a new drug application for approval in Japan of manufacturing and marketing of sofpironium bromide gel for primary axillary hyperhidrosis. We cannot provide any assurance that such new drug application will be approved or that any other regulatory approvals in Japan or other Asian countries will occur. We will not receive additional milestone or other payments from Kaken if Kaken is not successful in its development, regulatory and/or commercial activities.

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

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

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

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In the United States, although private third-party payors tend to follow Medicare and Medicaid practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as state to state. Consequently, the coverage determination process is often uncertain and a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require us to provide scientific, clinical

and health economics support for the use of sofpironium bromide compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what amount or time frame.

Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the United States and in international markets, 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 United States or international markets, which could harm our business, financial condition, operating results, and prospects.

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

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

- patient demand for approved products that treat hyperhidrosis;
- our ability to market and sell the drug, including through direct-to-consumer advertising and non-traditional sales strategies;
- the safety and effectiveness of sofpironium bromide, and ease of use, compared to other available hyperhidrosis therapies, whether approved or used by physicians off-label;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for sofpironium bromide;
- the cost of treatment with sofpironium bromide in relation to alternative hyperhidrosis treatments and willingness to pay for sofpironium bromide, if approved, on the part of patients;
- overcoming physician or patient biases toward particular therapies for the treatment of hyperhidrosis and achieving acceptance by physicians, major operators of clinics and patients of sofpironium bromide as a safe, effective, and economical hyperhidrosis treatment;
- patients' perception of hyperhidrosis as a disease and one for which medical treatment may be appropriate and a prescription therapy may be available;
- insurers' and physicians' willingness to see hyperhidrosis as a disease worth treating and for which reimbursement will be made available for treatment;
- proper administration of sofpironium bromide;
- patient satisfaction with the results and administration of sofpironium bromide and overall treatment experience;
- limitations or contraindications, warnings, precautions, or approved indications for use different than those sought by us that are contained in any final FDA-approved labeling for sofpironium bromide;
- any FDA requirement to undertake a risk evaluation and mitigation strategy, or results from any post-marketing surveillance studies that FDA may require as a condition of product approval;
- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, legal, medical, public relations, compliance, and distribution efforts;
- adverse publicity about sofpironium bromide or favorable publicity about competitive products;

- new government regulations and programs, including price controls and/or public or private institutional limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals or restrictions on sales representatives to market pharmaceuticals; and

- potential product liability claims or other product-related litigation or litigation related to licensing and or other commercial matters associated with sofpironium bromide.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Financial Operations

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

The advancement of the Phase 3 clinical trials for sofpironium bromide will require substantial additional financing. Pending our obtaining additional funding, we have taken, and expect to continue to take, actions to reduce our cash spend, including delaying the start of the clinical trials and/or staff reductions. Nonetheless, we will require substantial additional funds to conduct the costly and time-consuming clinical trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of sofpironium bromide in new indications or uses including completing our pivotal U.S. Phase 3 program for sofpironium bromide for treatment of primary axillary hyperhidrosis. Our future capital requirements will depend upon a number of factors, including but not limited to: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; compliance with our material contracts including the licensing agreement for sofpironium bromide; the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance for such product candidates; and overall stock market and global business conditions and trends.

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

Our ability to raise the significant additional funds required to complete the Phase 3 clinical trials for sofpironium bromide is uncertain and is limited given our small market capitalization. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders. Currently, we have a limited under of shares of common stock that are unreserved and available for future issuance, and therefore without additional authorized shares of common stock, we will be severely restricted in our ability to pursue the additional financing required to complete our U.S. Phase 3 clinical trials of sofpironium bromide and conduct the necessary research and development activities related to regulatory submissions for sofpironium bromide. We have scheduled a special meeting of stockholders for August 31, 2020, at which we will request that stockholders approve, among other matters, an increase in the number of authorized shares of common stock by 50,000,000. We cannot assure you that our stockholders will approve such increase. If the increase is not approved by our stockholders, our business development and financing alternatives may be limited by the lack of sufficient unissued and unreserved authorized shares of common stock, and stockholder value may be harmed, perhaps severely, by this limitation. In addition, our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel, and if the increase is not approved by our stockholders, the lack of sufficient unissued and unreserved authorized shares of common stock to provide future equity incentive opportunities that our Compensation Committee deems appropriate could adversely impact our ability to achieve these goals. In summary, if our stockholders do not approve the increase, we may not be able to access the capital markets, initiate or complete pivotal

clinical trials and other key development activities, complete corporate collaborations or partnerships, attract, retain and motivate employees and others required to make our business successful, and pursue other business opportunities integral to our growth and success, all of which could severely harm our company and our prospects.

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

Our operating results and liquidity could be affected negatively by global economic conditions generally, both in the United States and elsewhere around the world. The market for discretionary pharmaceutical products, medical devices and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider sofpironium bromide as discretionary, and if full reimbursement for the product is not available, demand for the product may be tied to the discretionary, out-of-pocket cash-spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, or a bear market ensues in the U.S. stock market, including as a result of the recent coronavirus outbreak, our operating results and liquidity could be affected adversely by those factors in many ways, including weakening demand for sofpironium bromide, making it more difficult for us to raise funds if necessary, and our stock price may decline.

Our stock price has been and may continue to be highly volatile, and our common stock may continue to be illiquid.

The market price of our common stock following the Merger has been subject to significant fluctuations. The closing price of our common stock fluctuated from $4.69 per share as of September 3, 2019, the first trading date following the closing of the Merger, to $1.00 per share as of June 30, 2020. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. Some of the factors that may cause the market price of our common stock to continue to fluctuate include, but are not limited to:

- material developments in, or the conclusion of, any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- the entry into, or termination of, or breach by us or our partners of material agreements, including key commercial partner or licensing agreements, including the 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 reaction of global markets to the coronavirus outbreak. These broad market fluctuations may also adversely affect the trading price of our common stock.

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

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

Our operations to date have been limited primarily to researching and developing sofpironium bromide and undertaking preclinical studies and clinical trials of sofpironium bromide. We (and our partners) have not yet obtained regulatory approvals for sofpironium bromide in any country. Consequently, any predictions you or we make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our revenue and profitability will depend on development funding, including obtaining the additional funds needed to complete the Phase 3 clinical trials for sofpironium bromide, the achievement of sales milestones and royalties under an agreement with Kaken, as well as any potential future collaboration and license agreements and sales of 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 incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

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

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

We qualify as a "smaller reporting company" under Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). As a smaller reporting company, we are entitled to rely on certain exemptions and reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements, in our SEC filings. These exemptions and decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock price may be more volatile. We will remain a "smaller reporting company" under Item 10(f)(1) of SEC

Regulation S-K as long as we maintain a public float as defined by that regulation of less than $250 million; or we have less than $100 million in annual revenues and (i) either no public float, or (ii) a public float of less than $700 million.

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

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

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

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

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

As of June 30, 2020, we had outstanding warrants to purchase (i) one share of our common stock at an exercise price of $0.07 per share; (ii) 490,683 shares of our common stock at an exercise price of $10.36 per share; (iii) 9,005 shares of our common stock at an exercise price of $33.31 per share; (iv) 1,556,420 shares of our common stock at an exercise price of $1.16 per share; (v) 17,500,000 shares of our common stock at an exercise price of $1.25 per share; and (vi) 1,113,424 shares of our common stock at an exercise price of $0.001 per share. As of June 30, 2020, we also had 1,578,231 options issued and outstanding to purchase our common stock at a weighted average exercise price of $13.03 per share and 253,045 shares of common stock underlying unvested restricted stock units outstanding. If the holders of our outstanding stock options and warrants exercise their rights to acquire our common stock and service conditions related to restricted stock units are met, the percentage ownership of our stockholders existing prior to the exercise of such rights will be diluted.

****We may not be able to access the full amounts available under 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 the date the conditions set forth in the Purchase Agreement are satisfied. All funds available under the Purchase Agreement are subject to the satisfaction of certain conditions specified in the Purchase Agreement, including that our common stock remains listed on Nasdaq, the effectiveness of a registration statement relating to the resale of the shares to be sold to Lincoln Park under the Purchase Agreement and that no event of default has occurred under the Purchase Agreement. Additionally, depending upon the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park if such a sale would result in us issuing to Lincoln Park more than 9.99% of our shares outstanding prior to entering into the Purchase Agreement. Further, we will be significantly limited in our ability to sell

shares of common stock under the Purchase Agreement if our stockholders do not approve an increase in the number of authorized shares of our common stock, as further described under "*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.*" In the event that we are unable to satisfy the conditions specified, the purchase commitment made by Lincoln Park will be unavailable to us and Lincoln Park will not be required to purchase any shares of our common stock. If obtaining funding from Lincoln Park were to prove unavailable, we will need to secure other sources of funding in order to satisfy our working capital needs. Additionally, even if we are able to sell all shares under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

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

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

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

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

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

As of December 31, 2019, we had approximately $403.9 million of federal and $350.6 million of state operating loss ("NOL") carryforwards available to offset future taxable income, which expire in varying amounts beginning in 2020 for federal and state purposes if unused. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. Under the U.S. Tax Cuts and Jobs Acts ("Tax Act"), U.S. federal NOLs incurred in 2018 and later years may be carried forward indefinitely, but our ability to utilize such U.S. federal NOLs to offset taxable income is limited to 80% of the current-year taxable income. It is uncertain if and to what extent various U.S. states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986 and corresponding provisions of U.S. state law, if a corporation undergoes an "ownership change" (which is generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have not determined whether we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is therefore subject to an annual limitation under Section 382. 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 U.S. state law has 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 net operating loss carryforwards to offset future taxable income will be limited following any such ownership change, and could be eliminated. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance on our financial statements.

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

Our corporate office is located in Boulder, Colorado, near a major flood and blizzard zone. If a disaster, power outage, computer hacking, or other event occurred that prevented us from using all or a significant portion of our office, that damaged

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

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

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants, and even the regulators who we rely on to advance our business, are vulnerable to damage from computer viruses, unauthorized access, computer hacking or breaches, natural disasters, epidemics and pandemics, terrorism, war, labor unrest, and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber-terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. In addition, since we sponsor clinical trials, any breach that compromises patient data and identities causing a breach of privacy could generate significant reputational damage and legal liabilities and costs to recover and repair, including affecting trust in us to recruit for future clinical trials. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products and product candidates could be delayed.

Risks Related to Our Business

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

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

Even after we or our partners achieve regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations, including on how the product is commercialized. For example, with respect to our product candidates for the U.S., the FDA may impose significant restrictions on the approved indicated use(s) for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product or include in the approved label restrictions on the product and how it may be used or sold. We also will be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, pharmacovigilance and adverse event reporting, storage, advertising, promotion, and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with cGMP requirements and with the FDA's GCP requirements and GLP requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval, as well as continued compliance with the FDA's laws governing commercialization of the approved product, including but not

limited to the FDA's Office of Prescription Drug Promotion regulation of promotional activities and direct-to-consumer advertising, fraud and abuse, antikickback, product sampling, debarment, scientific speaker engagements and activities, formulary interactions as well as interactions with healthcare practitioners, including various conflict-of-interest reporting requirements for any healthcare practitioners we may use as consultants, and laws relating to the pricing of drug products, including federal "best price" regulations that if not met can prohibit the company from participating in federal reimbursement programs like Medicare or Medicaid. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar or more onerous (e.g., prohibition on direct-to-consumer advertising and price controls that do not exist in the United States) restrictions and requirements imposed by laws and government regulators, and even private institutions, in those countries.

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

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

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

- change or restrict our product labeling; or

- seize or detain products or require us or our partners to initiate a product recall.

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

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

The outbreak of the novel Coronavirus (COVID-19) has evolved into a global pandemic. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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

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

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

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

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

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

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

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

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

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize, or restrictions on commercializing, our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing, or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management’s attention and other resources from our primary business;
- significant delay in product launch;
- debarment of our clinical trial investigators or other related healthcare practitioners working with our company;

- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

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

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

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

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

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

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

In the United States, engaging in impermissible promotion of our product candidates for off-label uses, or engaging in pre-approval promotion of an unapproved drug candidate, also can subject us to false claims litigation under federal and state

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

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

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

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

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

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

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

Additionally, in October 2018, the U.S. President proposed to lower Medicare Part B drug prices, in addition to contemplating other measures to lower or prescribe certain mandatory prescription drug prices or drug substitution policies. While these proposals have not yet been enacted, we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

significant protection against competitive products or otherwise be commercially valuable to us in every country of commercial significance that we may target, or that a legislative or executive branch of government may alter the rights and enforceability thereof at any time.

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

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

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

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

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

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

intellectual property rights. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from commercialization or other uses.

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

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patentholder's patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. Further, there is no guarantee that any country will not adopt or impose compulsory licensing in the future. In these situations, the royalty the court requires to be paid by the licenseholder receiving the compulsory license may not be calculated at fair market value and can be inconsequential, thereby disaffecting the patentholder's business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the United States. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. For example, in Brazil, pharmaceutical patents require prior initial approval of the Brazilian health agency (ANVISA). Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

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

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

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

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract

interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, or increase our financial or other obligations to our licensors.

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

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

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

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

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

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

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

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

ITEM 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 Number	Description of Exhibit	Filed Herewith
3.1	Restated Certificate of Incorporation, as currently in effect (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on September 3, 2019).	
3.2	Amended and Restated Bylaws, as currently in effect (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2020).	
4.1	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Company's amended Registration Statement on Form S-1/A filed with the SEC on June 17, 2020).	
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 to the Company's amended Registration Statement on Form S-1/A filed with the SEC on June 8, 2020).	
4.3	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.4 to the Company's amended Registration Statement on Form S-1/A filed with the SEC on June 17, 2020).	
10.1	At Market Issuance Sales Agreement, dated April 14, 2020, by and between Brickell Biotech, Inc. and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on April 14, 2020).	

10.2	Form of Indemnification Agreement by and between the Company and its directors and executive officers.	×
10.3	Form of Restricted Stock Unit Award Agreement under the Brickell Biotech, Inc. 2020 Omnibus Long-Term Incentive Plan.	×
10.4	Form of Non-Qualified Stock Option Award Agreement under the Brickell Biotech, Inc. 2020 Omnibus Long-Term Incentive Plan.	×
10.5†	Amendment to License, Development and Commercialization Agreement, dated February 24, 2016, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.2 to the Company's amended Registration Statement on Form S-1/A filed with the SEC on June 8, 2020).	
10.6†	Clinical Supply Agreement, dated as of July 30, 2019, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd., and First Amendment to Clinical Supply Agreement, dated as of October 18, 2019 (incorporated by reference to Exhibit 10.4 to the Company's amended Registration Statement on Form S-1/A filed with the SEC on June 8, 2020).	
10.7†	Letter Agreement for Supply of API, dated as of April 26, 2020, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.5 to the Company's amended Registration Statement on Form S-1/A filed with the SEC on June 8, 2020).	
10.8	Consulting Agreement, dated as of December 18, 2017, by and between Brickell Biotech, Inc. and Michael Carruthers; Amendment No. 1 to Consulting Agreement, dated as of March 1, 2019, by and between Brickell Biotech, Inc. and Michael Carruthers; and Amendment No. 2 to Consulting Agreement, dated as of December 23, 2019, by and between Brickell Biotech, Inc. and Michael Carruthers (incorporated by reference to Exhibit 10.14 to the Company's amended Registration Statement on Form S-1/A filed with the SEC on June 8, 2020).	
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)	×

† 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.

× Filed herewith.

* 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, 2020

By: /s/ Robert. B. Brown

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

By: /s/ R. Michael Carruthers

R. Michael Carruthers
Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)

Exhibit 10.2

INDEMNITY AGREEMENT

This Indemnification Agreement ("Agreement") is made effective retroactive as of ***[insert date person became a director/officer/employee/agent of the Company for which indemnification will be provided]***, by and between Brickell Biotech, Inc., a Delaware corporation (the "Company"), and _____, a _____ resident, with a domicile address of _____ ("Indemnitee").

RECITALS

WHEREAS, highly competent persons have become more reluctant to serve corporations as officers and directors or in other capacities unless they are provided by such corporations with adequate protection through insurance or adequate indemnification against inordinate risks of claims and actions against them for personal liability arising out of their service to and activities on behalf of the corporation they benefit;

WHEREAS, the Board of Directors of the Company (the "Board") has determined that, in order to attract and retain qualified individuals, the Company will maintain on an ongoing basis, at its sole cost, sufficient liability insurance to protect its officers and directors serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors and officers to corporations or business enterprises increasingly are being subjected to expensive and time-consuming litigation against them individually relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Certificate of Incorporation of the Company (the "Certificate of Incorporation") and the By-laws of the Company (the "By-laws) require indemnification of the officers and directors of the Company. Indemnitee also may be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Certificate of Incorporation, the By-laws and the DGCL do not require that the indemnification provisions set forth therein be exclusive, thereby allowing for contracts to be entered into between the Company and its directors, officers and other persons with respect to indemnification;

WHEREAS, the uncertainties relating to such insurance and to indemnification have increased the difficulty of attracting and retaining such qualified persons;

WHEREAS, the Board of the Company has determined that the increased difficulty in attracting and retaining such qualified persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of the protections described above now and in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance Expenses (defined below, Section 2) to be

incurred on behalf of, such qualified persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the By-laws and the Certificate of Incorporation and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder;

[WHEREAS, Indemnitee had served as [a director][an officer] of Brickell Subsidiary, Inc., a Delaware corporation ("Subsidiary" and, collectively with the Company, the "Covered Entities" and, also with the Company, each individually a "Covered Entity") prior to acquisition of Subsidiary by the Company and][WHEREAS, Indemnitee] has been serving as [a director][an officer] of the Company, or has been serving at the request of the Company as a director, officer, employee and/or other agent of another corporation, partnership, joint venture, trust or other Enterprise (defined below, Section 2) and in such capacity has been performing a valuable service for the Company; and

WHEREAS, Indemnitee did not regard the protection(s) available under the By-laws, the Certificate of Incorporation, insurance and the DGCL as necessarily adequate and may not be willing to continue serving as [a director][an officer] of the Company without additional adequate protection, and the Company desires Indemnitee to serve in such capacity; and Indemnitee is willing to serve on the condition that he/she be indemnified as herein provided;

WHEREAS, it is intended that Indemnitee shall be paid promptly by the Company all amounts necessary to effectuate in full the indemnity and benefits provided herein;

NOW, THEREFORE, in consideration of the premises and the covenants contained in this Agreement, and intending to be legally bound thereby, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. **Services to the Company.**

(a) Indemnitee agrees to serve as [a director][an officer] of the Company until such time as he or she resigns [or fails to stand for election] or is removed from his or her position. Indemnitee may at any time and for any reason resign or be removed from such position (subject to any other restriction on removal imposed by law), and the Company agrees that any such resignation or removal after the date of execution of this Agreement shall not affect the adequacy of the consideration received by the Company for its agreement to provide the protections set forth in this Agreement. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as [a director][an officer] of the Company, as provided in Section 16 hereof.

(b) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in consideration for the Indemnitee's past service as [a director][an officer] and in order to induce Indemnitee to

continue serving as [a director][an officer] of the Company. The Company acknowledges that Indemnitee is relying upon this Agreement in agreeing to continue serving as [a director][an officer] of the Company.

Section 2. **Definitions.** As used in this Agreement:

(a) References to "agent" shall mean any person who is or was a director, officer, or employee of [a Covered Entity][the Company] or a subsidiary of [a Covered Entity]the Company or other person authorized by [a Covered Entity][the Company] to act for [such Covered Entity][the Company], to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of [a Covered Entity][the Company] or a subsidiary of [a Covered Entity][the Company].

(b) A "Change in Control" shall be deemed to occur upon the earliest to occur after the date of execution of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) who is or becomes the Beneficial Owner (also as defined below), directly or indirectly, of securities of the Company representing twenty percent (20%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 51% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

iv. Liquidation. The approval by the stockholders of the Company of a complete liquidation, bankruptcy, dissolution or wind-down of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and/or

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 2(b) of the Agreement, the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "Person" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and/or (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "Beneficial Owner" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger or consolidation of the Company with another entity.

(c) "Corporate Status" describes the status of a person who is or was a director, trustee, partner, managing member, officer, employee, agent and/or fiduciary of [a Covered Entity][the Company] or of any other corporation, limited liability company, partnership or joint venture, trust or other enterprise which such person is or was serving at the request of [a Covered Entity][the Company].

(d) "Disinterested Director" shall mean a director of the Company who is not and was not a party to the Proceeding (as defined below) in respect of which indemnification is sought by Indemnitee.

(e) "Enterprise" shall mean the [Covered Entities][Company] and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of [a Covered Entity][the

Company] as a director, officer, trustee, partner, managing member, employee, agent and/or fiduciary.

(f) "Expenses" shall include all direct and indirect costs (including but not limited to reasonable attorneys' fees, retainers, court costs, transcripts, fees of experts and other professionals, witness fees, travel costs, duplicating costs, printing and binding costs, wiring fees, telephone charges, postage, delivery service fees, fax transmission charges, secretarial and administrative services, any federal, state, local or foreign or other governmental taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements, obligations or out-of-pocket expenses and reasonable compensation for time spent by Indemnitee for which he or she is otherwise not compensated by the Company) actually and reasonably incurred in connection with, or as a result of, a Proceeding or establishing or enforcing a right to indemnification under this Agreement, the DGCL, or otherwise. Expenses also shall include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including but not limited to the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, (ii) Expenses incurred in connection with recovery under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether the Indemnitee ultimately is determined to be entitled to such indemnification, advancement or Expenses or insurance recovery, as the case may be, and (iii) for purposes of Section 14(d) only, Expenses incurred by or on behalf of Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) "Independent Counsel" shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five (5) years has been, retained to represent: (i) the [Covered Entities][Company, Brickell Subsidiary, Inc.] or Indemnitee in any matter material to [either such party][any of them] (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either [the Company or] Indemnitee [or a Covered Entity] in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and cost of the Independent Counsel referred to above and to indemnify fully such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) The term "Proceeding" shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate

dispute resolution mechanism, investigation, audit, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of [a Covered Entity][the Company] or otherwise and whether of a civil, criminal, administrative, regulatory, legislative, or audit or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of the fact that Indemnitee is or was a director, officer, employee and/or agent of [a Covered Entity][the Company], by reason of any action taken by him/her (or a failure to take action by him/her) or of any action (or failure to act) on his/her part while acting pursuant to his/her Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph and the Agreement.

(i) References to "other enterprise" shall include but not be limited to employee benefit plans; references to "fines" shall include but not be limited to any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of [a Covered Entity][the Company]" shall include but not be limited to any service as a director, officer, employee and/or agent of [any Covered Entity][the Company] which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he/she reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the [Covered Entity][Company]" as referred to in this Agreement.

Section 3. **Indemnity in Third-Party Proceedings.**

The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of [a Covered Entity][the Company] to procure a judgment in its favor which shall be governed pursuant to Section 4 below. Pursuant to this Section 3, Indemnitee shall be indemnified by Company to the fullest extent permitted by applicable law against all Expenses, judgments, liabilities, fines, penalties and amounts paid in settlement (including but not limited to all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, liabilities, fines, penalties and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his/her behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity][Company] and, in the case of a criminal Proceeding had no reasonable cause to believe that his/her conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification or the like in excess of that expressly permitted by statute, including but not limited to any indemnification provided by the Company's Certificate of Incorporation, the

By-laws, vote of its stockholders or Disinterested Directors, or applicable law, including the DGCL.

Section 4. **Indemnity in Proceedings by or in the Right of [a Covered Entity.][the Company.]**

The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 of the Agreement if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of [a Covered Entity][the Company] to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity.] [Company.] If applicable law so provides, no indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the [Covered Entity][Company], unless and only to the extent the Court of Chancery of the State of Delaware or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5. **Indemnification for Expenses of Party Who is Wholly or Partly Successful.**

Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6. **Indemnification for Expenses as Witness or Some Other Capacity in a Proceeding.**

Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his/her Corporate Status, a witness or otherwise asked to participate in any aspect of a Proceeding to which Indemnitee is not a party, he/she shall be indemnified by Company against all Expenses actually and reasonably incurred by him/her or on his/her behalf in connection therewith.

Section 7. **Partial Indemnification.**

If Indemnitee is entitled under any provision of this Agreement to indemnification or the like by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company nevertheless shall indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8. **Additional Indemnification.**

(a) Notwithstanding any limitation in Sections 3, 4, or 5 of the Agreement, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to or threatened to be made a party to or a participant in any Proceeding (including a Proceeding by or in the right of [a Covered Entity][the Company] to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by or on behalf of Indemnitee in connection with the Proceeding.

(b) For purposes of Section 8(a) of this Agreement, the meaning of the phrase "to the fullest extent permitted by applicable law" shall include but not be limited to:

i. to the fullest extent permitted by the provision of the DGCL or other applicable law that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL or such other law, and

ii. to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL or other law adopted after the date of execution of this Agreement that increase the extent to which a corporation may indemnify its directors, officers, employees and/or agents.

Section 9. **Exclusions.**

Notwithstanding any other provision in this Agreement, the Company shall not be obligated under the Agreement to make any indemnification payment or advancement of Expenses in connection with any claim or demand made against Indemnitee:

(a) for which payment actually has been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; provided, however, that notwithstanding the availability of such other indemnification and reimbursement, Indemnitee may claim indemnification and advancement of Expenses pursuant to this Agreement by assigning to the Company, at its request, Indemnitee's claims under such insurance or other indemnity provision to the extent Indemnitee has been paid by the Company; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation, or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or (iii) the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act);

(c) except as provided in Section 14(d) of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against [a Covered Entity][the Company] or its directors, officers, employees, agents and/or other indemnitees, unless (i) such indemnification is expressly required to be made by the DGCL, (ii) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation, (iii) such payment arises in connection with any mandatory counterclaim or cross-claim or affirmative defense brought or raised by Indemnitee in any Proceeding (or any part of any Proceeding), or (iv) the Company provides the indemnification or the like, in its sole discretion, pursuant to the powers vested in the Company under applicable law;

(d) on account of Indemnitee's conduct that is established by a final judgment as constituting a breach of Indemnitee's duty of loyalty to [a Covered Entity][the Company] or resulting in any personal profit or advantage to which Indemnitee was not legally entitled; or

(e) if it is ultimately determined by a court of competent jurisdiction in a final judgment, not subject to appeal, that indemnification is not lawful (and, in this respect, both the Company and Indemnitee have been advised that the Securities and Exchange Commission believes that indemnification for liabilities arising under the federal securities laws is against public policy and is, therefore, unenforceable and that claims for indemnification should be submitted to appropriate courts for adjudication).

Section 10. **Advances of Expenses.**

Notwithstanding any provision of this Agreement to the contrary, the Company shall advance, to the extent not prohibited by law, the Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee, and such advancement shall be made within thirty (30) calendar days after receipt by the Company of a statement or statements requesting such advances from time to time (which shall include invoices received by the Indemnitee in connection with such Expenses but, in the case of invoices in connection with legal services, any references to legal work performed or to expenditures made that would cause Indemnitee to waive any privilege accorded by applicable law shall not be so included), whether prior to or after final disposition of any

Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including but not limited to Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined by a court of competent jurisdiction in a final judgment, not subject to appeal, that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution by both parties of this Agreement. This Section 10 of the Agreement shall not apply to any claim made by Indemnitee for which an indemnity is excluded pursuant to Section 9 thereof.

Section 11. **Procedure for Notification and Defense of Claim.**

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof or Indemnitee's becoming aware thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding, in each case to the extent actually known to Indemnitee. The Secretary of the Company, promptly upon receipt of such a request for indemnification, shall advise the Board in writing, copying the CEO and General Counsel of the Company, that Indemnitee has requested indemnification or the like.

(b) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification under this Agreement following the final disposition of such Proceeding. The failure by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee under this Agreement or otherwise, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement.

(c) The Company will be entitled to participate in the Proceeding at its own expense. Indemnitee agrees to provide any consent or other authorization promptly to allow such participation by the Company.

(d) The Company shall not be liable to indemnify Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without the Company's prior written consent; provided, however, that the Company will not unreasonably withhold its consent to any proposed settlement.

(e) Indemnitee shall submit any claim for indemnification and/or advancement of Expenses within a reasonable time not to exceed seven (7) years after any judgment, order, settlement, dismissal, arbitral award, conviction, acceptance of a plea of nolo contendere or its equivalent, final termination or other disposition or partial disposition of any Proceeding, whichever is the later date for which Indemnitee requests indemnification and/or advancement of Expenses.

Section 12. **Procedure Upon Application for Indemnification.**

(a) Upon written request by Indemnitee for indemnification pursuant to Section 11(a) of the Agreement, a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee, or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) business days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to make such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by or on behalf of Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company will advise Indemnitee promptly in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising him/her of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) calendar days after such written notice of selection shall have been given, deliver to the Company or to

Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Court of Chancery of the State of Delaware, United States of America, has determined that such objection is without merit. If, within twenty (20) calendar days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Court of Chancery of the State of Delaware, United States of America, for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. The Company shall pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting pursuant to this Section 12(b), and the Company shall pay all reasonable fees and expenses incident to the procedures of this Section 12(b), regardless of the manner in which such Independent Counsel was selected or appointed. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(c) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

Section 13. **Presumptions and Effect of Certain Proceedings.**

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement. The Company, to the fullest extent not prohibited by law, shall have the burden of proof and the burden of persuasion by clear and convincing evidence to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense

to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(e), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) calendar days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification, to the fullest extent not prohibited by law, shall be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification; provided, however, that such 60-calendar day period may be extended for a reasonable time, not to exceed an additional thirty (30) calendar days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 13(b) shall not apply if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a) of this Agreement and if (A) within fifteen (15) calendar days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) calendar days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) calendar days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) calendar days after having been so called and such determination is made thereat.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity][Company] or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his/her conduct was unlawful.

(d) The Company acknowledges that a settlement or other disposition short of final judgment may be successful if it permits a party to avoid expense, delay, distraction, disruption and uncertainty. In the event that any Proceeding to which Indemnitee is a party or in which Indemnitee is otherwise involved or a participant is resolved in any manner other than by adverse judgment against Indemnitee (including, without limitation, settlement of such Proceeding with or without payment of money or other consideration) it shall be presumed that Indemnitee has been successful on the merits or otherwise in such Proceeding. Anyone seeking to overcome this presumption shall have the burden of proof and the burden of persuasion by clear and convincing evidence.

(e) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors, officers, employees and/or agents of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with the reasonable care by the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement. Whether or not the foregoing provisions of this Section 13(d) are satisfied, it shall in any event be presumed that Indemnitee has at all times acted in good faith and in a manner he/she reasonably believed to be in or not opposed to the best interests of the [Covered Entity][Company].

(f) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 14. **Remedies of Indemnitee.**

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) calendar days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the last sentence of Section 12(a) of this Agreement within ten (10) business days after receipt by the Company of a written request therefor, (v) payment of indemnification pursuant to Section 3, 4 or 8 of this Agreement is not made within ten (10) business days after a determination has been made that Indemnitee is entitled to indemnification, (vi) the Company or any other person or entity takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or proceeding designed to deny, limit, or to recover from, Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, or (vii) Indemnitee otherwise seeks enforcement of this Agreement, Indemnitee shall be entitled to a final adjudication by a court of his/her entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at his/her option, may seek a final award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding seeking an adjudication or an award in arbitration within one hundred and eighty (180) calendar days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 14(a); provided, however, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his/her rights under Section 5 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is not entitled to indemnification, in whole or in part, any judicial proceeding or arbitration commenced pursuant to this Section 14 shall be conducted in all respects as a *de novo* trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14 the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to Section 12(a) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a specific finding (which has become final, conclusive and binding) by the Chancery Court of the State of Delaware, USA that all or any part of such indemnification is expressly prohibited by applicable law.

(d) The Company, to the fullest extent not prohibited by law, shall be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company (i) is bound by all the provisions of this Agreement and (ii) is precluded from making any assertion to the contrary. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) business days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by or on behalf of Indemnitee in connection with any request or action brought by Indemnitee for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) If the Company disputes a portion of the amounts for which indemnification is requested, the undisputed portion shall be paid and only the disputed portion withheld from Indemnitee pending resolution of any such dispute as governed by this Agreement.

Section 15. **Non-Exclusivity; Survival of Rights: Insurance; Subrogation.**

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement (i) shall not be deemed exclusive of any other rights to which Indemnitee may now or in the future be entitled under applicable law, the Company's Certificate of Incorporation, the By-laws, any agreement, a vote of stockholders or a resolution of the Board, or otherwise and (ii) shall be interpreted independently of, and without reference to, any other such rights to which Indemnitee may at any time be entitled. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his/her Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the DGCL or other applicable law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the By-laws or the Certificate of Incorporation of the Company and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change(s). No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance or other forms of indemnification or the like for directors, officers, employees or agents of the Enterprise, Indemnitee shall be covered by such policy or policies or other forms in accordance with its or their terms to the maximum extent of the coverage or allowance available for any such director, officer, employee and/or agent under such policy or policies or other forms. If, at the time of receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt written notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers or their other equivalent counterparts in accordance with the procedures set forth in the respective policies or other forms. The Company shall thereafter take all necessary or desirable action(s) to cause such insurers or other counterparts to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies or other forms.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights and Indemnitee shall take such actions promptly upon request by the Company.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement of Expenses is

provided hereunder) if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

Section 16. **Duration of Agreement.**

(a) This Agreement shall continue until and terminate upon the later of (i) twenty (20) years after the date that Indemnitee shall have ceased to serve as a director, officer, employee and/or agent of [a Covered Entity][the Company] or (ii) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding (including any appeal) commenced by Indemnitee pursuant to Section 14 of this Agreement relating thereto.

(b) The rights of indemnification and advancement of Expenses provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, acquisition, combination, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee and/or agent of [a Covered Entity][the Company] or of any other Enterprise for any reason, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, devisees, executors and administrators and other personal and legal representatives.

(c) The Company shall require and cause any successor (whether direct or indirect by purchase, merger, acquisition, combination, consolidation or otherwise) to all or substantially all of the business or assets of the Company to expressly, by written agreement with Indemnitee, assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession or assignment had taken place.

(d) No legal action will be brought and no cause of action will be asserted by or in the right of the Company against an Indemnitee or an Indemnitee's estate, spouse, heirs, executors or personal or legal representatives after the expiration of five (5) years from the date of accrual of such cause of action, and any claim or cause of action of the Company will be extinguished and deemed released unless asserted by the timely filing of a legal action within such five (5)-year period; provided, however, that if any shorter period of limitations is otherwise applicable to such cause of action, such shorter period will govern.

Section 17. **Severability.**

If any provision or provisions of this Agreement (or any portion thereof) shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including but not limited to each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent

permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including but not limited to each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 18. **Entire Agreement.**

This Agreement constitutes the entire agreement between the parties with respect to the specific subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the same subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Company's Certificate of Incorporation, the By-laws, any directors' and officers' insurance coverage maintained by the Company, and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 19. **Modification, Waiver, Termination and Cancellation.**

No supplement, modification, amendment, termination, or cancellation of this Agreement shall be binding unless executed in writing by both of the parties hereto, or as otherwise expressly provided herein. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement (whether or not similar), nor shall any waiver constitute a continuing waiver.

Section 20. **Notices.**

All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the fifth (5^{th}) business day after the date on which it is so mailed, (c) one (1) business day after timely deposit with a nationally recognized overnight courier for next business day delivery, or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received, in all cases with all postage, delivery or similar charges prepaid and addressed to the party or parties to be notified at the addresses set forth below:

(a) If to Indemnitee, at the address indicated on the first page of this Agreement for Indemnitee.

(b) If to the Company, at:

Brickell Biotech, Inc.
5777 Central Avenue, Suite 102
Boulder, CO 80301
Attention: Andy Sklawer, COO
Phone: 786-304-2083
Fax: 786-524-2721

Either party may change the address, fax or person to which any such notice shall be sent by like notice in writing to the other party, provided that no such change shall be effective as against a party unless and until actually received by such party.

Section 21. **Contribution.**

(a) To the fullest extent permissible under applicable law and not inconsistent with the remaining provisions of this Section 21, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by or on behalf of Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement, and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by [a Covered Entity][the Company] and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the [Covered Entity][Company] (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

(b) Whether or not the indemnification provided in this Agreement is available, in respect of any Proceeding in which [a Covered Entity] [the Company] is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such Proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any Proceeding in which [a Covered Entity][the Company] is jointly liable with Indemnitee (or would be if joined in such Proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.

(c) Without diminishing or impairing the obligations of the Company set forth in the preceding subparagraph, if, for any reason, Indemnitee shall elect or be required to pay all or any portion of any judgment or settlement in any Proceeding in which [a Covered Entity][the Company] is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall contribute to the amount of Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred and paid or payable by Indemnitee in proportion to the relative benefits received by the [Covered Entity][Company] and all officers, directors, employees or agents of the [Covered Entity] [Company], other than

Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such Proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the [Covered Entity] [Company] and all officers, directors, employees or agents of the [Covered Entity][Company] other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such Expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the [Covered Entity][Company] and all officers, directors, employees and/or agents of the [Covered Entity][Company], other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary, and the degree to which their conduct is active or passive.

Section 22. **Applicable Law and Consent to Jurisdiction.**

This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, USA, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware, USA (the "Delaware Court") and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum. If the laws of the State of Delaware, USA, are hereafter amended to permit the Company to provide broader indemnification rights than said laws permitted the Company to provide prior to such amendment, the rights of indemnification and advancement of Expenses conferred by this Agreement automatically shall be broadened to the fullest extent permitted by the laws of the State of Delaware, as so amended and of the effective date of such amendment.

Section 23. **Identical Counterparts.**

This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 24. **Miscellaneous.**

Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

[THIS SPACE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed between them as of the date of last signature immediately below.

BRICKELL BIOTECH, INC.

By: _____
Name: Robert B. Brown
Title: CEO
Date: _____

_____

By: _____
Name: _____
Title: _____
Date: _____

Exhibit 10.3

BRICKELL BIOTECH, INC.
2020 OMNIBUS LONG-TERM INCENTIVE PLAN

Restricted Stock Unit Award Agreement

Brickell Biotech, Inc. (the "Company"), pursuant to its 2020 Omnibus Long-Term Incentive Plan (the "Plan"), hereby grants an award of Restricted Stock Units to you, the Participant named below. The terms and conditions of this Award are set forth in this Restricted Stock Unit Award Agreement (the "Agreement"), consisting of this cover page and the Terms and Conditions on the following pages, and in the Plan document, a copy of which has been provided to you. Any capitalized term that is used but not defined in this Agreement shall have the meaning assigned to it in the Plan as it currently exists or as it is amended in the future.

Name of Participant: [_____]	
Number of Restricted Stock Units: [_____]	Grant Date: _____, 20__
Vesting Schedule:	
Scheduled Vesting Dates	Number of Restricted Stock Units that Vest

By signing below or otherwise evidencing your acceptance of this Agreement in a manner approved by the Company, you agree to all of the terms and conditions contained in this Agreement and in the Plan document. You acknowledge that you have received and reviewed these documents and that they set forth the entire agreement between you and the Company regarding this Award of Restricted Stock Units, except as set forth in any separate employment (or similar) agreement or severance plan to which you are a party or a participant.

PARTICIPANT:

_____

BRICKELL BIOTECH, INC.

By:_____
Title:_____

BRICKELL BIOTECH, INC.
2020 Omnibus Long-Term Incentive Plan
Restricted Stock Unit Award Agreement

Terms and Conditions

1. **Grant of Restricted Stock Units**. The Company hereby confirms the grant to you, as of the Grant Date and subject to the terms and conditions in this Agreement and the Plan, of the number of Restricted Stock Units specified on the cover page of this Agreement (the "Units"). Each Unit represents the right to receive one share of the Company's Common Stock. Prior to their settlement or forfeiture in accordance with the terms of this Agreement, the Units granted to you will be credited to an account in your name maintained by the Company. This account shall be unfunded and maintained for book-keeping purposes only, with the Units simply representing an unfunded and unsecured contingent obligation of the Company.

2. **Restrictions Applicable to Units**. Neither this Award nor the Units subject to this Award may be sold, assigned, transferred, exchanged or encumbered, voluntarily or involuntarily, other than a transfer upon your death in accordance with your will or by the laws of descent and distribution. Following any such transfer, this Award shall continue to be subject to the same terms and conditions that were applicable to this Award immediately prior to its transfer. Any attempted transfer in violation of this Section 2 shall be void and without effect. The Units and your right to receive shares of Common Stock ("Shares") in settlement of the Units under this Agreement shall be subject to forfeiture as provided in Section 5 until satisfaction of the vesting conditions set forth in Section 4.

3. **No Stockholder Rights**. The Units subject to this Award do not entitle you to any rights of a holder of Common Stock. You will not have any of the rights of a stockholder of the Company in connection with the grant of Units subject to this Agreement unless and until Shares are issued to you upon settlement of the Units as provided in Section 6.

4. **Vesting of Units**. For purposes of this Agreement, "Vesting Date" means any date, including the Scheduled Vesting Dates specified in the Vesting Schedule on the cover page of this Agreement, on which Units subject to this Agreement vest as provided in this Section 4.

(a) Scheduled Vesting. If you remain a Service Provider (which is defined as an individual who has not experienced a Termination Date) continuously from the Grant Date specified on the cover page of this Agreement, then the Units will vest in the amounts and on the Scheduled Vesting Dates specified in the Vesting Schedule.

(b) Accelerated Vesting. The vesting of outstanding Units will be accelerated under the circumstances provided below:

(1) *Death or Disability*. If your service to the Company or Related Companies terminates prior to the final Scheduled Vesting Date due to your death or Disability, then a pro rata portion (based on the number of days during which you were a Service Provider since the most recent Scheduled Vesting Date (or since the Grant Date if there was no previous Scheduled Vesting Date) as a percentage of the total number of days between such date and the next Scheduled Vesting Date) of the Units scheduled to vest as of the next Scheduled Vesting Date shall vest as of such Termination Date.

(2) *Change in Control*. If a Change in Control occurs while you continue to be a Service Provider and prior to the final Scheduled Vesting Date, the following provisions shall apply:

(a) If, within 24 months after a Change of Control (A) described in Section 2.6(a) or Section 2.6(d) of the Plan or (B) described in Section 2.6(b) of the Plan and in connection with which the surviving or acquiring entity (or its parent entity) has continued, assumed or replaced this Award, you cease to be a Service Provider due either to an involuntary termination for reasons other than Cause (as defined in Section 7 below) or a resignation for Good Reason (as defined in Section 7 below), then all unvested Units shall immediately vest in full.

(b) If this Award is not continued, assumed or replaced in connection with a Change in Control pursuant to Section 2.6(b) of the Plan, then all unvested Units shall immediately vest in full upon the occurrence of the Change in Control in accordance with Section 7.2 of the Plan.

(c) In the event of a Change of Control described in Section 2.6(c) of the Plan, then all unvested Units shall immediately vest in full upon the occurrence of the Change in Control.

(3) *Other Agreements or Plans.* Unvested Units shall also vest as provided in any separate employment (or similar) agreement or severance plan to which you are a party or a participant.

5. **Effect of Termination of Service**. Except as otherwise provided in accordance with Section 4(b) above, if you cease to be a Service Provider, you will forfeit all unvested Units.

6. **Settlement of Units**. After any Units vest pursuant to Section 4, the Company shall, as soon as practicable (but no later than the 15 th day of the third calendar month following the Vesting Date), cause to be issued and delivered to you (or to your personal representative or your designated beneficiary or estate in the event of your death, as applicable) one Share in payment and settlement of each vested Unit. Delivery of the Shares shall be effected by the issuance of a stock certificate to you, by an appropriate entry in the stock register maintained by the Company's transfer agent with a notice of issuance provided to you, or by the electronic delivery of the Shares to a brokerage account you designate, and shall be subject to the tax withholding provisions of Section 8 and compliance with all applicable legal requirements as provided in the Plan, and shall be in complete satisfaction and settlement of such vested Units. The Company will pay any original issue or transfer taxes with respect to the issue and transfer of Shares to you pursuant to this Agreement, and all fees and expenses incurred by it in connection therewith. If the Units that vest include a fractional Unit, the Company shall round the number of vested Units to the nearest whole Unit prior to issuance of Shares as provided herein.

7. **Definitions**.

(a) Cause. "Cause" shall, if you have an employment agreement with the Company, have the meaning set forth in your employment agreement. If you do not have an employment agreement with the

Company, "Cause" means: (i) an action or omission of the Participant which constitutes a willful and material breach of, or failure or refusal (other than by reason of his Disability) to perform his duties under any agreement between the Participant and the Company or the Related Companies which is not cured within fifteen (15) days after receipt by the Participant of written notice of same; (ii) fraud, embezzlement, misappropriation of funds or breach of trust in connection with his services to the Company or the Related Companies; (iii) conviction of any crime which involves dishonesty or a breach of trust; or (iv) gross negligence in connection with the performance of the Participant's duties, which is not cured within fifteen (15) days after written receipt by the Participant of written notice of same.

(b) Disability. "Disability" means (i) any permanent and total disability under any long-term disability plan or policy of the Company or the Related Companies that covers the Participant, or (ii) if there is no such long-term disability plan or policy, "total and permanent disability" within the meaning of Code Section 22(e)(3).

(c) Good Reason. "Good Reason" shall, if you have an employment agreement with the Company, have the meaning set forth in your employment agreement. If you do not have an employment agreement with the Company, "Good Reason" means: (i) the assignment to the Participant of any duties inconsistent in any respect with the Participant's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities, or any other action by the Company which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Participant; (ii) any failure by the Company to comply with any of the compensation-related provisions of any employment agreement to which the Participant is a party, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Participant; *provided however*, that in order to effect resignation for Good Reason all of the following must occur: (x) Participant must provide the Company with written notice within the sixty-day period following the event(s) giving rise to Participant's intent to voluntarily resign his employment for Good Reason (y) such event is not remedied by within thirty (30) days following the Company's receipt of such written notice; and (z) Participant's resignation is effective not later than thirty (30) days after the expiration of such thirty (30) day cure period.

8. **Tax Consequences and Withholding**. No Shares will be delivered to you in settlement of vested Units unless you have made arrangements acceptable to the Company for payment of any federal, state, local or foreign withholding taxes that may be due as a result of the delivery of the Shares. You hereby authorize the Company (or the Related Companies) to withhold from payroll or other amounts payable to you any sums required to satisfy such withholding tax obligations, and otherwise agree to satisfy such obligations in accordance with the provisions of Section 10.2 of the Plan. You may elect to satisfy such withholding tax obligations by having the Company withhold a number of Shares that would otherwise be issued to you in settlement of the Units and that have a fair market value equal to the amount of such withholding tax obligations by notifying the Company of such election prior to the Vesting Date.

9. **Notices**. Every notice or other communication relating to this Agreement shall be in writing and shall be mailed to or delivered (including electronically) to the party for whom it is intended at such address as may from time to time be designated by it in a notice mailed or delivered to the other party as herein provided. Unless and until some other address is so designated, all notices or communications by you to the Company shall be mailed or delivered to the Company, to the attention of its Chief Accounting Officer, at its office at 5777 Central Ave., Suite 102, Boulder, CO 80301, jbreton@brickellbio.com, and

all notices or communications by the Company to you may be given to you personally or may be mailed or, if you are still a Service Provider, emailed to you at the address indicated in the Company's records as your most recent mailing or email address.

10. **Additional Provisions**.

(a) No Right to Continued Service. This Agreement does not give you a right to continued service with the Company or the Related Companies, and the Company and the Related Companies may terminate your service at any time and otherwise deal with you without regard to the effect it may have upon you under this Agreement.

(b) Governing Plan Document. This Agreement and the Award are subject to all the provisions of the Plan, and to all interpretations, rules and regulations which may, from time to time, be adopted and promulgated by the Committee pursuant to the Plan. If there is any conflict between the provisions of this Agreement and the Plan, the provisions of the Plan will govern. If there is any conflict between this Agreement or the Plan and any separate employment (or similar) agreement or severance plan to which you are a party or a participant, the provisions of the other agreement or plan will govern.

(c) Choice of Law. This Agreement will be interpreted and enforced under the laws of the state of Delaware (without regard to its conflicts or choice of law principles).

(d) Severability. The provisions of this Agreement shall be severable and if any provision of this Agreement is found by any court to be unenforceable, in whole or in part, the remainder of this Agreement shall nevertheless be enforceable and binding on the parties. You also agree that any trier of fact may modify any invalid, overbroad or unenforceable provision of this Agreement so that such provision, as modified, is valid and enforceable under applicable law.

(e) Binding Effect. This Agreement will be binding in all respects on your heirs, representatives, successors and assigns, and on the successors and assigns of the Company.

(f) Section 409A of the Code. The award of Units as provided in this Agreement and any issuance of Shares or payment pursuant to this Agreement are intended to be exempt from Section 409A of the Code under the short-term deferral exception specified in Treas. Reg. § 1.409A-l(b)(4).

(g) Electronic Delivery and Acceptance. The Company may deliver any documents related to this Restricted Stock Unit Award by electronic means and request your acceptance of this Agreement by electronic means. You hereby consent to receive all applicable documentation by electronic delivery and to participate in the Plan through an on-line (and/or voice activated) system established and maintained by the Company or the Company’s third-party stock plan administrator.

By signing the cover page of this Agreement or otherwise accepting this Agreement in a manner approved by the Company, you agree to all the terms and conditions described above and in the Plan document.

Exhibit 10.4

BRICKELL BIOTECH, INC.
2020 OMNIBUS LONG-TERM INCENTIVE PLAN

Non-Qualified Stock Option Award Agreement

Brickell Biotech, Inc. (the "Company"), pursuant to its 2020 Omnibus Long-Term Incentive Plan (the "Plan"), hereby grants an Option to purchase shares of the Company's common stock to you, the Participant named below. The terms and conditions of the Option Award are set forth in this Non-Qualified Stock Option Award Agreement (the "Agreement"), consisting of this cover page and the Terms and Conditions on the following pages, and in the Plan document, a copy of which has been provided to you. Any capitalized term that is used but not defined in this Agreement shall have the meaning assigned to it in the Plan as it currently exists or as it is amended in the future.

Name of Participant: [_____]	
Number of Shares Covered: [_____]	Grant Date: _____, 20__
Exercise Price Per Share: $[_____]	Expiration Date: _____, 20__
Vesting and Exercise Schedule: Scheduled Vesting Dates	Portion of Shares as to Which Option Becomes Vested and Exercisable

By signing below or otherwise evidencing your acceptance of this Agreement in a manner approved by the Company, you agree to all of the terms and conditions contained in this Agreement and in the Plan document. You acknowledge that you have received and reviewed these documents and that they set forth the entire agreement between you and the Company regarding your right to purchase shares of the Company's common stock pursuant to this Option, except as set forth in any separate employment (or similar) agreement or severance plan to which you are a party or a participant.

PARTICIPANT:

_____

BRICKELL BIOTECH, INC.

By:_____
Title:_____

BRICKELL BIOTECH, INC.
2020 Omnibus Long-Term Incentive Plan
Non-Qualified Stock Option Award Agreement

Terms and Conditions

1. **Non-Qualified Stock Option**. This Option is not intended to be an "incentive stock option" within the meaning of Section 422 of the Internal Revenue Code and will be interpreted accordingly.

2. **Vesting and Exercisability of Option**.

(a) Scheduled Vesting. This Option will vest and become exercisable as to the number of shares of Common Stock ("Shares") and on the dates specified in the Vesting and Exercise Schedule on the cover page to this Agreement, so long as you remain a Service Provider (which is defined as an individual who has not experienced a Termination Date) on such dates. The Vesting and Exercise Schedule is cumulative, meaning that to the extent the Option has not already been exercised and has not expired or been terminated or cancelled, you or the person otherwise entitled to exercise the Option as provided in this Agreement may at any time purchase all or any portion of the Shares subject to the vested portion of the Option.

(b) Accelerated Vesting. The vesting of outstanding Options will be accelerated under the circumstances provided below:

(1) *Death or Disability*. If your service to the Company or Related Companies terminates prior to the final Scheduled Vesting Date due to your death or Disability, then a pro rata portion (based on the number of days during which you were a Service Provider since the most recent Scheduled Vesting Date (or since the Grant Date if there was no previous Scheduled Vesting Date) as a percentage of the total number of days between such date and the next Scheduled Vesting Date) of the Options scheduled to vest as of the next Scheduled Vesting Date shall vest as of such Termination Date.

(2) *Change in Control*. If a Change in Control occurs while you continue to be a Service Provider and prior to the final Scheduled Vesting Date, the following provisions shall apply:

(a) If, within 24 months after a Change of Control (A) described in Section 2.6(a) or Section 2.6(d) of the Plan or (B) described in Section 2.6(b) of the Plan and in connection with which the surviving or acquiring entity (or its parent entity) has continued, assumed or replaced this Award, you cease to be a Service Provider due either to an involuntary termination for reasons other than Cause (as defined in Section 11 below) or a resignation for Good Reason (as defined in Section 11 below), then all unvested Options shall immediately vest in full.

(b) If this Award is not continued, assumed or replaced in connection with a Change in Control pursuant to Section 2.6(b) of the Plan, then all unvested Options shall immediately vest in full upon the occurrence of the Change in Control and paid out in accordance with Section 7.2 of the Plan.

(c) In the event of a Change of Control described in Section 2.6(c) of the Plan, then all unvested Options shall immediately vest in full upon the occurrence of the Change in Control and paid out in accordance with Section 7.2 of the Plan.

(3) *Other Agreements or Plans.* Unvested Options shall also vest as provided in any separate employment (or similar) agreement or severance plan to which you are a party or a participant.

3. **Expiration**. This Option will expire and will no longer be exercisable at 5:00 p.m. Eastern Time on the earliest of:

(a) The expiration date specified on the cover page of this Agreement;

(b) Upon your Termination Date if you are terminated for Cause;

(c) Upon the expiration of any applicable period specified in Sections 2 and 4 of this Agreement during which this Option may be exercised after your termination of service; or

(d) The date (if any) fixed for termination or cancellation of this Option pursuant to Section 7.2 of the Plan.

4. **Service Requirement.** Except as otherwise provided below or in Section 2 of this Agreement, this Option may be exercised only while you continue to provide service to the Company or Related Companies, and only if you have continuously provided such service since the Grant Date of this Option. If your service with the Company and all the Related Companies terminates, the following provisions shall apply:

(a) Upon termination of service for Cause, all unexercised Options shall be immediately forfeited without consideration.

(b) Upon termination of service for any other reason, all unexercisable portions of the Options shall be immediately forfeited without consideration.

(c) Upon termination of service for any reason other than Cause, death or Disability, the currently vested and exercisable portion of the Options may be exercised for a period of three months after the date of such termination. However, if a Participant thereafter dies during such three-month period, the vested and exercisable portion of the Options may be exercised for a period of one year after the date of such termination.

(d) Upon termination of service due to death or Disability, the currently vested and exercisable portion of the Options may be exercised for a period of one year after the date of such termination.

5. **Exercise of Option**. Subject to Section 4, the vested and exercisable portion of this Option may be exercised in whole or in part at any time during the Option term by delivering a written or electronic notice of exercise to the person or entity designated by the Company, and by providing for payment of the exercise price of the Shares being acquired and any related withholding taxes. The notice of exercise must be in a form approved by the Company and state the number of Shares to be purchased, the method of payment of the aggregate exercise price and the directions for the delivery of the Shares to be acquired, and must be signed or otherwise authenticated by the person exercising the Option. If you are not the

person exercising the Option, the person submitting the notice also must submit appropriate proof of his/her right to exercise the Option.

6. **Payment of Exercise Price**. When you submit your notice of exercise, you must include payment of the exercise price of the Shares being purchased through one or a combination of the following methods:

(a) Cash or by promissory note;

(b) By means of a broker-assisted cashless exercise in which you irrevocably instruct your broker to deliver proceeds of a sale of all or a portion of the Shares to be issued pursuant to the exercise to the Company in payment of the exercise price of such Shares; or

(c) By delivery to the Company of Shares (by actual delivery or attestation of ownership in a form approved by the Company) already owned by you that are not subject to any security interest and that have an aggregate Fair Market Value on the date of exercise equal to the exercise price of the Shares being purchased; or

(d) By authorizing the Company to retain, from the total number of Shares as to which the Option is being exercised, that number of Shares having a Fair Market Value on the date of exercise equal to the exercise price for the total number of Shares as to which the Option is being exercised.

7. **Withholding Taxes**. You may not exercise this Option in whole or in part unless you make arrangements acceptable to the Company for payment of any federal, state, local or foreign withholding taxes that may be due as a result of the exercise of this Option. You hereby authorize the Company (or the Related Companies) to withhold from payroll or other amounts payable to you any sums required to satisfy such withholding tax obligations, and otherwise agree to satisfy such obligations in accordance with the provisions of Section 10.2 of the Plan. You may satisfy such withholding tax obligations by delivering Shares you already own or by having the Company retain a portion of the Shares being acquired upon exercise of the Option, provided you notify the Company in advance of any exercise of your desire to pay withholding taxes in this manner. Delivery of Shares upon exercise of this Option is subject to the satisfaction of applicable withholding tax obligations.

8. **Delivery of Shares.** As soon as practicable after the Company receives the notice of exercise and payment of the exercise price as provided above, and has determined that all other conditions to exercise, including satisfaction of any withholding tax obligations and compliance with applicable laws, have been satisfied, it shall deliver to the person exercising the Option, in the name of such person, the Shares being purchased, as evidenced by issuance of a stock certificate or certificates, electronic delivery of such Shares to a brokerage account designated by such person, or book-entry registration of such Shares with the Company's transfer agent. The Company shall pay any original issue or transfer taxes with respect to the issue or transfer of the Shares and all fees and expenses incurred by it in connection therewith. All Shares so issued shall be fully paid and nonassessable.

9. **Transfer of Option**. During your lifetime, only you may exercise this Option except in the case of a transfer described below. You may not assign or transfer this Option except for a transfer upon your death in accordance with your will or by the laws of descent and distribution. The Option held by any such transferee will continue to be subject to the same terms and conditions that were applicable to the Option immediately prior to its transfer and may be exercised by such transferee as and to the extent that the Option has become exercisable and has not terminated in accordance with the provisions of the Plan and this Agreement.

10. **No Stockholder Rights Before Exercise**. Neither you nor any permitted transferee of this Option will have any of the rights of a stockholder of the Company with respect to any Shares subject to this Option until a certificate evidencing such Shares has been issued, electronic delivery of such Shares has been made to your designated brokerage account, or an appropriate book entry in the Company's stock register has been made. No adjustments shall be made for dividends or other rights if the applicable record date occurs before your stock certificate has been issued, electronic delivery of your Shares has been made to your designated brokerage account, or an appropriate book entry in the Company's stock register has been made, except as otherwise described in the Plan.

11. **Definitions**.

(a) Cause. "Cause" shall, if you have an employment agreement with the Company, have the meaning set forth in your employment agreement. If you do not have an employment agreement with the Company, "Cause" means: (i) an action or omission of the Participant which constitutes a willful and material breach of, or failure or refusal (other than by reason of his disability) to perform his duties under any agreement between the Participant and the Company or the Related Companies which is not cured within fifteen (15) days after receipt by the Participant of written notice of same; (ii) fraud, embezzlement, misappropriation of funds or breach of trust in connection with his services to the Company or the Related Companies; (iii) conviction of any crime which involves dishonesty or a breach of trust; or (iv) gross negligence in connection with the performance of the Participant's duties, which is not cured within fifteen (15) days after written receipt by the Participant of written notice of same.

(b) Disability. "Disability" means (i) any permanent and total disability under any long-term disability plan or policy of the Company or the Related Companies that covers the Participant, or (ii) if there is no such long-term disability plan or policy, "total and permanent disability" within the meaning of Code Section 22(e)(3).

(c) Good Reason. "Good Reason" shall, if you have an employment agreement with the Company, have the meaning set forth in your employment agreement. If you do not have an employment agreement with the Company, "Good Reason" means (i) the assignment to the Participant of any duties inconsistent in any respect with the Participant's position (including status, offices, titles and reporting requirements), authority, duties or responsibilities, or any other action by the Company which results in a diminution in such position, authority, duties or responsibilities, excluding for this purpose an isolated, insubstantial and inadvertent action not taken in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Participant; (ii) any failure by the Company to comply with any of the compensation-related provisions of any employment agreement to which the Participant is a party, other than an isolated, insubstantial and inadvertent failure not occurring in bad faith and which is remedied by the Company promptly after receipt of notice thereof given by the Participant; *provided however*, that in order to effect resignation for Good Reason all of the following must occur: (x) Participant must provide the Company with written notice within the sixty-day period following the event(s) giving rise to Participant's intent to voluntarily resign his employment for Good Reason (y) such event is not remedied by within thirty (30) days following the Company's receipt of such written notice; and (z) Participant's resignation is effective not later than thirty (30) days after the expiration of such thirty (30) day cure period.

12. **Additional Provisions**.

(a) No Right to Continued Service. This Agreement does not give you a right to continued service with the Company or the Related Companies, and the Company and the Related Companies may

terminate your service at any time and otherwise deal with you without regard to the effect it may have upon you under this Agreement.

(b) Governing Plan Document. This Agreement and Option are subject to all the provisions of the Plan, and to all interpretations, rules and regulations which may, from time to time, be adopted and promulgated by the Committee pursuant to the Plan. If there is any conflict between the provisions of this Agreement and the Plan, the provisions of the Plan will govern. If there is any conflict between this Agreement or the Plan and any separate employment (or similar) agreement or severance plan to which you are a party or a participant, the provisions of the other agreement or plan will govern.

(c) Choice of Law. This Agreement will be interpreted and enforced under the laws of the state of Delaware (without regard to its conflicts or choice of law principles).

(d) Severability. The provisions of this Agreement shall be severable and if any provision of this Agreement is found by any court to be unenforceable, in whole or in part, the remainder of this Agreement shall nevertheless be enforceable and binding on the parties. You also agree that any trier of fact may modify any invalid, overbroad or unenforceable provision of this Agreement so that such provision, as modified, is valid and enforceable under applicable law.

(e) Binding Effect. This Agreement will be binding in all respects on your heirs, representatives, successors and assigns, and on the successors and assigns of the Company.

(f) Other Agreements. You agree that in connection with the exercise of this Option, you will execute such documents as may be necessary to become a party to any stockholder, voting or similar agreements as the Company may require.

(g) Electronic Delivery and Acceptance. The Company may deliver any documents related to this Option Award by electronic means and request your acceptance of this Agreement by electronic means. You hereby consent to receive all applicable documentation by electronic delivery and to participate in the Plan through an on-line (and/or voice activated) system established and maintained by the Company or the Company's third-party stock plan administrator.

By signing the cover page of this Agreement or otherwise accepting this Agreement in a manner approved by the Company, you agree to all the terms and conditions described above and in the Plan document.

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, 2020

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, R. Michael Carruthers, 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, 2020

By: /s/ R. Michael Carruthers
R. Michael Carruthers
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 R. Michael Carruthers, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2020, 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, 2020

/s/ R. Michael Carruthers

R. Michael Carruthers

Chief Financial Officer
(Principal Financial Officer)

Date: August 12, 2020

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