

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 March 31, 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
(State or other jurisdiction of incorporation or organization)

93-0948554
(I.R.S. Employer Identification No.)

5777 Central Avenue, Boulder, CO
(Address of principal executive offices)

80301
(Zip Code)

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

Securities registered pursuant to Section 12(b) of the 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 May 7, 2020, there were 9,674,409 shares of the registrant's common stock outstanding.

BRICKELL BIOTECH, INC.
FORM 10-Q
INDEX

PART I. FINANCIAL INFORMATION	
ITEM 1. Financial Statements (Unaudited)	<u>4</u>
ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>20</u>
ITEM 3. Quantitative and Qualitative Disclosures About Market Risk	<u>27</u>
ITEM 4. Controls and Procedures	<u>27</u>
PART II. OTHER INFORMATION	
ITEM 1. Legal Proceedings	<u>29</u>
ITEM 1A. Risk Factors	<u>29</u>
ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds	<u>30</u>
ITEM 3. Defaults Upon Senior Securities	<u>30</u>
ITEM 4. Mine Safety Disclosures	<u>30</u>
ITEM 5. Other Information	<u>30</u>
ITEM 6. Exhibits	<u>31</u>

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,127	\$ 7,232
Marketable securities, available-for-sale	—	4,497
Prepaid expenses and other current assets	5,765	6,240
Total current assets	12,892	17,969
Property and equipment, net	13	16
Operating lease right-of-use asset	133	159
Total assets	<u>\$ 13,038</u>	<u>\$ 18,144</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,137	\$ 2,245
Accrued liabilities	5,124	6,379
Lease liability, current portion	80	78
Deferred revenue	750	1,795
Total current liabilities	7,091	10,497
Lease liability, net of current portion	53	73
Total liabilities	7,144	10,570
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, \$0.01 par value, 50,000,000 shares authorized at March 31, 2020 and December 31, 2019; 9,671,904 and 8,480,968 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	97	85
Additional paid-in capital	94,880	92,497
Accumulated other comprehensive loss	—	(28)
Accumulated deficit	(89,083)	(84,980)
Total stockholders' equity	5,894	7,574
Total liabilities and stockholders' equity	<u>\$ 13,038</u>	<u>\$ 18,144</u>

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 March 31,	
	2020	2019
Collaboration revenue	\$ 1,046	\$ 3,492
Operating expenses:		
Research and development	2,664	6,019
General and administrative	2,481	2,066
Total operating expenses	5,145	8,085
Loss from operations	(4,099)	(4,593)
Investment and other income (loss), net	(4)	6
Interest expense	—	(224)
Change in fair value of warrant liability	—	231
Net loss	(4,103)	(4,580)
Reduction of redeemable convertible preferred stock to redemption value	—	10,519
Net income (loss) attributable to common stockholders	\$ (4,103)	\$ 5,939
Net income (loss) per common share attributable to common stockholders, basic	\$ (0.45)	\$ 10.08
Net loss per common share attributable to common stockholders, diluted	\$ (0.45)	\$ (2.48)
Weighted-average shares used to compute net income (loss) per share attributable to common stockholders, basic	9,106,209	589,001
Weighted-average shares used to compute net loss per share attributable to common stockholders, diluted	9,106,209	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 March 31,	
	2020	2019
Net loss	\$ (4,103)	\$ (4,580)
Other comprehensive loss:		
Unrealized gain on available-for-sale marketable securities arising during holding period, net of tax benefit of \$0	28	—
Total comprehensive loss	<u>\$ (4,075)</u>	<u>\$ (4,580)</u>

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

	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)

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (4,103)	\$ (4,580)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	3	12
Accretion of discount on marketable securities	25	—
Change in fair value of warrant liability	—	(231)
Amortization of discounts and financing costs	—	101
Stock-based compensation	403	384
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	483	40
Accounts payable	(1,108)	2,521
Accrued liabilities	(1,268)	(72)
Deferred revenue	(1,045)	(3,491)
Net cash used in operating activities	<u>(6,610)</u>	<u>(5,316)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturities of marketable securities	4,500	—
Capital expenditures	—	(2)
Net cash provided by (used in) investing activities	<u>4,500</u>	<u>(2)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock and warrants, net of offering cost	1,990	—
Proceeds from the exercise of warrants	15	—
Proceeds from issuance of convertible promissory notes	—	1,315
Payments of principal of note payable	—	(795)
Net cash provided by financing activities	<u>2,005</u>	<u>520</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	<u>(105)</u>	<u>(4,798)</u>
CASH AND CASH EQUIVALENTS—BEGINNING	<u>7,232</u>	<u>8,067</u>
CASH AND CASH EQUIVALENTS—ENDING	<u>\$ 7,127</u>	<u>\$ 3,269</u>
Supplement Disclosure of Cash Flow Information:		
Interest paid	\$ —	\$ 127
Supplement Disclosure of Non-Cash Investing and Financing Activities:		
Reduction of redeemable convertible preferred stock to redemption value	\$ —	\$ (10,519)
Warrants to purchase common stock issued with convertible promissory notes	\$ —	\$ 264
Derivative liability issued with convertible promissory notes	\$ —	\$ 256
Accretion of redeemable convertible preferred stock issuance costs	\$ —	\$ 10

See accompanying notes to these condensed consolidated financial statements.

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

NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

Brickell Biotech, Inc. (the “Company” or “Brickell”) is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated prescription therapeutics for 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 three months ended March 31, 2020, the Company had a net loss of \$4.1 million and net cash used in operating activities of \$6.6 million. As of March 31, 2020, the Company had cash and cash equivalents of \$7.1 million and an accumulated deficit of \$89.1 million.

The Company believes that its cash and cash equivalents as of March 31, 2020, combined with \$4.0 million in refundable prepaid research and development expenses, funds received under the Paycheck Protection Program (see Note 9. “Subsequent Events”), 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. If the Company is unable to raise additional capital, including under the Purchase Agreement, the Company expects to conserve resources, including but not limited to potentially reducing cash compensation arrangements to management, employee and/or contractor downsizing, and further reductions in operating expenditures. The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company’s research and development activities. Additional funding beyond the sale of additional shares of common stock under the Purchase Agreement will be required in the future to proceed with the Company’s current and proposed research activities, including conducting the 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 months ended March 31, 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 tables set forth the fair value of the Company’s financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

	Level 1 (1)	
	March 31, 2020	December 31, 2019
Assets:		
Money market funds	\$ 7,127	\$ 7,232
U.S. treasuries	—	4,497
Total	\$ 7,127	\$ 11,729

(1) No assets or liabilities as of each respective date were identified as Level 2 or 3 based on the three-tier fair value hierarchy.

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 soffipronium 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 fees were representative of this type of a relationship. If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, 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 sofipronium 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 March 31, 2020 and 2019, the Company recognized revenue of \$1.0 million and \$3.5 million, respectively, related to the Kaken R&D Payment. As of March 31, 2020 and December 31, 2019, the Company had a deferred revenue balance related to the Kaken R&D Payment of \$0.8 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 loss per common share, because their inclusion would be anti-dilutive:

	Three Months Ended March 31,	
	2020	2019
Outstanding warrants	2,662,529	94,572
Outstanding options	1,654,198	625,428
Unvested restricted stock units	201,488	—
Redeemable convertible preferred stock (as converted into common stock)	—	1,256,466
Promissory notes (as converted into common stock)	—	42,442
Total	4,518,215	2,018,908

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):

	March 31, 2020	December 31, 2019
Accrued contracted research and development services	\$ 4,758	\$ 4,532
Accrued professional fees	273	1,788
Accrued compensation	93	59
Total	\$ 5,124	\$ 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 months ended March 31, 2019, the Company recognized \$13 thousand of interest expense, including \$10 thousand of accretion of discounts using an effective interest rate of 12.00%. During the three months ended March 31, 2020, no interest expense was recognized.

NOTE 5. NOTE PAYABLE

On February 18, 2016, the Company entered into a loan and security agreement (the "Loan Agreement") with Hercules Capital, Inc. (the "Lender") under which the Company borrowed \$7.5 million upon the execution of the Loan Agreement on February 18, 2016. The interest rate applicable to each tranche was variable based upon the greater of either (i) 9.2% and (ii) the sum of (a) the Prime Rate as reported in The Wall Street Journal minus 3.5%, plus (b) 9.2%. 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 March 31, 2020, there were no remaining unaccreted debt discounts and issuance costs.

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 \$18 thousand for the three months ended March 31, 2020, and was included in operating expense. As of March 31, 2020, the remaining lease term was 1.6 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 March 31, 2020 and 2019 was \$23 thousand and \$28 thousand, respectively.

The following is a summary of the contractual obligations related to operating lease commitments as of March 31, 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	\$	92
1-3 years		54
3-5 years		—
More than 5 years		—
Imputed interest		(13)
Total	\$	<u>133</u>

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. The Company is required to further 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) a specified cash amount following the occurrence of certain new milestone events.

The Company also agreed to issue to Bodor (i) \$500,000 of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time the Company enrolls its first patient in a Phase 3 pivotal clinical trial in the United States for subjects with hyperhidrosis and (ii) \$1.0 million of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time the Company submits a new drug application with the FDA for a product containing sofpironium bromide. If the Company enters into a change of control transaction prior to the occurrence of either of such triggering events, any amount not previously paid in shares of common stock will be accelerated and become payable in cash, in lieu of shares of common stock, upon the closing of the change of control transaction. The Amended and Restated License Agreement also imposes various diligence, sublicensing, patent cost reimbursement, and other customary obligations and restrictions on the Company. Both parties have the right to terminate the Amended and Restated License Agreement if the other party commits a material breach and fails to cure it within the applicable cure period. If the Company were to commit a material breach of the Amended and Restated License Agreement and fails to cure that breach within the applicable cure period, and if in response Bodor were to exercise its termination right, the Company would lose its rights under the Amended and Restated License Agreement and be forced to discontinue development and/or commercialization of sofpironium bromide.

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 March 31, 2020 as follows:

	March 31, 2020
Common stock options outstanding	1,654,198
Common stock warrants	2,662,529
Unvested restricted stock units	201,488
Options available for grant under the 2009 Plan	46,828
Options available for grant under the Vical Plan	7,561
Total	4,572,604

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 25,000 shares, provided that the closing sale price of the common stock is not below \$3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 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.

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 March 31, 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 amended and 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

The Company's 2009 Equity Incentive Plan, as amended and restated (the "2009 Plan"), provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors, and consultants of the Company. At March 31, 2020, the total shares authorized under the 2009 Plan were 1,634,655 shares. The board of directors or a designated committee of the board of directors is responsible for the administration of the 2009 Plan and determines the term, exercise price, and vesting terms of each option. Options granted under the 2009 Plan have an exercise price equal to the market value of the common stock at the date of grant and expire ten years from the date of grant. At March 31, 2020, a total of 46,828 shares were available for grant under the 2009 Plan.

In connection with the Merger, the Company adopted Vical's Equity Incentive Plan (the "Vical Plan"). At March 31, 2020, the total shares authorized under the Vical Plan were 413,710 shares. The Vical Plan, as amended, provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors, and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares, including restricted stock. The exercise price of stock options must equal at least the fair market value of the underlying common stock on the date of grant. The maximum term of options granted under the plan is ten years. The Vical Plan also limits the number of options that may be granted to any plan participant in a single calendar year to 1,300,000 shares. At March 31, 2020, a total of 7,561 shares were available for grant under the Vical Plan.

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 March 31,	
	2020	2019
Research and development	\$ 104	\$ 78
General and administrative	299	306
Total stock-based compensation expense	<u>\$ 403</u>	<u>\$ 384</u>

NOTE 9. SUBSEQUENT EVENTS

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.

2020 Omnibus Plan

On April 20, 2020, the Company's shareholders approved the 2020 Omnibus Long-Term Incentive Plan ("Omnibus Plan"), which replaces, with respect to new award grants, the two predecessor plans (the 2009 Plan and the Vical Plan) that were in

effect as of March 31, 2020. The number of shares available for issuance under the Omnibus Plan includes 625,000 new shares and 54,389 shares that remained available for future grants pursuant to the 2009 Plan and the Vical Plan, plus any shares that are forfeited pursuant to outstanding grants under the 2009 Plan or the Vical Plan that would have again become available for grants pursuant to the terms of those other plans. Following the approval of the Omnibus Plan on April 20, 2020, no additional grants will be made pursuant to the 2009 Plan or the Vical Plan, but awards outstanding under those plans as of that date will remain outstanding in accordance with their terms.

Paycheck Protection Program

On April 15, 2020, the Company executed an unsecured promissory note to IberiaBank (the “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 plans to use the Loan proceeds for covered payroll costs and certain other permitted costs in accordance with the relevant terms and conditions of the CARES Act.

The Loan is in the principal amount of \$437,123, bears interest at a fixed rate of 1.00% per annum and matures on April 15, 2022. The Loan requires equal monthly payments of principal and interest commencing on November 15, 2020. The Loan may be prepaid by the Company at any time prior to maturity without penalty. Under the terms of the PPP, the Company may apply for forgiveness of the amount due on the Loan.

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 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, sofipronium 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. Sofipronium 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 sofipronium 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 sofipronium 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 sofipirionium 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 sofipirionium 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 sofipirionium bromide in Japan and certain other Asian countries. In March 2019, Kaken completed a Phase 3 trial in patients with primary axillary hyperhidrosis in Japan, achieving statistical significance ($p < 0.05$) on all primary and secondary endpoints. In January 2020, we announced that Kaken submitted a new drug application (“NDA”) for approval in Japan of manufacturing and marketing of sofipirionium bromide for primary axillary hyperhidrosis.

Based on the positive results in the clinical trials for sofipirionium bromide globally to date, we intend to initiate two pivotal Phase 3 clinical trials in up to 350 subjects per trial with primary axillary hyperhidrosis in the United States, subject to obtaining substantial additional funding. Assuming the results of the Phase 3 clinical trials are favorable, we plan thereafter to submit an NDA to the U.S. Food and Drug Administration (the “FDA”), for the treatment of primary axillary hyperhidrosis by sofipirionium bromide.

Recent Developments

Study Announcements

On May 13, 2020, we announced that, based on a preliminary review of the top-line results from the 12-month Phase 3 open-label long-term safety study, in 300 subjects >9 years old with primary axillary hyperhidrosis, sofipirionium bromide gel, 5% and 15% 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.

On March 4, 2020, we announced that positive results from Kaken’s Phase 3 pivotal study of topically applied sofipirionium bromide gel, 5% in Japanese subjects with primary axillary hyperhidrosis were selected for oral presentation at the Late-Breaking Research Program of the American Academy of Dermatology (“AAD”) Annual Meeting. Due to concerns related to COVID-19, the AAD canceled the conference and it is now rescheduled to be a virtual forum on June 12, 2020.

On February 20, 2020, we announced that positive results from our Phase 2b study with sofipirionium bromide in patients with primary axillary hyperhidrosis were published in the peer-reviewed *Journal of the American Academy of Dermatology* (“JAAD”). In this Phase 2b dose-finding study, sofipirionium bromide elicited clinically meaningful and statistically significant sustained reductions in sweating severity and was well tolerated. For additional information regarding the results of this study, see Part I, Item 1. “Business - Clinical Development of Sofipirionium Bromide - Phase 2b U.S. Clinical Trial (BBI-4000-CL-203)” in our Annual Report on Form 10-K for the year ended December 31, 2020.

On January 19, 2020, we presented the results from pharmacokinetics and long-term safety extension trials with sofipirionium bromide gel, 15% in pediatric patients (ages 9 to <17) with primary axillary hyperhidrosis at the Dermatology, Aesthetic & Surgical Conference. Sofipirionium bromide was safe and well-tolerated over 24 weeks of treatment in this clinical trial.

At the Market Agreement

On April 14, 2020, we entered into an At Market Issuance Sales Agreement (the “ATM Agreement”) with Oppenheimer & Co. Inc. 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

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.

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. We are required to further 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) a specified cash amount following the occurrence of certain new milestone events.

We also agreed to issue to Bodor (i) \$500,000 of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time we enroll our first patient in a Phase 3 pivotal clinical trial in the United States for subjects with hyperhidrosis and (ii) \$1.0 million of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time we submit a new drug application with the FDA for a product containing sofpironium

bromide. If we enter into a change of control transaction prior to the occurrence of either of such triggering events, any amount not previously paid in shares of common stock will be accelerated and become payable in cash, in lieu of shares of common stock, upon the closing of the change of control transaction. The Amended and Restated License Agreement also imposes various diligence, sublicensing, patent cost reimbursement, and other customary obligations and restrictions on us. Both parties have the right to terminate the Amended and Restated License Agreement if the other party commits a material breach and fails to cure it within the applicable cure period. If we were to commit a material breach of the Amended and Restated License Agreement and fail to cure that breach within the applicable cure period, and if in response Bodor were to exercise its termination right, we would lose our rights under the Amended and Restated License Agreement and be forced to discontinue development and/or commercialization of sofipironium bromide.

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 sofipironium 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 March 31, 2020, we have raised or generated an aggregate of \$126.6 million to fund our operations, of which \$39.1 million was through license and collaboration agreements, \$37.0 million was from cash and investments acquired in the Merger, \$33.6 million was from the sale of convertible preferred stock, \$7.5 million was from the sale of debt, \$7.4 million was from the sale of convertible notes, and \$2.0 million was from the sale of common stock and warrants. As of March 31, 2020, we had cash and cash equivalents of \$7.1 million. In addition, we had approximately \$4.0 million in refundable prepaid expenses related to the Phase 3 program of sofipironium bromide.

Since inception, we have incurred operating losses. We recorded a net loss of \$4.1 million and \$4.6 million for the three months ended March 31, 2020 and 2019, respectively. As of March 31, 2020, we had an accumulated deficit of \$89.1 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 sofipironium bromide in the United States;
- contract to manufacture product candidates;
- advance research and development-related activities to develop and expand our product pipeline;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific, and management personnel; and
- add operational and finance personnel to support product development efforts and to support operating as a public company.

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

Key Components of Operations

Collaboration Revenue

Collaboration 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 sofipirionium 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.

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Direct program expenses related to sofipirionium bromide	\$ 1,767	\$ 5,027
Personnel and other expenses		
Salaries, benefits, and stock-based compensation	763	860
Regulatory and compliance	54	109
Other expenses	80	23
Total research and development expenses	<u>\$ 2,664</u>	<u>\$ 6,019</u>

General and Administrative Expenses

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

We expect our overall general and administrative expenses to decrease in the near term, however, we expect additional 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 (Loss), Net

Investment and other income (loss), 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 \$1.3 million of convertible promissory note principal during the three months ended March 31, 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 note was 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. 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 three months ended March 31, 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, 2020, 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 March 31, 2020 and 2019

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Collaboration revenue	\$ 1,046	\$ 3,492
Research and development expenses	(2,664)	(6,019)
General and administrative expenses	(2,481)	(2,066)
Total other income (expense), net	(4)	13
Net loss	\$ (4,103)	\$ (4,580)

Collaboration Revenue

Collaboration revenue decreased by \$2.4 million, or 70%, for the three months ended March 31, 2020 compared to the three months ended March 31, 2019. Revenue in both periods was driven by research and development activities related to the Kaken Agreement for which Kaken provided funding. The decrease in revenue recognized was attributable to the Phase 3 long-term safety study of sofpironium bromide gel and other ancillary studies that were ongoing in 2019 but were concluded or winding down by the first quarter of 2020. Conducting these studies is the basis for revenue recognition for a \$15.6 million R&D payment that was received from Kaken in the second quarter of 2018.

Research and Development

Research and development expenses decreased by \$3.4 million, or 56%, for the three months ended March 31, 2020 compared to the three months ended March 31, 2019, which was primarily due to a decrease in clinical study and other related regulatory and administrative costs of the Phase 3 long-term safety study of sofpironium bromide gel and other ancillary studies that were ongoing in 2019, but were concluded or winding down by the first quarter of 2020.

General and Administrative Expenses

General and administrative expenses increased by \$0.4 million, or 20%, for three months ended March 31, 2020 compared to the three months ended March 31, 2019. This increase was primarily due to \$0.3 million in higher fees for directors' and officers' liability insurance, \$0.2 million in higher stock and other compensation expense that was driven by increased headcount, and \$0.1 million in reduced other miscellaneous expenses.

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 three months ended March 31, 2020 and 2019, we had a net loss of \$4.1 million and \$4.6 million, respectively. As of March 31, 2020 and December 31, 2019, we had an accumulated deficit of \$89.1 million and \$85.0 million, respectively. As of March 31, 2020, we had cash and cash equivalents of \$7.1 million. Since inception, we have financed operations primarily through payments received under strategic collaboration and licensing agreements, cash and investments acquired in the Merger, and funds received from the sale of convertible preferred stock, debt, convertible notes, common stock, and warrants.

We believe that our cash and cash equivalents as of March 31, 2020, combined with \$4.0 million in refundable prepaid research and development expenses, funds received under the Paycheck Protection Program (see Note 9, "Subsequent Events" of the notes to the condensed consolidated financial statements included elsewhere in this Quarterly Report), 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. If we are unable to raise additional capital, including under the Purchase Agreement, we expect to conserve resources, including but not limited to potentially reducing cash compensation arrangements to management, employee and/or contractor downsizing.

and further reductions in operating expenditures. We expect to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Additional funding beyond the sale of additional shares of common stock under the Purchase Agreement will be required in the future to proceed with our current and proposed research activities, including conducting the pivotal U.S. Phase 3 clinical trials of sofipronium 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:

	Three Months Ended March 31,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	\$ (6,610)	\$ (5,316)
Net cash provided by (used in) investing activities	4,500	(2)
Net cash provided by financing activities	2,005	520
Net decrease in cash and cash equivalents	<u>\$ (105)</u>	<u>\$ (4,798)</u>

Operating Activities

Net cash used in operating activities of \$6.6 million during the three months ended March 31, 2020 increased compared to \$5.3 million during the same period in the prior year primarily due to an increase related to changes in working capital of \$1.9 million, partially offset by a decrease in net loss of \$0.5 million and an increase of other non-cash expenses of \$0.1 million.

Investing Activities

Net cash provided by investing activities of \$4.5 million during the three months ended March 31, 2020 increased compared to cash used in investing activities of \$2 thousand during the same period in the prior year. The \$4.5 million increase was primarily the result of maturities of marketable securities in 2020.

Financing Activities

Net cash provided by financing activities of \$2.0 million during the three months ended March 31, 2020 increased compared to \$0.5 million during the prior year. The increase was primarily related to higher net proceeds received in 2020 from the issuance of common stock and warrants of \$2.0 million, compared to net proceeds received in 2019 from the issuance of convertible promissory notes of \$1.3 million and the impact of repayment of principal associated the Loan Agreement in 2019 of \$0.8 million.

Off-Balance Sheet Arrangements

As of March 31, 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 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 Securities Exchange Act of 1934, as amended, or 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 March 31, 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 March 31, 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 in Part I, Item 1A of our 2019 Annual Report on Form 10-K, filed with the SEC on March 18, 2020 (the “2019 Annual Report”), under the heading “Risk Factors.” 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, and, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price. There have been no material changes to our risk factors since our 2019 Annual Report, except as set forth below. In addition, the COVID-19 pandemic could exacerbate or trigger other risks discussed in our 2019 Annual Report, any of which could materially affect our business, financial condition and results of operations.

The following risk factor is added:

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 coronavirus has spread to many regions of the world. 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.

Should the coronavirus continue to spread, our business operations could be delayed or interrupted. For instance, our clinical trials may be affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, manufacturing 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. If the coronavirus continues to spread, 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 the spread of the coronavirus pandemic continues and 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-party 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.

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

On February 17, 2020, the Company agreed to issue to Bodor (i) \$500,000 of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time the Company enrolls its first patient in a Phase 3 pivotal clinical trial in the United States for subjects with hyperhidrosis and (ii) \$1.0 million of shares of common stock (at a price per share equal to the closing price on the day preceding such issuance) at the time the Company submits a new drug application with the FDA for a product containing sofipironium bromide. If the Company enters into a change of control transaction (as described in the Amended and Restated License Agreement) prior to the occurrence of either of the triggering events described in the preceding sentence, any amount not previously paid in shares of common stock will be accelerated and become payable in cash, in lieu of shares of common stock, upon the closing of the change of control transaction. The nature of the transaction and the consideration received by the Company are described in Part I, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Recent Developments - Amended and Restated License Agreement with Bodor” above in this Quarterly Report. Such issuances were exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On May 8, 2020, the Company’s Board of Directors approved and adopted amendments to the Company’s Amended and Restated By-Laws to remove provisions related to the number of members of the Board of Directors and its committees being an odd number. Specifically, Article II, Section 2 was amended to remove a phrase related to maintaining an odd number for the Board, and Article II, Section 14 was amended to remove a phrase requiring the total number of Board committee members to be an odd number.

The foregoing summary is qualified in its entirety by reference to the full text of the Amended and Restated By-Laws, as so amended, a copy of which is filed as Exhibit 3.2 hereto and incorporated herein by reference.

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.	×
10.1	At Market Issuance Sales Agreement, dated April 14, 2020, by and between the Company 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†	Amended and Restated License Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).	
10.3†	Settlement Agreement, dated February 17, 2020, by and among Brickell Biotech, Inc., Brickell Subsidiary, Inc., Bodor Laboratories, Inc., and Dr. Nicholas S. Bodor (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).	
10.4	Securities Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (schedules omitted) (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).	
10.5	Series A Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-3 filed with the SEC on February 28, 2020).	
10.6	Series B Warrant issued by Brickell Biotech, Inc. to Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-3 filed with the SEC on February 28, 2020).	
10.7	Purchase Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).	
10.8	Registration Rights Agreement, dated February 17, 2020, by and between Brickell Biotech, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.7 to the Company's Current Report on Form 8-K filed with the SEC on February 18, 2020).	
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.

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

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: May 14, 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)

**AMENDED AND RESTATED
BYLAWS
OF
BRICKELL BIOTECH, INC.**

ARTICLE I

MEETINGS OF STOCKHOLDERS

Section 1. Place of Meetings. All meetings of the stockholders shall be held at such place within or outside the State of Delaware as may be fixed from time to time by the Board of Directors or the chief executive officer, or if not so designated, at the registered office of the corporation.

Section 2. Annual Meeting. An annual meeting of stockholders shall be held at such date, time and place as designated by the Board of Directors or the chief executive officer and stated in the notice of meeting. At the annual meeting the stockholders shall elect by a plurality vote those directors to hold office based on the number of directors in the class whose terms are expiring and do so for a term of three (3) years until the annual meeting of stockholders coinciding with the end of such term.

At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business either (i) must be specified in a written notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors or the chief executive officer or secretary of the corporation, (ii) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (iii) otherwise properly brought before the meeting by a stockholder. In addition to any other applicable requirements, for business to be properly brought before an annual meeting by a stockholder, the stockholder must have given timely notice thereof in writing to the secretary of the corporation. To be timely, a stockholder's notice must be delivered to or mailed and received at one of the principal executive office(s) of the corporation, not less than ninety (90) calendar days nor more than one-hundred and twenty (120) calendar days prior to the annual meeting; provided, however, that in the event that less than forty-five (45) calendar days' notice or prior public disclosure of the date of the annual meeting is given or made to stockholders, notice by the stockholder to be timely must be so received not later than the close of business on the tenth (10th) business day following the day on which such notice of the date of the annual meeting was mailed or such public disclosure was made. A stockholder's notice to the secretary of the corporation shall set forth as to each matter the stockholder proposes to bring before the annual meeting (i) a brief description of the business desired to be brought before the annual meeting and the reasons for conducting such business at the annual meeting, (ii) the name and record address of the stockholder proposing such business, (iii) the class and number of shares of the corporation which are beneficially owned by the stockholder and (iv) any material interest of the stockholder in such business. In no event shall the adjournment or postponement of an annual meeting commence a new notice time period (or extend any notice time period).

Notwithstanding anything in these bylaws to the contrary, no business shall be conducted at the annual meeting except in accordance with the procedures set forth in this Section 2 by any stockholder of any business properly brought before the annual meeting in accordance with said procedure.

The chairperson of an annual meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the provisions of this Section 2, or is otherwise not compliant with these bylaws, and if the chairperson should so determine, the chairperson shall so declare to the meeting and any such business not properly brought before the meeting shall not be transacted.

Section 3. Special Meetings. Special meetings of the stockholders, for any purpose or purposes, unless otherwise prescribed by statute or by the corporation's certificate of incorporation, may be called only by the chief executive officer at his or her discretion, or by a resolution adopted by the affirmative vote of a majority of the Board of Directors. Business transacted at any special meeting shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

Section 4. Notice of Meetings. Except as otherwise provided by law, written notice of each meeting of stockholders, annual or special, stating the place, date and hour of the meeting and, in the case of a special meeting, the purpose or purposes for which the meeting is called, shall be given not less than ten (10) nor more than sixty (60) calendar days before the date of the meeting, to each stockholder entitled to vote at such meeting. Without limiting the manner by which notices of meetings otherwise may be given to stockholders, any such notice may be given by electronic transmission in the manner provided in Section 232 of the Delaware General Corporation Law and as that statute may be amended. Notice of any meeting need not be given to any stockholder who, either before or after the meeting, shall submit a waiver of notice or who shall attend such meeting, except when the stockholder attends for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of the meeting shall be bound by the proceedings of the meeting in all respects as if due notice thereof had been given.

Section 5. Voting List. The officer responsible for the stock ledger of the corporation shall prepare and make, at least ten (10) calendar days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder limited to any purpose germane to the meeting for a period of at least ten (10) calendar days before the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list was provided with the notice of the meeting; (b) during ordinary business hours, at the principal place of business of the corporation; or (c) either at a place within the city or town where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list also shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. Except as provided by

applicable law, the stock ledger of the corporation shall be the only evidence as to who are the stockholders entitled to examine the stock ledger and the list of stockholders or to vote in person or by proxy at any meeting of stockholders.

Section 6. Quorum. The holders of one-third (1/3) of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of stockholders for transaction of business, except as otherwise provided by statute, the certificate of incorporation or these bylaws. A quorum, once established, shall not be broken by subsequent withdrawal of enough votes to leave less than a quorum.

Section 7. Adjournments. Any meeting of stockholders may be adjourned from time to time to any other time and/or any other place at which a meeting of stockholders may be held under these bylaws, which time and place shall be announced at the meeting, by a majority of the stockholders present in person or represented by proxy at the meeting and entitled to vote, though less than a quorum, or, if no stockholder is present or represented by proxy, by any officer entitled to preside at or to act as corporate secretary of such meeting, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) calendar days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 8. Action at Meetings. When a quorum is present at any meeting, the vote of the holders of a majority of the stock present in person or represented by proxy and entitled to vote on the question shall decide any question brought before such meeting, unless the question is one upon which by express provision of law, the corporation's certificate of incorporation or these bylaws, a different vote is required, in which case such express provision shall govern and control the decision of such question.

Section 9. Voting and Proxies. Unless otherwise provided in the corporation's certificate of incorporation, each stockholder shall at every meeting of the stockholders be entitled to one vote, in person or by proxy, for each share of capital stock having voting power held of record by such stockholder. Each stockholder entitled to vote at a meeting of stockholders, or to express consent or dissent to corporate action in writing without a meeting, may authorize another person or persons to act for such stockholder by proxy; provided that the instrument authorizing such proxy to act shall have been executed in writing (which shall include telegraphing, cabling or other means of electronically transmitted written copy) and signed and dated by the stockholder personally or by the stockholder's duly authorized attorney in fact. No such proxy shall be voted or acted upon after three (3) years from its effective date, unless the proxy expressly provides for a longer period.

Section 10. Action by Consent. Unless otherwise restricted by the corporation's certificate of incorporation or these bylaws, any action required or permitted to be taken at any annual or special meeting of the stockholders of the corporation may be taken without a meeting,

if a majority of the stockholders of the corporation consent thereto in writing or by electronic transmission.

ARTICLE II DIRECTORS

Section 1. Number, Election, Tenure and Qualification. The number of directors which shall constitute the whole board shall not be less than five (5) nor more than nine (9). Within and according to such limit, the actual number of directors shall be determined by resolution of the Board of Directors, or by the stockholders at the annual , or at any special meeting of stockholders. The directors shall be elected at the annual meeting or at any special meeting of the stockholders, except as provided in Section 3 of this Article, and each director elected shall hold office until such director's successor is elected and qualified or until the director's earlier death, resignation, disqualification, or removal. Directors need not be stockholders. Directors shall serve according to a set of staggered terms such that in any given year there is no more than twenty-five percent (25%) turnover of the Board.

Section 2. Enlargement. The number of the Board of Directors may be increased at any time by vote of a majority of the directors then in office.

Section 3. Nominations. Subject to the rights of holders of any class or series of stock having a preference over the common stock as to dividends or upon liquidation, nominations for election to the Board of Directors of the corporation at a meeting of stockholders may be made on behalf of the board by the nominating committee appointed by the board, or by any stockholder of the corporation entitled to vote for the election of directors at such meeting. Such nominations, other than those made by the nominating committee on behalf of the board, shall be made by notice in writing delivered or mailed by first class United States mail or a nationally recognized courier service, postage prepaid, to the secretary or assistant secretary of the corporation, and received by such officer not less than one hundred-twenty (120) calendar days prior to any meeting of stockholders called for the election of directors; provided, however, that if less than ninety (90_ calendar days' notice of the meeting is given to stockholders, such nomination shall have been mailed or delivered to the secretary or the assistant secretary of the corporation not later than the close of business on the seventh (7th) calendar day following the day on which the notice of meeting was mailed. Such notice shall set forth as to each proposed nominee who is not an incumbent director (i) the name, age, business address and, if known, residence address of each nominee proposed in such notice, (ii) the principal occupation or employment of each such nominee, (iii) the number of shares of stock of the corporation which are owned beneficially by each such nominee and by the nominating stockholder, (iv) any other information concerning the nominee that must be disclosed of nominees in proxy solicitations regulated by Regulation 14A of the Securities Exchange Act of 1934, as amended, and (v) a written questionnaire with respect to the background and qualification of such nominee (which questionnaire shall be provided by the corporate secretary upon written request) and a written statement and agreement executed by each such nominee acknowledging that such person consents to being named in the corporation's proxy statement as a nominee and to serving as a director if elected.

The chairperson of the meeting, if the facts warrant, may determine and declare to the meeting that a nomination was not made in accordance with the foregoing procedure, and if the chairperson should so determine, the chairperson shall so declare the meeting and the defective nomination shall be disregarded.

Section 4. Vacancies. Vacancies and newly created directorships resulting from any increase in the authorized number of directors may be filled by a majority of the directors then in office, though less than a quorum, or by a sole remaining director, and the directors so chosen shall hold office until the next annual election at which the term of the class to which they have been elected expires and until their successors are duly elected and shall qualify or until the director's earlier death, resignation, disqualification, or removal. If there are no directors in office, then an election of directors may be held in the manner provided by statute. In the event of a vacancy in the Board of Directors, the remaining directors, except as otherwise provided by law or these bylaws, may exercise the powers of the full board until the vacancy is filled.

Section 5. Resignation and Removal. Any director may resign at any time for any reason upon giving written or electronic notice to the corporation at its principal place of business or to the chief executive officer or the secretary of the corporation. Such resignation shall be effective upon receipt of such notice by any of the foregoing unless the notice specifies such resignation to be effective at some other time or upon the happening of some other event. Any director or the entire Board of Directors may be removed, but only for cause, by the holders of a majority of the shares then entitled to vote at an election of directors, unless otherwise specified by law or the certificate of incorporation of the corporation.

Section 6. General Powers. The business and affairs of the corporation shall be managed by its Board of Directors, which may exercise all powers of the corporation and do all such lawful acts and things as are not by statute or by the certificate of incorporation or by these bylaws directed or required to be exercised or done solely by the stockholders.

Section 7. Chairperson of the Board. If the Board of Directors appoints a chairperson of the board, such chairperson, when present, shall preside at all meetings of the stockholders and the Board of Directors. The chairperson shall perform such duties and possess such powers as are customarily vested in the office of the chairperson of the board or as may be vested in the chairperson by the Board of Directors.

Section 8. Place of Meetings. The Board of Directors may hold meetings, both regular and special, either within or outside the State of Delaware to the extent held in the United States of America.

Section 9. Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and at such place as shall from time to time be determined by the board; provided that any director who is absent when such a determination is made shall be given prompt written notice of such determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders. Notwithstanding the foregoing, the board shall meet at a minimum frequency of quarterly.

Section 10. Special Meetings. Special meetings of the board may be called by the chief executive officer, secretary of the corporation, or on the written request of three (3) or more directors, or by one (1) director in the event that there is only one (1) director in office. Four (4) hours' notice to each director, either personally or by e-mail or other electronic transmission, commercial delivery service or similar means sent to such director's business or home address, or three (3) calendar days' notice by written notice deposited in the mail or delivered by a nationally recognized courier service, shall be given to each director by the secretary of the corporation or by the officer or one of the directors calling the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

Section 11. Quorum, Action at Meeting, Adjournments. At all meetings of the board, a majority of directors then in office, but in no event less than one third (1/3) of the entire board, shall constitute a quorum for the transaction of business and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board of Directors, except as may be provided otherwise specifically by law or by the corporation's certificate of incorporation. For purposes of this Section 11, the term "entire board" shall mean the number of directors last fixed by the stockholders or directors, as the case may be, in accordance with law and these bylaws; provided, however, that if less than all the number so fixed of directors were elected, the "entire board" shall mean the greatest number of directors so elected to hold office at any one time pursuant to such authorization. If a quorum shall not be present at any meeting of the Board of Directors, a majority of the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present.

Section 12. Action by Consent. Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the board or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or transmission or transmissions are filed with the minutes of proceedings of the board or committee.

Section 13. Telephonic Meetings. Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board of Directors or of any committee thereof may participate in a meeting of the Board of Directors or of any committee, as the case may be, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

Section 14. Committees. The Board of Directors, by resolution passed by a majority of the whole board, may designate one or more committees of the board, each committee to consist of one or more of the directors of the corporation. The board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. Any such committee, to the extent provided in the resolution of the Board of Directors, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation, and may

authorize the seal of the corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to amending the certificate of incorporation of the corporation or these bylaws, adopting an agreement of merger, acquisition or consolidation of the corporation in its entirety, recommending to the stockholders the sale, lease or exchange of all or substantially all of the corporation's property and assets, recommending to the stockholders a dissolution of the corporation or a revocation of a dissolution; and, unless the resolution designating such committee or the corporation's certificate of incorporation expressly so provide, no such committee shall have the power or authority to declare a dividend or to authorize the issuance of stock or stock options or warrants. Such committee or committees shall have such name or names as may be determined from time to time by resolution adopted by the Board of Directors. Each committee shall keep regular minutes of its meetings and make such reports to the Board of Directors as the Board of Directors may request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business in compliance with applicable laws and these bylaws and the corporation's certificate of incorporation, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these bylaws for the conduct of its business by the Board of Directors.

Section 15. Compensation. Unless otherwise restricted by the certificate of incorporation of this corporation or these bylaws, the Board of Directors shall have the authority to fix from time to time the compensation of directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board of Directors and the performance of their responsibilities as directors and may be paid a fixed sum for attendance at each meeting of the Board of Directors and/or a stated salary as director. Payment may be by cash or by stock or stock option or warrant, as determined by the Board of Directors otherwise in accordance with these bylaws. No such payment shall preclude any director from serving the corporation or its parent or subsidiary corporations in any other capacity and receiving compensation therefor. The Board of Directors may also allow compensation for members of special or standing committees for service on such committees.

ARTICLE III

OFFICERS

Section 1. Enumeration. The officers of the corporation shall be chosen by the Board of Directors and shall be a president, a secretary and a treasurer and such other officers with such titles, terms of office and duties as the Board of Directors may from time to time determine, including one or more vice-presidents, and one or more assistant secretaries and assistant treasurers. If authorized by resolution of the Board of Directors, the chief executive officer may be empowered to appoint from time to time assistant secretaries and assistant treasurers. Any number of offices may be held by the same person, unless the certificate of incorporation or these bylaws otherwise provide.

Section 2. Election. The Board of Directors at its first meeting after each annual meeting of stockholders shall choose a president, a secretary and a treasurer. Other officers may

be appointed by the Board of Directors at such meeting, at any other meeting, or by written consent.

Section 3. Tenure. The officers of the corporation shall hold office until their successors are chosen and qualify, unless a different term is specified in the vote choosing or appointing such officer, or until such officer's earlier death, resignation or removal. Any officer elected or appointed by the Board of Directors or by the chief executive officer may be removed at any time by the affirmative vote of a majority of the Board of Directors or a committee of the board duly authorized to do so, except that any officer appointed by the chief executive officer also may be removed at any time by the chief executive officer. Any vacancy occurring in any office of the corporation may be filled by the Board of Directors, at its discretion. Any officer may resign by delivering such officer's written or electronic resignation to the corporation at its principal place of business or to the chief executive officer or the secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some other time or upon the happening of some other event.

Section 4. President. The president shall be the chief executive officer unless the Board of Directors otherwise provides. The president, unless the Board of Directors provides otherwise in a specific instance or generally, shall (i) preside at all meetings of the stockholders and the Board of Directors, (ii) conduct general and active management of the business of the corporation, and (iii) be responsible that all orders and resolutions of the Board of Directors are implemented. The president further shall execute bonds, mortgages, and other contracts requiring a seal, under the seal of the corporation, except where required or permitted by law to be otherwise signed and executed and except where the signing and execution thereof shall be expressly delegated by the Board of Directors to some other officer or agent of the corporation.

Section 5. Vice-Presidents. In the absence of the president or in the event of the president's inability or refusal to act, the vice-president, or if there be more than one vice-president, the vice-presidents in the order designated by the Board of Directors or the chief executive officer (or in the absence of any designation, then in the order determined by their tenure in office) shall perform the duties of the president, and when so acting, shall have all the powers of and be subject to all the restrictions upon the president. The vice-presidents shall perform such other duties and have such other powers as the Board of Directors or the chief executive officer may from time to time prescribe.

Section 6. Secretary. The secretary shall have such powers and perform such duties as are incident to the office of secretary. The secretary shall maintain a stock ledger and prepare lists of stockholders and their addresses as required and shall be the custodian of corporate records. The secretary shall attend all meetings of the Board of Directors and all meetings of the stockholders and record all the proceedings of the meetings of the corporation and of the Board of Directors in a book to be kept for that purpose and shall perform like duties for the standing committees when required. The secretary shall give, or cause to be given, notice of all meetings of the stockholders and special meetings of the Board of Directors, and shall perform such other duties as may be from time to time prescribed by the Board of Directors or chief executive officer, under whose supervision the secretary shall be. The secretary shall have custody of the

corporate seal of the corporation and the secretary, or an assistant secretary, shall have authority to affix the same to any instrument requiring it and when so affixed, it may be attested by the secretary's signature or by the signature of such assistant secretary. The Board of Directors may give general authority to any other officer to affix the seal of the corporation and to attest the affixing by such officer's signature.

Section 7. Chief Financial Officer. The chief financial officer shall be the principal financial officer of the corporation and shall have such powers and perform such duties as may be assigned by the Board of Directors or the chief executive officer.

Section 8. Other Officers. Such other officers as the Board of Directors may choose shall perform such duties and have such powers as from time to time may be assigned to them by the Board of Directors.

Section 9. Bond. If required by the Board of Directors, any officer shall give the corporation a bond in such sum and with such surety or sureties and upon such terms and conditions as shall be satisfactory to the Board of Directors, including without limitation a bond for the faithful performance of the duties of such officer's office and for the restoration to the corporation of all books, papers, vouchers, money and other property of whatever kind in such officer's possession or under such officer's control and belonging to the corporation.

Section 10. Delegation of Authority. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officers or agents, notwithstanding any provision hereof.

ARTICLE IV

NOTICES

Section 1. Delivery. Whenever, under the provisions of law, or of the certificate of incorporation or these bylaws, written notice is required to be given by the corporation to any director, officer or stockholder, such notice may be given by mail, addressed to such director, officer or stockholder, at such person's address as it appears on the records of the corporation, with postage thereon prepaid, and such notice shall be deemed to be given at the time when the same shall be deposited by the corporation in the United States mail or delivered to a nationally recognized courier service. Unless written notice by mail is required by law, written notice may also be given by e-mail or electronic transmission, commercial delivery services or similar means, addressed to such director, officer or stockholder at such person's e-mail or address as it appears on the records of the corporation, in which case such notice shall be deemed to be given when delivered by the corporation into the control of the persons charged with effecting such transmission, the transmission charge to be paid by the corporation or the person sending such notice and not by the addressee. Oral notice or other in-hand delivery, in person or by telephone, shall be deemed given at the time it actually is given.

Section 2. Waiver of Notice. Whenever any notice is required to be given by the corporation under the provisions of law or of the certificate of incorporation or of these bylaws, a

waiver thereof in writing, signed and dated by the person or persons entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent thereto.

ARTICLE V

INDEMNIFICATION

Section 1. Actions Other than by or in the Right of the Corporation. The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, investigative or otherwise (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceedings, had no reasonable cause to believe such person's conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person's conduct was unlawful.

Section 2. Actions by or in the Right of the Corporation. The corporation shall indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, investigative or otherwise, by or in the right of the corporation to procure a judgment or legally binding decision in its favor by reason of the fact that such person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action, suit or proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable for negligence, fraud or misconduct in the performance of such person's duty or obligations to the corporation unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery of the State of Delaware or such other court shall deem proper.

Section 3. Success on the Merits. To the extent that any person described in Section 1 or 2 of this Article V has been successful on the merits or otherwise in defense of any

action, suit or proceeding referred to in said Sections, or in defense of any claim, issue or matter therein, such person shall be indemnified by the corporation against their expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

Section 4. Specific Authorization. Any indemnification under Section 1 or 2 of this Article V (unless ordered by a court) shall be made by the corporation only as authorized in the specific case upon a determination that indemnification of any person described in said Sections is proper in the circumstances because such person has met the applicable standards of conduct set forth in said Sections. Such determination shall be made (1) by the Board of Directors by a majority vote of a quorum consisting of directors who were not parties to such action, suit or proceeding, or (2) if such a quorum is not obtainable, or even if obtainable a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, or (3) by a majority vote of a quorum of the stockholders of the corporation.

Section 5. Advance Payment. Expenses incurred in defending a civil, criminal, administrative, investigative or other action, suit or proceeding for which indemnification is appropriate under these bylaws may be paid by the corporation in advance of the final disposition of such action, suit or proceeding as authorized by the Board of Directors in the manner provided for in Section 4 of this Article V upon receipt of an undertaking by or on behalf of any person described in said Section to repay such amount unless it ultimately is determined that such person is entitled to indemnification by the corporation as authorized in this Article V.

Section 6. Non-Exclusivity. The indemnification provided by this Article V shall not be deemed exclusive of any other rights to which those indemnified may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise, both as to action in such person's official capacity and as to action in any other capacity while holding such office, and shall continue as to a person who has ceased to be director, officer, employee or agent of the corporation and shall inure to the benefit of the heirs, executors and administrators of such a person.

Section 7. Insurance. The Board of Directors may authorize, by a vote of the majority of the full board, the corporation to purchase and maintain insurance of any type and amount on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of this Article V or applicable law.

Section 8. Severability. If any word, clause or provision of this Article V or any award made hereunder shall for any reason be determined to be invalid, the provisions hereof shall not be affected otherwise thereby but shall remain in full force and effect.

Section 9. Intent of Article. The intent of this Article V is to provide for indemnification to the fullest extent permitted by section 145 of the General Corporation Law of

Delaware or any other applicable law. To the extent that such Section or any successor section, or other applicable law, may be amended or supplemented from time to time, this Article V shall be amended automatically and construed so as to permit indemnification to the fullest extent from time to time permitted by the law.

ARTICLE VI

CAPITAL STOCK

Section 1. Certificates of Stock. Every holder of stock in the corporation shall be entitled to have a certificate, signed by, or in the name of the corporation by, the chairperson or vice-chairperson of the Board of Directors, or the president or a vice-president and the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the corporation, certifying the number of shares owned by such stockholder in the corporation. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. Certificates may be issued for partly paid shares and in such case upon the face or back of the certificates issued to represent any such partly paid shares, the total amount of the consideration to be paid therefor, and the amount paid thereon shall be specified.

Section 2. Lost Certificates. The Board of Directors may direct a new stock certificate or certificates to be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen or destroyed. When authorizing such issue of a new certificate or certificates, the Board of Directors may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed stock certificate or certificates, or such owner's legal representative, to give reasonable evidence of such loss, theft or destruction, to advertise the same in such manner as it shall require and/or to give the corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen or destroyed or the issuance of such new certificate.

Section 3. Transfer of Stock. Upon surrender to the corporation or the transfer agent of the corporation of a certificate for shares, duly endorsed or accompanied by proper evidence of succession, assignment, or authority to transfer, and proper evidence of compliance with other conditions to rightful transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate, and record the transaction upon its books.

Section 4. Record Date for Action at a Meeting or for Other Purposes. In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not be more than sixty (60) calendar days nor less than ten (10) calendar days before the date of such meeting, nor

more than sixty (60) calendar days prior to any other action to which such record date relates. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting. If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. The record date for determining stockholders for any other purpose within this Section 4 of Article VI shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

Section 5. Registered Stockholders. The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and any other rights related to ownership of these shares, and to vote as such owner, and to hold liable for calls and assessments a person registered on its books as the owner of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

ARTICLE VII

CERTAIN TRANSACTIONS

Section 1. Transactions with Interested Parties. No contract or transaction between the corporation and one or more of its directors or officers, or between the corporation and any other corporation, partnership, association or other organization in which one or more of the corporation's directors or officers also are directors or have a financial interest, shall be void or voidable solely for these reasons, or solely because the director or officer is present at or participates in the meeting of the board or committee thereof which authorizes the contract or transaction, or solely because the vote or votes of such director or officer are counted for such purpose, if:

(a) the material facts as to such person's relationship or interest and as to the contract or transaction are disclosed or are known to the Board of Directors or the committee of the board, and the board or committee in good faith authorizes the contract or transaction by written consent or the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum; or

(b) the material facts as to such person's relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction specifically is approved in good faith by written consent or a majority vote of a quorum of the stockholders; or

(c) the contract or transaction is fair and reasonable as to the corporation as of the time it is authorized, approved or ratified, by the Board of Directors, a committee thereof, or the stockholders.

Section 2. Quorum. Common or interested directors may be counted in determining the presence of a quorum at a meeting of the Board of Directors or of a committee which authorizes the contract or transaction.

ARTICLE VIII

GENERAL PROVISIONS

Section 1. Dividends. Dividends upon the capital stock of the corporation, if any, may be declared by the Board of Directors at any regular or special meeting of the board or stockholders, or by written consent, pursuant to applicable law. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the certificate of incorporation.

Section 2. Reserves. The directors may set apart out of any funds of the corporation available for dividends a reserve or reserves for any proper purpose and, separately, may abolish any such reserve.

Section 3. Checks. All checks or demands for money and notes of the corporation shall be signed either by the corporation's chief financial officer, chief accounting officer, or such officer or officers, or such other person or persons, as the Board of Directors may from time to time designate in writing.

Section 4. Fiscal Year. The fiscal year of the corporation shall be fixed by resolution of the Board of Directors and may change at the discretion of the board.

Section 5. Seal. The Board of Directors, by resolution, may adopt a corporate seal but is not required to do so. The corporate seal shall have inscribed thereon the name of the corporation, the year of its organization, and the word "Delaware". The seal may be used by causing it or a facsimile thereof to be impressed or affixed or otherwise reproduced. The seal may be altered from time to time by the Board of Directors.

ARTICLE IX

AMENDMENTS

The Board of Directors is expressly empowered to adopt, amend or repeal these bylaws, provided, however, that any adoption, amendment or repeal of these bylaws by the Board of Directors shall require the approval of at least sixty-six and two-thirds percent (66 $\frac{2}{3}$ %) of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any resolution providing for adoption, amendment or repeal is presented to the board). The stockholders also shall have power to adopt, amend or repeal these bylaws, provided, however, that in addition to any vote of the holders of any class or series of stock of this corporation required by law or by the certificate of incorporation of this corporation, the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 $\frac{2}{3}$ %) of the voting power of all of the then outstanding shares of the stock of the corporation

entitled to vote generally in the election of directors, voting together as a single class, shall be required for such adoption, amendment or repeal by the stockholders of any provisions of these bylaws.

**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: May 14, 2020

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

**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: May 14, 2020

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

SECTION 1350 CERTIFICATION

Each of the undersigned, Robert. B. Brown, Chief Executive Officer of Brickell Biotech, Inc., a Delaware corporation (the "Company"), and R. Michael Carruthers, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended March 31, 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: May 14, 2020

/s/ R. Michael Carruthers

R. Michael Carruthers
Chief Financial Officer
(Principal Financial Officer)
Date: May 14, 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.