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

FORM 10-Q

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

For the quarterly period ended September 30, 2019

Or

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

For the transition period from to

Commission File Number: 000-21088

BRICKELL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of November 7, 2019, there were 7,810,680 shares of the registrant's common stock outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 7,225	$ 8,067
Marketable securities, available-for-sale	18,473	—
Prepaid expenses and other current assets	5,034	204
Total current assets	30,732	8,271
Property and equipment, net	20	37
Operating lease right-of-use asset	176	—
Intangible assets	441	441
Total assets	$ 31,369	$ 8,749
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,291	$ 4,067
Accrued liabilities	3,475	3,272
Lease liability, current portion	75	—
Deferred revenue, current portion	2,464	8,117
Note payable	—	4,639
Total current liabilities	7,305	20,095
Contingent consideration	145	145
Lease liability, net of current portion	94	—
Warrant liability	—	242
Deferred revenue, net of current portion	—	1,595
Research and development funding liability	5,600	—
Total liabilities	13,144	22,077
Redeemable convertible preferred stock (Series A, B, C and C-1), $0.01 par value, 5,000,000 and 4,182,943 shares authorized at September 30, 2019 and December 31, 2018, respectively; 0 and 1,256,466 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively; aggregate liquidation preference of $0 and $46,985 at September 30, 2019 and December 31, 2018, respectively	—	58,290
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Common stock, $0.01 par value, 50,000,000 and 8,000,000 shares authorized at September 30, 2019 and December 31, 2018, respectively; 7,810,680 and 589,001 issued and outstanding at September 30, 2019 and December 31, 2018, respectively	78	6
Additional paid-in capital	92,276	—
Accumulated other comprehensive loss	(11)	—
Accumulated deficit	(74,118)	(71,624)
Total stockholders' equity (deficit)	18,225	(71,618)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 31,369	$ 8,749

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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue	$ 1,183	$ 3,042	$ 7,248	$ 8,415
Operating expenses:				
Research and development	3,337	4,135	13,585	8,571
General and administrative	3,901	1,206	7,290	4,694
Total operating expenses	7,238	5,341	20,875	13,265
Loss from operations	(6,055)	(2,299)	(13,627)	(4,850)
Investment and other income, net	54	23	64	45
Gain on extinguishment	2,318	—	2,318	—
Interest expense	(1,098)	(267)	(1,982)	(769)
Change in fair value of derivative liability	—	—	(11)	—
Change in fair value of warrant liability	—	2	223	8
Net loss	(4,781)	(2,541)	(13,015)	(5,566)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	(82)	(966)	10,274	(5,071)
Net loss attributable to common stockholders	$ (4,863)	$ (3,507)	$ (2,741)	$ (10,637)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.65)	$ (5.98)	$ (1.98)	$ (18.13)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	2,943,896	586,738	1,382,592	586,701

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (4,781)	$ (2,541)	$ (13,015)	$ (5,566)
Other comprehensive loss:				
Unrealized loss on available-for-sale marketable securities arising during holding period, net of tax benefit of $0	(11)	—	(11)	—
Total comprehensive loss	$ (4,792)	$ (2,541)	$ (13,026)	$ (5,566)

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 and per share data)
(unaudited)

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Carrying Value	Shares	Par Value				
Balance, December 31, 2018	1,256,466	$ 58,290	589,001	$ 6	$ —	$ —	$ (71,624)	$ (71,618)
Stock based compensation	—	—	—	—	384	—	—	384
Reduction of redeemable convertible preferred stock to redemption value	—	(10,521)	—	—	—	—	10,521	10,521
Net loss	—	—	—	—	—	—	(4,580)	(4,580)
Balance, March 31, 2019 (unaudited)	1,256,466	47,769	589,001	6	384	—	(65,683)	(65,293)
Stock based compensation	—	—	—	—	299	—	—	299
Accretion of redeemable convertible preferred stock to redemption value	—	165	—	—	(165)	—	—	(165)
Net loss	—	—	—	—	—	—	(3,654)	(3,654)
Balance, June 30, 2019 (unaudited)	1,256,466	47,934	589,001	6	518	—	(69,337)	(68,813)
Accretion of redeemable convertible preferred stock to redemption value	—	82	—	—	(82)	—	—	(82)
Conversion of redeemable convertible preferred stock and preferred stock dividends to common stock	(1,256,466)	(48,016)	2,783,951	28	47,988	—	—	48,016
Common stock issued in recapitalization	—	—	3,367,988	34	36,059	—	—	36,093
Conversion of convertible notes payable and accrued interest to common stock	—	—	1,069,740	10	5,082	—	—	5,092
Reclassification of warrant liability to equity	—	—	—	—	1,511	—	—	1,511
Common stock warrants issued in connection with the research and development funding liability	—	—	—	—	876	—	—	876
Stock based compensation	—	—	—	—	324	—	—	324
Unrealized loss on available-for-sale marketable securities	—	—	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	—	—	(4,781)	(4,781)
Balance, September 30, 2019 (unaudited)	—	$ —	7,810,680	$ 78	$ 92,276	$ (11)	$ (74,118)	$ 18,225

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

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Carrying Value	Shares	Par Value				
Balance, December 31, 2017	1,256,466	$ 52,354	585,262	6	—	$ —	(59,942)	(59,936)
Effect of adoption of Topic 606	—	—	—	—	—	—	2,734	2,734
Stock based compensation	—	—	—	—	190	—	—	190
Issuance of common stock through exercise of stock option	—	—	1,438	—	17	—	—	17
Accretion of redeemable convertible preferred stock to redemption value	—	3,240	—	—	(207)	—	(3,033)	(3,240)
Net income	—	—	—	—	—	—	527	527
Balance, March 31, 2018 (unaudited)	1,256,466	55,594	586,700	6	—	—	(59,714)	(59,708)
Stock based compensation	—	—	—	—	175	—	—	175
Accretion of redeemable convertible preferred stock to redemption value	—	865	—	—	(175)	—	(690)	(865)
Net loss	—	—	—	—	—	—	(3,552)	(3,552)
Balance, June 30, 2018 (unaudited)	1,256,466	56,459	586,700	6	—	—	(63,956)	(63,950)
Stock based compensation	—	—	—	—	151	—	—	151
Issuance of common stock through exercise of stock option	—	—	863	—	10	—	—	10
Accretion of redeemable convertible preferred stock to redemption value	—	966	—	—	(161)	—	(805)	(966)
Net loss	—	—	—	—	—	—	(2,541)	(2,541)
Balance, September 30, 2018 (unaudited)	1,256,466	$ 57,425	587,563	$ 6	$ —	$ —	$ (67,302)	$ (67,296)

See accompanying notes to these condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (13,015)	$ (5,566)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation	25	37
Accretion of discount on marketable securities	(25)	—
Non-cash interest expense	666	—
Change in fair value of derivative liability	11	—
Change in fair value of warrant liability	(223)	(8)
Gain on extinguishment	(2,318)	—
Amortization of operating lease right-of-use assets	50	—
Amortization of convertible promissory notes discount	828	—
Amortization of debt discounts and financing costs	215	310
Stock-based compensation	1,007	516
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,480)	14
Accounts payable	(2,776)	473
Accrued liabilities	(2,207)	(343)
Lease liability	(50)	—
Research and development funding liability	5,600	—
Deferred revenue	(7,248)	12,188
Net cash provided by (used in) operating activities	(21,940)	7,621
CASH FLOWS FROM INVESTING ACTIVITIES:		
Cash and cash equivalents acquired in recapitalization	13,017	—
Maturities of marketable securities	5,500	—
Capital expenditures	(8)	(8)
Net cash provided by (used in) investing activities	18,509	(8)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments of principal of note payable	(4,808)	(509)
Proceeds from issuance of convertible promissory notes	7,397	—
Proceeds from the exercise of stock options	—	27
Net cash provided by (used in) financing activities	2,589	(482)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(842)	7,131
CASH AND CASH EQUIVALENTS—BEGINNING	8,067	5,399
CASH AND CASH EQUIVALENTS—ENDING	$ 7,225	$ 12,530
Supplement Disclosure of Cash Flow Information:		
Interest paid	$ 319	$ 310
Supplement Disclosure of Non-Cash Investing and Financing Activities:		
Conversion of redeemable convertible preferred stock and preferred stock dividends to common stock	$ 48,016	$ —
Accretion (reduction) of redeemable convertible preferred stock to redemption value	$ (10,377)	$ 5,041
Shares issued in recapitalization	$ 23,076	$ —
Accretion of redeemable convertible preferred stock issuance costs	$ 103	$ 30
Derivative liability issued with convertible promissory notes	$ 1,442	$ —
Warrants to purchase common stock issued with funding agreement	$ 876	$ —
Warrants to purchase common stock issued with convertible promissory notes	$ 1,492	$ —
Change in unrealized loss on available-for-sale marketable securities	$ (11)	$ —

See accompanying notes to these condensed consolidated financial statements.

NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

Brickell Biotech, Inc. (the "Company" or "Brickell") is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. The Company's pipeline consists of potential novel therapeutics for hyperhidrosis, cutaneous T-cell lymphoma, psoriasis, and other prevalent dermatological conditions. Its 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 is developing sofpironium bromide as a potential best-in-class, self-administered, once daily, topical therapy for the treatment of primary axillary hyperhidrosis. The Company's operations to date have been limited to business planning, raising capital, developing its pipeline assets (in particular sofpironium bromide), identifying product candidates, and other research and development.

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

The accompanying 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 of Private Brickell for the year ended December 31, 2018, included in the Company's Form 8-K filed with the Securities and Exchange Commission (the "SEC") on September 3, 2019.

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

On August 31, 2019, all shares of preferred stock of Private Brickell converted into shares of common stock of Private Brickell on a one-for-one basis.

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

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

Funding Agreement with NovaQuest

On August 31, 2019, concurrent with the Merger Agreement, the Company entered into a research and development arrangement with NovaQuest Capital Management, LLC ("NovaQuest") pursuant to which NovaQuest committed up to $25.0 million in research and development funding to the Company following the closing of the Merger (the "Funding Agreement"). These proceeds will partially fund the Company's Phase 3 clinical trials in the United States for sofpironium bromide. The Company issued a warrant to NovaQuest to purchase 241,225 shares of common stock. Additional details of this agreement are described in Note 4. In October 2019, additional funding was temporarily suspended. Refer to Note 11 for additional details.

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 nine months ended September 30, 2019, the Company had a net loss of $13.0 million and net cash used in operating activities of $21.9 million. As of September 30, 2019, the Company had cash, cash equivalents, and marketable securities of $25.7 million, and an accumulated deficit of $74.1 million.

Pending resolution of the contentious matter discussed further in Note 11 and NovaQuest resuming additional funding, the Company intends to conserve its resources. The advancement of the Phase 3 clinical trials for sofpironium bromide may be negatively impacted by these developments. The Company may take actions to reduce its cash spend, including delaying the start of the clinical trials or staff reductions. Taking these measures into account, the Company believes that its cash, cash equivalents, and marketable securities as of September 30, 2019 would be sufficient to fund its operations for at least the next 12 months from the issuance of these condensed consolidated financial statements.

The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Additional funding will be required in the future to maintain the Company's current and proposed research activities. There can be no assurance that additional equity or debt financing will be available on acceptable terms, if at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations.

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., are presented in U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") and applicable rules and regulations of the SEC for interim reporting. As permitted under those rules and regulations, certain footnotes or other financial information normally included in financial statements prepared in accordance with US GAAP have been condensed or omitted. These condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments, which are necessary for a fair presentation of the Company's financial information. The results of operations for the three and nine months ended September 30, 2019 are not necessarily indicative of the results to be expected for the full year ending December 31, 2019, for any other interim period, or for any other future period. The condensed consolidated balance sheet as of December 31, 2018 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 Merger has been accounted for as a recapitalization. Prior to the Merger, Vical wound down its pre-merger business assets and liabilities. The owners and management of Private Brickell have actual and effective voting and operating control of the combined company. In the Merger transaction, Vical is the accounting acquiree and Private Brickell is the accounting acquirer. A recapitalization is equivalent to the issuance of stock by the private operating company for the net monetary assets of the accounting acquiree accompanied by a recapitalization with accounting similar to that resulting from a reverse acquisition, except that no goodwill or intangible assets are recorded.

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

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

In connection with the Merger, the Company assumed warrants previously held by Vical, which provide the warrantholder the right to purchase 891,582 shares of common stock at an exercise price of $0.07 (the “Vical Warrants”). The Vical Warrants were classified as equity.

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

Use of Estimates

The Company’s 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 production of the compounds, dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents and other intellectual property rights, clinical implementation and success, the lengthy and expensive regulatory approval process, compliance with regulatory and other legal requirements, competition from other products; uncertainty of broad adoption of its approved products, if any, by physicians and patients; significant competition; ability to manage third-party manufacturers, suppliers, contract research organizations, business partners and other alliance management, and obtaining additional financing to fund the Company’s efforts.

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

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

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 as of September 30, 2019 and December 31, 2018 (in thousands):

	September 30, 2019		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	$ 7,225	$ —	$ —
U.S. treasuries	18,473	—	—
Total	$ 25,698	$ —	$ —
Liabilities:			
Contingent consideration	$ —	$ —	$ 145

	December 31, 2018		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	$ 8,067	$ —	$ —
Liabilities:			
Redeemable convertible preferred stock warrant liability	$ —	$ —	$ 242
Contingent consideration	—	—	145
Total	$ —	$ —	$ 387

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

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

As of September 30, 2019, the Company's available-for-sale securities had an amortized cost of $18.5 million, fair value of $18.5 million, and an unrealized gain of $20 thousand. Because the securities were acquired in August 2019 in connection to the Merger, there were no related balances as of December 31, 2018.

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

Redeemable Convertible Preferred Stock Warrant Liability—These amounts represented potential future obligations to transfer assets to the holders at a future date. The Company remeasured these warrants to current fair value at each balance sheet date, and any change in fair value was recognized as a change in fair value of warrant liability in the condensed consolidated statements of operations. The Company estimated the fair value of these warrants at December 31, 2018 using the Black-Scholes option-pricing model (Level 3 of the fair value hierarchy table). These warrants converted from warrants exercisable for redeemable convertible preferred stock to common stock in August 2019 in connection to the Merger (see further discussion in Note 7).

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

The fair value of the outstanding warrants was remeasured as of each period end using the Black-Scholes option-pricing model with the following assumptions:

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

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

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

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

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

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

Derivative Liability—These amounts represented potential future obligations to transfer assets to the holders at a future date. The fair value of the derivative liability has historically been determined with the assistance of a third-party valuation firm (Level 3 of the fair value hierarchy table) (see further discussion in Note 6). At the inception of the liability, there was no public market for the Company's common stock, and a third-party valuation firm determined fair value of the stock by considering a number of objective and subjective factors, including valuation of comparable companies, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors. The derivative liability was marked-to-market each measurement period and any change in fair value was recorded in the condensed consolidated statements of operations. In August 2019, in connection to the Merger, the derivative liability was reclassified to equity in the condensed consolidated balance sheet (see further discussion in Note 6).

Common Stock Warrant Liability—These amounts represented potential future obligations to transfer assets to the holders at a future date. The fair value of the warrants was historically determined with the assistance of a third-party valuation firm (Level 3 of the fair value hierarchy table) (see further discussion in Note 6). At the inception of the liability, there was no public market for the Company's common stock, and a third-party valuation firm determined fair value of the stock by considering a number of objective and subjective factors, including valuation of comparable companies, sales of common stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, among other factors. The warrant liability was remeasured to fair value at each balance sheet date, and any change in fair value was recognized as a change in fair value of warrant liability in the condensed consolidated statements of operations. The Company estimated the fair value of these warrants using the Black-Scholes option-pricing model. In August 2019, in connection to the Merger, the warrant liability was reclassified to equity in the condensed consolidated balance sheet (see further discussion in Note 6).

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

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

	Derivative Liability	Common Stock Warrant Liability	Redeemable Convertible Preferred Stock Warrant Liability	Contingent Consideration Liabilities
Fair value as of December 31, 2018	$ —	$ —	$ 242	$ 145
Fair value of financial instruments issued	1,442	1,492	—	—
Change in fair value	11	17	(240)	—
Reclassification to equity	(1,453)	(1,509)	(2)	—
Fair value as of September 30, 2019	$ —	$ —	$ —	$ 145

Leases

On January 1, 2019, the Company adopted Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 842, Leases ("ASC 842"), using the modified retrospective method for all lease arrangements at the beginning of the

period of adoption. Results for reporting periods beginning January 1, 2019 are presented under ASC 842, while prior period amounts were not adjusted and continue to be presented in accordance with the Company's historical accounting under ASC Topic 840, Leases. ASC 842 had an impact on the Company's condensed consolidated balance sheets but did not have a significant impact on the Company's net loss.

Under ASC 842, the Company determines if an arrangement is a lease at inception. Leases with a term greater thanone 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.

Redeemable Convertible Preferred Stock

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

Preferred stock issuance costs represent costs related to the Company's issuance of redeemable convertible preferred stock. These amounts were included as a reduction of redeemable convertible preferred stock and were amortized over the estimated redemption period until its conversion to common stock in August 2019. For the nine months ended September 30, 2019 and 2018, amortization of preferred stock issuance costs amounted to approximately$0.1 million and $30 thousand, respectively.

Redeemable Convertible Preferred Stock Warrants

The Company accounted for warrants to purchase shares of its redeemable convertible preferred stock as liabilities at their estimated fair value because the underlying shares were redeemable, which obligated the Company to transfer assets to the holders at a future date. The warrants were subject to remeasurement to fair value at each balance sheet date, and any fair value adjustments were recognized as change in fair value of redeemable convertible preferred stock warrant liability in the condensed consolidated statements of operations. The Company continued to adjust the liability for changes in fair value until the conversion of the redeemable convertible preferred stock into common stock in August 2019. At that time, the redeemable convertible preferred stock warrant liability was adjusted to fair value in the condensed consolidated statements of operations with the final fair value reclassified to equity.

Revenue Recognition

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

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

In March 2015, the Company entered into a license and collaboration agreement with Kaken Pharmaceutical, Co., Ltd. ("Kaken"), which is referred to as the "Collaboration Agreement." Under the Collaboration Agreement, the Company granted to Kaken an exclusive right to develop, manufacture, and commercialize the Company's sofpironium bromide compound (formerly BBI-4000), a topical anticholinergic, in Japan and certain other Asian countries (the "Territory"). In exchange, Kaken paid the Company an upfront, non-refundable payment of $11.0 million (the "upfront fee"). In addition, the Company is 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 Collaboration Agreement further provides that Kaken will be responsible for funding all development and commercial costs for the program in the Territory and, until such time, if any, as Kaken elects to establish its own source of supply of drug product, Kaken can purchase product supply from the Company to perform all non-clinical studies, and Phase 1 and Phase 2 clinical trials in Japan at cost. Kaken is also required to enter into negotiations with the Company, to supply the Company, at cost, with clinical supplies to perform Phase 3 clinical trials in the United States.

Collaboration Arrangement Subsequent to Adoption of Topic 606

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

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

Under Topic 606, the entire transaction price of $11.0 million was allocated to the license performance obligation. The license was deemed to be delivered in 2015 in connection with the execution of the Collaboration Agreement and upon transfer of the underlying intellectual property the performance obligation was fully satisfied. As a result, a cumulative adjustment to reduce deferred revenue and the corresponding sublicensing costs of $2.7 million was recorded upon the adoption of Topic 606 on January 1, 2018. As of September 30, 2019, the Company does not have a deferred revenue or deferred sublicensing costs balance related to the upfront fee on the condensed consolidated balance sheet.

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

originally due upon the first commercial sale in Japan was removed from the Collaboration Agreement and all future royalties to the Company under the Collaboration Agreement were reduced 150 basis points.

Consequently, during the three and nine months ended September 30, 2019, the Company recognized revenue of $1.2 million and $7.2 million, respectively related to the Collaboration R&D Payment. As of September 30, 2019, the Company has a deferred revenue balance related to the Collaboration R&D Payment of $2.5 million, which is recorded in deferred revenue, current portion 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, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration or other revenues and earnings in the period of adjustment.

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

The Collaboration Agreement was further amended in March 2018 to accelerate payment of the Phase 3 Milestone. The Phase 3 Milestone was modified to be due upon the successful completion of the End of Phase 2 Meeting with the PMDA by Kaken on March 8, 2018, as determined by Kaken in its reasonable discretion (the "Third Milestone"). In March 2018, Kaken triggered the Third Milestone and paid the Company $5.0 million (the "Third Milestone Payment"). Upon receipt of the non-refundable Third Milestone Payment, the ROFN Agreement was amended (the "Amended ROFN Agreement") to grant an additional option to exercise upon completion of a Subsequent Clinical Trial (first clinical trial after the Initial POC) for the Company's other product candidates. The Company has determined that the ROFN Agreement is not a material right and has not allocated transaction price to this provision. As of September 30, 2019, Kaken has not exercised the Amended ROFN Agreement. In March 2018, the Company recognized collaboration revenue related to the Collaboration Agreement of $5.0 million in connection with the Third Milestone. Additionally, the Company recognized sublicensing costs of $1.0 million, which are included in general and administrative expenses.

Royalties

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

Under collaborative arrangements, the Company has been reimbursed for a portion of the Company's research and development expenses, including costs of drug supplies. When the research and development services are performed under a reimbursement

or cost sharing model with a collaboration partner, the Company records these reimbursements as a reduction of research and development expense in the Company's condensed consolidated statements of operations.

Net Loss per Common Share

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

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

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

	Three and Nine Months Ended September 30,	
	2019	2018
Warrants to purchase common stock	1,632,495	55,360
Options to purchase common stock	1,802,895	1,347,500
Redeemable convertible preferred stock (as converted into common stock)	—	1,256,466
Warrants to purchase redeemable convertible preferred stock (as converted into common stock)	—	9,005
Total	3,435,390	2,668,331

NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"), which amends certain disclosure requirements over Level 1, Level 2, and Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2018-13, but does not anticipate it will have a material impact on its disclosures.

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

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

NOTE 4. NOVAQUEST FUNDING ARRANGEMENT

On August 31, 2019, concurrent with the Merger Agreement, the Company entered into a research and development arrangement with NovaQuest pursuant to which NovaQuest committed up to $25.0 million in research and development funding to the

Company following the closing of the Merger. These proceeds will partially fund the Company's Phase 3 clinical trials in the United States for its product candidate that contains sofpironium bromide, which treats hyperhidrosis of the skin. The Company is obligated to use commercially reasonable efforts to complete the clinical trials and file to obtain regulatory approval. The funding was projected to cover 67% of the product development costs up to $25.0 million.

As there is a substantive and genuine transfer of risk, the development funding is accounted for as an obligation to perform contractual services. However, given the potential obligation to repay the amounts received, the Company defer any funding received as a liability unless and until it becomes probable that the Company will not have to make a repayment of the received funding to NovaQuest. If the research and development is successful and the product candidate is ultimately approved by the FDA, NovaQuest will be entitled to a payment in the amount of $37.5 million, with $20.0 million due upon approval and the remainder due within two years of approval. Additionally, NovaQuest will be entitled to royalty payments based on annual net sales (except for Japan and certain other Asian countries) of the product candidate based on a sliding scale starting from the date that is two years after the first commercial sale. The portion of the approval payment, should it occur, that exceeds any liabilities recorded on the balance sheet, will be expensed immediately as interest expense. The royalties will be expensed as incurred and will also be included in cost of sales.

If the funding arrangement is terminated in certain circumstances, the Company will be required to pay NovaQuest $25.0 million plus interest, ranging from 8% to 12%. However, in the event that the Company terminates its development program for sofpironium bromide for other specified reasons, including serious safety issues, a failure of the product's Phase 3 studies, or the FDA's unwillingness to approve the product, the Company will not be obligated to make any payments to NovaQuest.

In conjunction with the transaction, the Company issued a fully vested warrant to NovaQuest providing it with the right to purchase 241,225 shares of common stock at an exercise price of $10.36 that is exercisable any time within ten years of the execution of the research and development arrangement (the "NovaQuest Warrant"). At issuance, the NovaQuest Warrant was classified as equity and recorded at fair value with no subsequent remeasurement. The fair value of the outstanding warrants was derived from the Black-Scholes option-pricing model using the following assumptions: expected volatility of 85.56%; risk free interest rate of 1.50%; expected term of 10 years; and expected dividend yield of 0.00%.

As of September 30, 2019, $5.6 million of funding had been received from NovaQuest, of which $0.9 million was allocated to the NovaQuest Warrant and deferred on the balance sheet within other current assets and will be recorded as interest expense over the term of the NovaQuest Warrant. In October 2019, NovaQuest notified the Company that additional funding was suspended temporarily based on a material adverse event. Refer to Note 11 for additional details.

NOTE 5. ACCRUED LIABILITIES

Accrued liabilities consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued contracted research and development services	$ 1,715	$ 847
Accrued professional fees	992	1,269
Accrued compensation	768	569
Accrued note issuance costs	—	587
Total	$ 3,475	$ 3,272

NOTE 6. CONVERTIBLE PROMISSORY NOTES

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

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

At inception of the Prom Notes offering, the Company analyzed the conversion feature of the agreement for derivative accounting consideration under ASC 815 and determined that the embedded conversion features should be classified as a derivative because the exercise price of the Prom Notes are subject to a variable conversion rate. The Company determined that the variable conversion feature was a redemption feature that was not clearly and closely related to the Prom Notes and was therefore required to be bifurcated. In accordance with AC 815, the Company bifurcated the conversion feature of the Prom Notes and recorded a derivative liability.

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

The Company evaluated the conversion option to discern whether a beneficial conversion feature existed based upon comparing the effective exercise price of the convertible notes to the fair value of the shares they were convertible into. The Company concluded no beneficial conversion feature existed. During the three months ended September 30, 2019, the Company recognized $1.1 million of interest expense, including $0.4 million of accretion of discounts using an effective interest rate of 12.00%. During the nine months ended September 30, 2019, the Company recognized $2.0 million of interest expense, including $0.8 million of accretion of discounts using an effective interest rate of 12.00%.

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

NOTE 7. NOTE PAYABLE

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

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

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

NOTE 8. 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 $17 thousand and $50 thousand for the three and nine months ended September 30, 2019, respectively, and was included in operating expense. As of September 30, 2019, the remaining lease term was 2.1 years.

The terms of the Boulder Lease provide for rental payments on a monthly basis on a graduated scale. The Company recognizes rent expense on a straight-line basis over the lease period. Lease expense for the three and nine months ended September 30, 2019 and 2018 was $22 thousand and $0.1 million, respectively.

NOTE 9. CAPITAL STOCK

Common Stock

Each share of common stock is entitled to one vote, and the holders of common stock are entitled to receive dividends when and as declared or paid by its board of directors. At the effective date of the Merger, each outstanding share of the Company's common stock was converted into the right to receive approximately 2.4165 shares of the Private Brickell's common stock.

The Company has reserved authorized shares of common stock, on an as-converted basis, for future issuance as September 30, 2019 as follows:

	September 30, 2019
Common stock options outstanding	1,802,895
Common stock warrants	1,632,495
Options available for grant under the Vical Plan	119,070
Options available for grant under the 2009 Plan	17,232
Total	3,571,692

Preferred Stock

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

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

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

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

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

As of September 30, 2019, the Company had no outstanding shares of redeemable convertible preferred stock and had not designated the rights, preferences, or privileges of any class or series of preferred stock. Although, the Company's board of directors has the authority, at its discretion, to issue preferred stock in one or more classes or series and to fix the designations, powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion right, voting rights, terms of redemption, liquidation preferences, and the number of shares constituting any class or series of preferred stock, without further vote or action by the stockholders.

NOTE 10. 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 September 30, 2019, the total shares authorized under the 2009 Plan were1,634,655 shares. The Board of Directors or a designated Committee of the Board 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 September 30, 2019, a total of 17,232 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 September 30, 2019, the total shares authorized under the Vical Plan were 413,710 shares The Vical Plan, as amended, provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Board of Directors, and consultants of the Company. The plan provides for the grant of incentive and nonstatutory stock options and the direct award or sale of shares, including restricted stock. The exercise price of stock options must equal at least the fair market value of the underlying common stock on the date of grant. The maximum term of options granted under the plan is ten years. The Vical Plan also limits the number of options that may be granted to any plan participant in a single calendar year to 1,300,000 shares. At September 30, 2019, a total of 119,070 shares were available for grant under the Vical Plan.

Share-based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 81	$ 76	$ 237	$ 263
General and administrative	243	75	770	253
Total stock-based compensation expense	$ 324	$ 151	$ 1,007	$ 516

NOTE 11. SUBSEQUENT EVENTS

On October 23, 2019, Bodor Laboratories, Inc. ("Bodor") notified the Company of its termination of the license agreement entered into between Bodor and the Company, dated December 15, 2012, 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 "License Agreement"). Bodor alleges that the Company materially breached the License Agreement resulting in its termination.

On October 23, 2019, Bodor and Nicholas S. Bodor (the "Plaintiffs"), filed a complaint (the "Bodor Complaint") against the Company in the United States District Court for the Southern District of Florida. The complaint alleges damages incurred by the Plaintiffs in connection with the Company's alleged breach of the License Agreement. The complaint seeks: (i) a declaratory judgment that the termination of the License Agreement by the Plaintiffs was valid and enforceable; (ii) an injunction requiring the Company to cease and desist use of the Plaintiffs' intellectual property; and (iii) damages for breach of contract and breach of the covenant of good faith and fair dealing.

On October 25, 2019, NovaQuest provided written notice to the Company of its determination that a "Material Adverse Event" (as defined in Section 1.1 of the Funding Agreement) occurred as a result of the matters described above. As a result, NovaQuest exercised its right under Section 3.3(e) of the Funding Agreement to suspend further Development Payments (as defined in Section 3.1(a) of the Funding Agreement). Pursuant to the Funding Agreement, NovaQuest is obligated to resume Development Payments if the Material Adverse Event is resolved or cured by the Company to NovaQuest's reasonable satisfaction by October 25, 2020. If the Material Adverse Event is not resolved or cured to NovaQuest's reasonable satisfaction by such date, then NovaQuest may, in its sole discretion, terminate any future payment obligation under the Funding Agreement and Brickell may be obligated to make certain payments to NovaQuest.

On October 30, 2019, the Company initiated an arbitration proceeding pursuant to Article 9 of the License Agreement with the American Arbitration Association ("AAA") in Florida against Bodor and Nicholas S. Bodor. This arbitration seeks a declaratory judgment that the purported termination of the License Agreement by Bodor and Nicholas S. Bodor was invalid and unenforceable and asserts (i) a claim for breach of the License Agreement against Bodor and Nicholas S. Bodor, in his individual capacity, and (ii) a claim against Bodor and Nicholas S. Bodor, in his individual capacity, for tortious interference with the Company's business relations. The Company requested expedited treatment of the arbitration proceeding and concurrent mandatory mediation under the AAA rules. On October 30, 2019, the Company concurrently filed with the United States District Court for the Southern District of Florida a motion to dismiss the complaint brought against the Company by Bodor and Nicholas S. Bodor described above.

As a result of the matters described above, the timeline for the Company's Phase 3 clinical trials in patients with primary axillary hyperhidrosis in the United States may be negatively impacted. Any potential impact to the financial statements with respect to loss contingencies for asserted legal and other claims is not estimable by the Company at this time.

FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q, or this 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 report data from ongoing and 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 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 Securities and Exchange Commission, or the SEC, in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report, may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

You should also read carefully the factors described in the "Risk Factors" section of this Quarterly Report to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. You are advised to consult any further disclosures we make on related subjects in our audited financial statements of for the year ended December 31, 2018, included in the Form 8-K filed with the SEC on September 3, 2019, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and our website.

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, cutaneous T-cell lymphoma, psoriasis, and other prevalent dermatological conditions. We believe that our portfolio of product candidates targets significant market opportunities where innovative therapies are needed. 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 strategy is to leverage this experience to in-license, acquire, develop, and commercialize innovative products that we believe can be successful in the currently underserved dermatology global marketplace.

Our pivotal Phase 3-ready clinical-stage product candidate, sofpironium bromide, is a proprietary new molecular entity. It belongs to a class of medications called anticholinergics. Anticholinergics block the action of acetylcholine, a chemical that transmits signals within the nervous system that are responsible for a range of bodily functions, including activation of the sweat glands. Sofpironium bromide was retrometabolically designed. Retrometabolic drugs are designed to exert their action topically and are potentially rapidly metabolized once absorbed into the blood. This proposed mechanism of action may allow for highly effective doses to be used while limiting systemic side effects. We are developing sofpironium bromide as a potential best-in-class, self-administered, once-daily, topical therapy for the treatment of primary axillary hyperhidrosis. Hyperhidrosis is a life-altering condition of sweating beyond what is physiologically required to maintain normal thermal regulation. It is believed to be caused by an overactive cholinergic response of the sweat glands and affects an estimated 15.3 million, or 4.8%, of the U.S. population. According to a 2016 update on the prevalence and severity of hyperhidrosis in the United States by Doolittle et al., axillary (underarm) hyperhidrosis, which is the targeted first potential indication for sofpironium bromide, is the most common occurrence of hyperhidrosis, affecting approximately 65% of patients in the United States or an estimated 10 million individuals.

We and our development partner in Asia, Kaken, have conducted 19 clinical trials of sofpironium bromide gel that encompass over 1,200 subjects in the U.S. and Japan. These trials evaluated the potential safety, tolerability, pharmacokinetics, and efficacy of sofpironium bromide gel in adult and pediatric primary axillary hyperhidrosis patients and healthy adult subjects. In March 2019, Kaken completed a Phase 3 trial in patients with primary axillary hyperhidrosis in Japan, achieving statistical significance on all primary and secondary endpoints. Based on the positive results of these clinical trials, we intend to initiate two pivotal Phase 3 clinical trials in up to 450 subjects per trial with primary axillary hyperhidrosis in the United States, subject to resolution of matters currently in dispute with Bodor Laboratories, Inc. and Nicholas S. Bodor, or collectively, Bodor, and assuming the results of the Phase 3 clinical trials are favorable, we plan to submit a New Drug Application, or an NDA, to the U.S. Food and Drug Administration, or the FDA, for the treatment of primary axillary hyperhidrosis.

Our second product candidate, BBI-3000, is a selective, potentially highly tolerable and potent novel RXR agonist being developed for the oral treatment of CTCL. Retinoids are derivatives of vitamin A that play a pivotal role in a diverse group of biologic processes including, but not limited to, cellular proliferation, differentiation, apoptosis, and development. The biological activity and tolerability of retinoids depends in part on the binding availability to retinoic acid and RXR receptors. There are several topical and oral retinoids currently on the market that have shown efficacy in the treatment of several skin conditions, such as CTCL (e.g., bexarotene/Targretin®), acne and psoriasis (e.g., tazarotene, adapalene and tretinoin). BBI-3000 currently is being tested by the National Cancer Institute, or NCI, in two Phase 1 clinical studies as a chronic, orally-administered chemoprevention agent for breast cancer. The product candidate has been well tolerated in the NCI clinical investigations conducted to date, providing an encouraging signal of the potential overall favorable systemic safety profile of BBI-3000 for CTCL.

Our third product candidate, BBI-6000, is a novel RORg inhibitor that we are developing for the topical treatment of mild-to-moderate psoriasis. RORg inhibition targets the pathway of IL-17 that has been implicated in the pathogenesis of psoriasis. Monoclonal antibodies targeting IL-17 recently have shown significant efficacy in the treatment of psoriasis, and we are planning to develop BBI-6000 as a topically applied, potent and selective small-molecule therapeutic targeting this pathway. BBI-6000 is currently in the preclinical stages of development.

Recent Developments

On October 23, 2019, Bodor notified us of its purported termination of the license agreement entered into between Bodor and us, dated December 15, 2012, 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, or the License Agreement. Bodor alleges that we materially breached the License Agreement resulting in its termination. On October 23, 2019, Bodor and Nicholas S. Bodor, or the Plaintiffs, filed a complaint, or the Bodor Complaint, against us in the United States District Court for the Southern District of Florida. The Bodor Complaint alleges damages incurred by the Plaintiffs in connection with our alleged breach of the License Agreement. The Bodor Complaint seeks: (i) a declaratory judgment that the termination of the License Agreement by the Plaintiffs was valid and enforceable; (ii) an injunction requiring us to cease and desist use of the Plaintiffs' intellectual property; and (iii) damages for breach of contract and breach of the covenant of good faith and fair dealing. We vigorously deny and dispute these allegations. In response, Brickell moved to dismiss the Bodor Complaint in the federal court and filed an arbitration demand as the License Agreement requires against Bodor, seeking a declaratory judgment that the license is not terminated, and that it is in fact Bodor who materially breached the License Agreement, and filing a claim against Bodor for tortious interference with our business relations. The timeline for our Phase 3 clinical trials in patients with primary axillary hyperhidrosis in the United States may be negatively impacted. Any potential impact to the financial statements with respect to loss contingencies for asserted legal and other claims is not estimable by us at this time.

Merger Agreement

On August 31, 2019, the company then known as Vical Incorporated, or Vical, and Brickell Biotech, Inc., a then privately-held Delaware corporation that began activities in September 2009, or 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 August 30, 2019, or the Merger Agreement, by and among Vical, Vical Subsidiary, Inc., a wholly owned subsidiary of Vical, or 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, or 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.", or the Company, and Private Brickell changed its name from "Brickell Biotech, Inc." to "Brickell Subsidiary, Inc."

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

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

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

Funding Agreement

On August 31, 2019, concurrent with the Merger Agreement, we entered into a research and development arrangement with NovaQuest, or the Funding Agreement, pursuant to which NovaQuest committed to us up to $25.0 million in research and development funding to partially fund our Phase 3 clinical trials for sofpironium bromide in the United States, with $5.6 million of the commitment paid in September 2019. We are obligated to use commercially reasonable efforts to complete the clinical trials and file to obtain regulatory approval with the FDA. The funding will cover 67% of the product development costs up to $25.0 million, however, as of October 2019, additional funding has been suspended temporarily as described below.

If the research and development is successful and the product candidate is ultimately approved by the FDA, NovaQuest will be entitled to a payment in the amount of $37.5 million, with $20.0 million due upon approval and the remainder due within two years of approval. Additionally, NovaQuest will be entitled to royalty payments based on annual net sales (except for Japan and certain other Asian countries) of the product candidate based on a sliding scale starting from the date that is two years after the first commercial sale. If the funding arrangement is terminated in certain circumstances, we will be required to pay NovaQuest $25.0 million plus interest. However, in the event that we terminate our development program for sofpironium bromide for other specified reasons, including serious safety issues, a failure of the product's Phase 3 studies, or the FDA's unwillingness to approve the product, we will not be obligated to make any payments to NovaQuest.

Under the Funding Agreement, we make various representations and warranties and commit to comply with various covenants. NovaQuest may terminate the Funding Agreement and terminate its obligation to make payments in the event of our material uncured breach of a representation or covenant under the Funding Agreement. We also entered into a security agreement with NovaQuest, or the Security Agreement, immediately following consummation of the Merger. Under the Security Agreement, NovaQuest will be able to exercise certain rights in the event of an uncured default by us of the Funding Agreement. NovaQuest's rights following an uncured event of default include, among other things, foreclosing on our assets in the United States relating to sofpironium bromide and, in certain circumstances, accelerating payment obligations under the Funding Agreement. NovaQuest also has the right to suspend its funding obligations owed to them by us under the Funding Agreement in the event of certain adverse developments relating to sofpironium bromide and in the event that certain of our senior executives leave the Company and we do not find replacements acceptable to NovaQuest.

On October 25, 2019, NovaQuest provided written notice to us of its determination that a "Material Adverse Event" (as defined in Section 1.1 of the Funding Agreement) occurred as a result of the matters under dispute with Bodor. As a result, NovaQuest exercised its right under Section 3.3(e) of the Funding Agreement to suspend further Development Payments (as defined in Section 3.1(a) of the Funding Agreement). Pursuant to the Funding Agreement, NovaQuest is obligated to resume Development Payments if the Material Adverse Event is resolved or cured by us to NovaQuest's reasonable satisfaction by October 25, 2020. If the Material Adverse Event is not resolved or cured to NovaQuest's reasonable satisfaction by such date, then NovaQuest may, in its sole discretion, terminate any future payment obligation under the Funding Agreement and Brickell may be obligated to make certain payments to NovaQuest.

Financial Overview

Our operations to date have been limited to business planning, raising capital, developing our pipeline assets (in particular sofpironium bromide), identifying product candidates, and other research and development. To date, we have financed operations primarily through private placements of convertible preferred stock, debt, funds received from license and collaboration agreements, the funds received in connection with the Merger, and funds received in connection with the NovaQuest Funding Agreement. We do not have any products approved for sale and have not generated any product sales. Since inception and through September 30, 2019, we have raised an aggregate of $130.8 million to fund our operations, of which $39.1 million was through license and collaboration agreements, $37.0 million was from cash and investments acquired in the Merger, $33.6 million was from the sale of convertible preferred stock, $7.5 million was from the sale of debt, and $7.4 million was from the sale of convertible notes, and $5.6 million was from research and development arrangements. As of September 30, 2019, we had cash and cash equivalents totaling $7.2 million and marketable securities of $18.5 million.

Since inception, we have incurred operating losses. We recorded a net loss of $13.0 million and $5.6 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $74.1 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

- pursue mediation, arbitration, and/or litigation in connection with the License Agreement;
- initiate and complete our two pivotal Phase 3 clinical trials for sofpironium bromide;
- 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 the recently commenced litigation with Bodor. Accordingly, we expect we will need to raise additional capital prior to the regulatory approval and commercialization of any of our product candidates. Until such time, if ever, that we generate substantial product revenues, we expect to finance our operations through public or private equity or debt financings, collaborations or licenses, or other available financing transactions. However, we may be unable to raise additional funds through these or other means when needed.

Key Components of Operations

Collaboration Revenue

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

Research and Development

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands)			
Direct program expenses related to sofpironium bromide	$ 2,452	$ 3,496	$ 10,871	$ 5,359
Personnel and other expenses				
Salaries, benefits, and stock-based compensation	863	691	2,518	2,485
Regulatory and compliance	18	116	158	603
Other expenses	4	(168)	38	124
Total research and development expenses	$ 3,337	$ 4,135	$ 13,585	$ 8,571

We intend to conserve our resources. The advancement of the clinical trials may be negatively impacted by recent developments discussed above. Once NovaQuest has resumed additional funding, we intend to increase our investments in research and development in order to advance our clinical trials.

General and Administrative

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

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

Total Other Income (Expense)

Investment and Other Income, Net

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

Gain on Extinguishment

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

Interest Expense

Interest expense consists primarily of interest and amortization related to the issuance of $7.4 million of convertible promissory note principal in 2019 and principal borrowings of $7.5 million provided by the loan and security agreement entered into with Hercules Capital, Inc. on February 18, 2016, or the Loan Agreement.

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 31, 2019, and at that time the final warrant liability fair value was reclassified to equity in the condensed consolidated balance sheets.

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, or 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 information on our significant accounting policies, please refer Note 2 to our condensed consolidated financial statements.

Revenue Recognition

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

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

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

Licenses of Intellectual Property

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

Milestone payments

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

Royalties

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

For a complete discussion of accounting for collaborative licensing agreements, see Note 2, to our condensed consolidated financial statements. Our revenue to date has been generated primarily from collaboration and licensing fees received under our Collaboration Agreement with Kaken.

Research and Development

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

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

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

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

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

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

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

Stock-Based Compensation

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

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

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

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding our future performance, including the successful completion of future clinical trials and the time to liquidity, as well as the determination of the appropriate valuation methods at each valuation date. If different assumptions

were used, our valuation could have been different. The foregoing valuation methodologies are not the only methodologies available, and they are not be used to value the common stock after the date of the Merger. Accordingly, stockholders and investors should not place undue reliance on the foregoing valuation methodologies as an indicator of the Company's future stock price.

Redeemable Convertible Preferred Stock

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

Convertible Promissory Notes

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

During the nine months ended September 30, 2019, we issued an aggregate principal amount of $7.4 million of convertible debt to investors containing a redemption feature, which was deemed an embedded derivative and required us to bifurcate and separately account for the embedded derivative as a liability. The warrants also required fair value accounting and were accounted as a liability. The discount on the debt was amortized through interest expense based on the effective interest method. On August 31, 2019, the convertible promissory notes and related accrued interest converted into 1,069,740 shares of common stock, which resulted in a gain on extinguishment of $2.3 million.

Recent Accounting Pronouncements

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

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Collaboration revenue	$ 1,183	$ 3,042
Research and development expenses	(3,337)	(4,135)
General and administrative expenses	(3,901)	(1,206)
Total other income (expense), net	1,274	(242)
Net loss	$ (4,781)	$ (2,541)

Collaboration Revenue

Collaboration revenue decreased by $1.9 million, or 61%, for the three months ended September 30, 2019 from the three months ended September 30, 2018. The decrease is due primarily to the completion of certain research and development activities during the three months ended September 30, 2019 related to the Collaboration Agreement for which Kaken provided funding.

Research and Development

Research and development expense decreased by $0.8 million, or 19%, for the three months ended September 30, 2019 from the three months ended September 30, 2018, primarily due to a decrease in clinical studies costs associated with sofpironium bromide, as we prepared to and began initiation of activities to start the Phase 3 clinical trials of sofpironium bromide.

General and Administrative Expenses

General and administrative expenses increased by $2.7 million, or 223%, for the three months ended September 30, 2019 from the three months ended September 30, 2018, primarily due to an increase of $1.8 million in professional fees for legal, accounting, and auditing services, including Merger-related costs, an increase of $0.5 million in payroll expenses due to increased headcount, and an increase of $0.2 million for insurance and travel costs.

Total Other Income (Expense), Net

Total other income, net increased to $1.3 million for the three months ended September 30, 2019, compared to total other expense, net of $0.2 million, for the three months ended September 30, 2018, primarily due to a gain of $2.3 million related to conversion of the convertible promissory notes in August 2019 and a decrease of $0.8 million in interest expense related to issuance of convertible promissory notes in 2019 and principal borrowings provided by the Loan Agreement.

Comparison of the Nine Months Ended September 30, 2019 and 2018

	Nine Months Ended September 30,	
	2019	**2018**
	(in thousands)	
Collaboration revenue	$ 7,248	$ 8,415
Research and development expenses	(13,585)	(8,571)
General and administrative expenses	(7,290)	(4,694)
Total other income (expense), net	612	(716)
Net loss	$ (13,015)	$ (5,566)

Collaboration Revenue

Collaboration revenue decreased by $1.2 million, or 14%, for the nine months ended September 30, 2019 from the nine months ended September 30, 2018. The revenue recognized for the nine months ended September 30, 2019 was due to research and development activities related to the Collaboration Agreement for which Kaken provided funding. The revenue recognized for the nine months ended September 30, 2018 was primarily the result of a milestone payment in March 2018 from Kaken in the amount of $5.0 million for the achievement of a certain regulatory milestone and the remainder was due to research and development activities related to the Collaboration Agreement for which Kaken provided funding.

Research and Development

Research and development expenses increased by $5.0 million, or 58%, for the nine months ended September 30, 2019 from the nine months ended September 30, 2018, primarily due to an increase of $5.5 million in clinical studies costs associated with sofpironium bromide, an increase of $0.4 million in supply costs, a decrease of $0.4 million in regulatory and compliance costs, and a $0.1 million decrease in other costs.

General and Administrative Expenses

General and administrative expenses increased by $2.6 million, or 55%, for nine months ended September 30, 2019 from the nine months ended September 30, 2018, primarily due to increases of $2.3 million in fees for legal, accounting, and auditing services, including Merger-related costs, and $0.9 million in payroll expenses due to increased headcount, partially offset by a decrease of $1.0 million in sub-licensing fees.

Total Other Income (Expense), Net

Total other income, net increased by $1.3 million, or 185%, for the nine months ended September 30, 2019 from the nine months ended September 30, 2018, due to a gain of $2.3 million related to the conversion of the convertible promissory notes in August 2019, which was partially offset by a $1.2 million in interest expense related to issuance of convertible promissory notes in 2019 and principal borrowings provided by the Loan Agreement.

Liquidity and Capital Resources

We have incurred significant operating losses and have an accumulated deficit as a result of ongoing efforts to develop our product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. For the nine months ended September 30, 2019 and 2018, we had a net loss of $13.0 million and $5.6 million, respectively. As of September 30, 2019 and December 31, 2018, we had an accumulated deficit of $74.1 million and $71.6 million, respectively. As of September 30, 2019 and December 31, 2018, we had cash, cash equivalents, and marketable securities of $25.7 million and $8.1 million, respectively. Since inception, we have financed operations primarily through sales of equity securities, convertible promissory notes, and warrants, as well as payments received under strategic collaboration and licensing agreements.

On August 31, 2019, concurrent with the Merger Agreement, we entered into a research and development arrangement with NovaQuest pursuant to which NovaQuest committed to us up to $25.0 million in research and development funding to partially fund our Phase 3 clinical trials for sofpironium bromide, with $5.6 million of the commitment paid in September 2019. We are obligated to use commercially reasonable efforts to complete the clinical trials and file to obtain regulatory approval. The funding will cover 67% of the product development costs up to $25.0 million, however, as of October 2019, additional funding was temporarily suspended.

If the research and development is successful and the product candidate is approved ultimately by the FDA, NovaQuest will be entitled to a payment in the amount of $37.5 million, with $20.0 million due upon approval and the remainder due within two years of approval. Additionally, NovaQuest will be entitled to royalty payments based on annual net sales (except for Japan and certain other Asian countries) of the product candidate based on a sliding scale starting from the date that is two years after the first commercial sale. If the funding arrangement is terminated in certain circumstances, we will be required to pay NovaQuest $25.0 million plus interest. However, in the event that we terminate our development program for sofpironium bromide for other specified reasons, including serious safety issues, a failure of the product's Phase 3 studies, or the FDA's unwillingness to approve the product, we will not be obligated to make any payments to NovaQuest.

We expect to continue to incur additional substantial losses in the foreseeable future as a result of litigation or arbitration related expenses and our research and development activities. Pending resolution of the contentious matter discussed further in Note 11 and NovaQuest resuming additional funding, we intend to conserve our resources. The advancement of the Phase 3 clinical trials for sofpironium bromide may be negatively impacted by these developments. We may take actions to reduce our cash spend, including further delaying the start of the clinical trials or staff reductions. Taking these measures into account, we believe that our cash, cash equivalents, and marketable securities as of September 30, 2019 would be sufficient to fund our operations for at least the next 12 months from the issuance of this Quarterly Report.

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:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash provided by (used in) operating activities	$ (21,940)	$ 7,621
Net cash provided by (used in) investing activities	18,509	(8)
Net cash provided by (used in) financing activities	2,589	(482)
Net increase (decrease) in cash and cash equivalents	$ (842)	$ 7,131

Operating Activities

Net cash used in operating activities of $21.9 million during the nine months ended September 30, 2019 increased compared to cash provided by operating activities of $7.6 million during the same period in the prior year primarily due to $20.6 million milestone and research and development funding received from Kaken during the nine months ended September 30, 2018 as well as an increase in net loss of $7.4 million, a gain on extinguishment of the convertible promissory note of $2.3 million, and an increase in other changes in working capital of $0.9 million.

Investing Activities

Net cash provided by investing activities of $18.5 million during the nine months ended September 30, 2019 increased compared to cash used in investing activities of $8 thousand during the same period in the prior year. The $18.5 million increase was primarily the result of the cash acquired in the Merger and maturities of marketable securities in 2019.

Financing Activities

Net cash provided by financing activities of $2.6 million during the nine months ended September 30, 2019 increased compared to net cash used in financing activities of $0.5 million during the prior year. The increase was primarily related to proceeds of $7.4 million from the issuance of convertible promissory notes in 2019, partially offset by payments of $4.8 million in 2019 towards the note payable pursuant to the Loan Agreement.

Contractual Obligations and Commitments

The following is a summary of the contractual obligations related to operating lease commitments as of September 30, 2019 and the effect such obligations are expected to have on the liquidity and cash flows in future periods (in thousands):

Less than 1 year	$ 83
1-3 years	124
3-5 years	—
More than 5 years	—
Total	$ 207

Under various agreements, including the Funding Agreement and License Agreement, we will be required to make milestone or other payments and pay royalties and other amounts to third parties, including NovaQuest and Bodor. We have not included any contingent payment obligations, such as milestones or royalties, in the table above as the amount, timing, and likelihood of such payments are not known.

We enter into contracts in the normal course of business with CROs for clinical trials, preclinical research studies and testing, chemistry and manufacturing, and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that the non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

As of September 30, 2019 and December 31, 2018, we had not been involved in any material off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are subject to interest rate risk. Our investment portfolio is maintained in accordance with our investment policy which defines allowable investments, specifies credit quality standards, and limits the credit exposure of any single issuer. Our investment portfolio consists of cash equivalents and marketable securities, including government agency securities and money market funds, and are classified as available-for-sale securities. The average maturity of our investments is approximately three months. Because of the short-term nature of our investment portfolio, a hypothetical increase of 1% in interest rates would not be material.

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 and financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act as of the end of the period covered by this 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 September 30, 2019.

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 September 30, 2019 before or after the Merger that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. No processes or systems of Vical continued subsequent to the Merger.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company is subject to certain legal proceedings and claims that could materially impact the company and which have not been fully resolved and that have arisen in the ordinary course of business. The nature of these material legal proceedings is described in Part I, Item 1 of this Form 10-Q in the Notes to Condensed Consolidated Financial Statements in Note 11, "Subsequent Events." The Company is assessing the impact of these recently asserted legal claims. Any potential impact to the financial statements with respect to loss contingencies for asserted legal and other claims is not estimable by the Company at this time.

The outcome of arbitration or litigation is inherently uncertain. If one or more legal matters were resolved against the Company in a reporting period for amounts in excess of management's expectations, the Company's financial condition and operating results for that reporting period could be materially adversely affected. Refer to the risk factor "We are currently involved in litigation with Bodor relating to our right to continue to develop sofpironium bromide and NovaQuest has suspended product development payments to us as a result," in Part II, Item 1A of this Form 10-Q under the heading "Risk Factors."

ITEM 1A. RISK FACTORS

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

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

We are currently involved in litigation with Bodor relating to our right to continue to develop sofpironium bromide and NovaQuest has suspended product development payments to us as a result.

On October 23, 2019, Bodor notified us of its termination of the License Agreement. Bodor alleges that we materially breached the License Agreement resulting in its termination. In connection with the termination, on October 23, 2019, the Plaintiffs filed the Bodor Complaint. The complaint alleges damages incurred by the Plaintiffs in connection with our alleged breach of the License Agreement. The complaint seeks: (i) a declaratory judgment that the termination of the License Agreement by the Plaintiffs was valid and enforceable; (ii) an injunction requiring us to cease and desist use of the Plaintiffs' intellectual property; and (iii) damages for breach of contract and breach of the covenant of good faith and fair dealing.

On October 25, 2019, NovaQuest provided written notice to us of its determination that a "Material Adverse Event" (as defined in Section 1.1 of the Funding Agreement) occurred as a result of the matters described above. As a result, NovaQuest exercised its right under Section 3.3(e) of the Funding Agreement to suspend further Development Payments (as defined in Section 3.1(a) of the Funding Agreement). Pursuant to the Funding Agreement, NovaQuest is obligated only to resume Development Payments if the Material Adverse Event is resolved or cured by us to NovaQuest's reasonable satisfaction by October 25, 2020. If the Material Adverse Event is not resolved or cured to NovaQuest's reasonable satisfaction by such date, then NovaQuest may, in its sole discretion, terminate any future payment obligation under the Funding Agreement and we may be obligated to make certain payments to NovaQuest. See "Risks Related to Our Dependence on Third Parties" below for a further discussion of the Funding Agreement and related risks.

On October 30, 2019, we initiated an arbitration proceeding pursuant to Article 9 of the License Agreement with the American Arbitration Association, or AAA, in Florida against Bodor and Nicholas S. Bodor. This arbitration seeks a declaratory judgment that the purported termination of the License Agreement by Bodor and Nicholas S. Bodor was invalid and unenforceable and asserts (i) a claim for breach of the License Agreement against Bodor and Nicholas S. Bodor, in his individual capacity, and (ii) a claim against Bodor and Nicholas S. Bodor, in his individual capacity, for tortious interference with our business relations. We requested expedited treatment of the arbitration proceeding and concurrent mandatory mediation under the AAA rules. On October 30, 2019, we concurrently filed with the United States District Court for the Southern District of Florida a motion to dismiss the complaint brought against us by Bodor and Nicholas S. Bodor described above.

As a result of these matters, the timeline for the Company's Phase 3 clinical trials in subjects with primary axillary hyperhidrosis in the United States may be negatively impacted. In addition, the Company will be required to devote substantial financial resources to address the Bodor Complaint. Mediation, arbitration, and litigation are expensive and may likely be time-consuming and divert management's attention and the Company's resources away from other clinical development activities.

The outcome of arbitration or litigation is inherently uncertain. If one or more of the legal claims made by Bodor were resolved against us, we may become subject to additional litigation claims, and our ability to continue to develop sofpironium bromide and our financial condition and operating results could be materially adversely affected. While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise.

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

The success of our business, including our prospective ability to finance our operations and generate revenue, primarily depends on the successful development, regulatory approval, and commercialization of sofpironium bromide, at least in the United States. The clinical and commercial success of sofpironium bromide depends on a number of factors, including but not limited to the following:

- timely and successful completion of Phase 3 clinical trials in the United States not yet initiated, which may be significantly slower, particularly in light of the Bodor Complaint, or costlier than we currently anticipate and/or produce results that do not achieve the endpoints of the trials or which are ultimately deemed not to be clinically meaningful;

- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials beyond those currently planned to support the approval and commercialization of sofpironium bromide;

- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our and their contractual obligations and with all regulatory and legal requirements applicable to sofpironium bromide;

- ability of third parties with which we contract to manufacture consistently adequate clinical trial and commercial supplies of sofpironium bromide, to remain in good standing with regulatory agencies and to develop, validate and maintain or supervise commercially viable manufacturing processes that are compliant with FDA-regulated Current Good Manufacturing Practices, or cGMPs, and the product's package insert;

- a continued acceptable safety profile during clinical development and following approval of sofpironium bromide;

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

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

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

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

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

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

If we do not achieve one or more of these factors, many of which are beyond our reasonable control, in a timely manner or at all, and with adequate financing, we could experience significant delays or an inability to obtain regulatory approvals or commercialize sofpironium bromide. Even if regulatory approvals are obtained, we may never be able to successfully

commercialize sofpironium bromide. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of sofpironium bromide, or any current primary asset, to continue our business.

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

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

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

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

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

Use of patient-reported outcome assessments, PROs, in sofpironium bromide clinical trials may delay the development of sofpironium bromide gel or increase our development costs.

Due to the difficulty of objectively measuring the symptoms of hyperhidrosis in a clinical trial, which is the primary target of treatment for sofpironium bromide, PROs will have an important role in the development and regulatory approval of sofpironium bromide. PROs involve patients' own subjective assessments of efficacy, and this subjectivity increases the uncertainty of determining and achieving clinical endpoints and obtaining regulatory approval. Such assessments can be influenced by factors outside of our reasonable control and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial, notwithstanding that regulators may or may not accept PROs as part of the drug approval process.

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

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

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

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

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

The license agreement we entered into with Kaken granted Kaken an exclusive Japan license and certain rights to additional Asian countries to develop and commercialize sofpironium bromide. Under the terms of the agreement, as amended, we received an up-front payment, development milestones and research and development payments and are eligible to receive future milestones and a royalty on net sales.

Kaken has final decision-making authority for the overall regulatory, development and commercialization strategy for sofpironium bromide, market access activities, pricing and reimbursement activities, promotion, distribution, packaging, sales and safety and pharmacovigilance in Japan and certain other Asian countries. In exercising its final decision-making authority in such territories, Kaken may make decisions regarding product development or regulatory strategy based on its determination of how best to preserve and extend regulatory approvals in these territories for sofpironium bromide, which may delay or prevent achieving regulatory approval for sofpironium bromide in Kaken's territories, as well as by us in the United States and the other territories where we maintain exclusive rights. Additionally, Kaken is responsible for conducting certain nonclinical and API (chemistry, manufacturing, and controls)-related activities that will be required for FDA approval in the United States, and as a result, we are reliant on Kaken to execute successfully, in a timely and efficient manner, such activities on our behalf. To the extent Kaken experiences delays and/or difficulties in performing its development activities, this could prevent or cause substantial delays in our ability to seek approval for sofpironium bromide gel in the United States and other territories in which we maintain exclusive rights. We will not receive additional milestone or other payments from Kaken if Kaken is not successful in its development activities.

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

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

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

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare and Medicaid practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as state to state. Consequently, the coverage determination process is often uncertain and a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require us to provide scientific, clinical and health economics support for the use of sofpironium bromide compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what amount or time frame.

Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for sofpironium bromide may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results, and prospects.

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

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

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

- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, legal, medical, and distribution efforts;

- adverse publicity about sofpironium bromide or favorable publicity about competitive products;

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

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

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

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

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

We anticipate that sofpironium bromide would compete with other therapies currently used for hyperhidrosis, including but not limited to:

- Self-Administered Treatments. Self-administered treatments, such as OTC and prescription topical antiperspirants, and recently approved (June 2018) Qbrexza® (glycopyrronium) 2.4% topical cloths. Oral and compounded topical anticholinergics also may be used off-label.

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

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

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

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

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

Upon expiration of primary patent protection in 2031 in the United States for sofpironium bromide, and in the absence of receiving a pending composition of matter patent that would provide protection through 2040, we could lose a significant portion of then-existing sales of sofpironium bromide in a short period of time, which could expose us to liability and would adversely affect our business, financial condition, operating results, and prospects.

We have in the past relied, and expect to continue to rely, on third-partyCROs and other third parties to conduct and oversee our sofpironium bromide clinical trials. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, sofpironium bromide.

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

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

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

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

development of our internal sales, marketing, distribution, and pricing/reimbursement/access capabilities would impact adversely the commercialization of these products.

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

Risks Related to Our Business

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

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

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

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

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

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

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

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

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

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

applicable home country. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

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

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

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

- withdrawal or delay of recruitment or decreased enrollment rates of clinical trial participants;
- termination or increased government regulation of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- significant delay in product launch;
- debarment of our clinical trial investigators or other related healthcare practitioners working with our company;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance;
- withdrawal of reimbursement or formulary inclusion; or
- loss of revenue.

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

to launch. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, decrease our cash, expose us to liability and harm our business, financial condition, operating results, and prospects.

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

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

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

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

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

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

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

We are evaluating the next clinical development steps for BBI-3000 and BBI-6000 as each is in an early stage of clinical (prior to Phase 3) and preclinical development. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, costly, and inherently unpredictable, especially for early-stage product candidates. The time required to obtain approval for early-stage product candidates from the FDA and comparable foreign authorities is unpredictable but typically takes many years, involves significant expenditures, and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Our early-stage product candidates will require substantial additional preclinical and clinical development before

we will be able to submit an application to the FDA, if at all. Accordingly, we cannot assure you that we will be able to seek or obtain regulatory approval for any of our early-stage product candidates.

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

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

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

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

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

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

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

There are also calls to severely curtail or ban all direct-to-consumer advertising of pharmaceuticals, which would limit our ability to market our product candidates. The United States is already in a minority of jurisdictions that allow this kind of advertising and its removal could limit the potential reach of a marketing campaign.

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

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

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

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

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

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

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

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

The process of proposing, negotiating, and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales, legal and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited

resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable or at all.

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

Risks Related to Our Dependence on Third Parties

Under the Funding Agreement with NovaQuest, NovaQuest has the right to suspend product development payments or take other actions adverse to Brickell's interests in certain circumstances.

Concurrent with the execution of the Merger Agreement with Vical, on June 2, 2019, we entered into the Funding Agreement with NovaQuest pursuant to which NovaQuest committed to partially fund our expenses relating to product development activities in respect of sofpironium bromide, subject to the terms and conditions contained in the Funding Agreement. NovaQuest may suspend its payments under the Funding Agreement in certain limited circumstances, including: (i) adverse regulatory events relating to sofpironium bromide; (ii) termination of any material clinical study in respect of sofpironium bromide; (iii) an event reasonably expected to delay U.S. approval or launch of sofpironium bromide by 12 months or more; (iv) a material amendment of the study protocol for our U.S. Phase 3 clinical trials in respect of our sofpironium bromide product candidate without NovaQuest's consent; (v) if we determine that sofpironium bromide is unsafe; (vi) the failure of sofpironium bromide to achieve the primary endpoints for our Phase 3 clinical trials; (vii) sofpironium bromide receiving a final non-approval letter from the FDA or European Medicines Agency; and/or (viii) if certain of our senior executives cease to work for us and we do not hire replacements reasonably acceptable to NovaQuest in a reasonable time. NovaQuest's obligation to make the payments will resume upon NovaQuest's notice to us that the condition allowing NovaQuest to suspend payments has been resolved or cured. NovaQuest may terminate its obligation to pay any further payments if such condition is not resolved or cured within 12 months. If NovaQuest's payment obligations terminate in these circumstances, we will remain obligated to make the milestone payments contemplated in the Funding Agreement to NovaQuest in the event we nonetheless receive FDA approval for sofpironium bromide, and we will remain obligated to make revenue sharing payments in the territory covered by the Funding Agreement in the event we launch sofpironium bromide anywhere in that territory.

If we suspend or terminate the development program for sofpironium bromide under certain circumstances, we will be obligated to pay NovaQuest $25 million plus interest.

Under the Funding Agreement with NovaQuest, we are not permitted to suspend or discontinue the development program in respect of sofpironium bromide except in certain circumstances. If we suspend or terminate the development program following completion of U.S. Phase 3 clinical trials because the FDA requires an additional study or additional, unexpected development work, and we reasonably determine that the additional study or work would take longer than 18 months to complete or cost more than an established threshold, we are entitled to terminate the development program. In that case, we would be obligated to pay NovaQuest $25 million plus interest from the date of the Funding Agreement until the date on which the payment is made (however, in the event that we terminate our development program for sofpironium bromide for certain reasons, including serious safety issues, a failure of the product's U.S. Phase 3 studies, or the failure of the FDA to approve the product, we will not be obligated to make any payments to NovaQuest). If we subsequently resume development of sofpironium bromide, we will remain obligated to make the milestone payments contemplated in the Funding Agreement to NovaQuest in the event we nonetheless receive FDA approval for sofpironium bromide, and we will remain obligated to make revenue sharing payments in the territory covered by the Funding Agreement in the event we launch sofpironium bromide anywhere in that territory, with any such payment made upon termination of the program credited against the milestone payment or revenue sharing payments.

If we breach the Funding Agreement, NovaQuest may terminate the agreement and exercise rights under a related Security Agreement, including foreclosing on our assets relating to sofpironium bromide in the United States and accelerating certain payments.

Under the Funding Agreement, we make various representations and warranties and commit to comply with various covenants. NovaQuest may terminate the Funding Agreement and terminate its obligation to make certain payments in the event of our material uncured breach of a representation or covenant under the Funding Agreement. We also entered into a Security Agreement with NovaQuest immediately following consummation of the Merger. Under the Security Agreement, NovaQuest is able to exercise certain rights in the event of default. An event of default would occur if (i) we fail to make payments due under the Funding Agreement, (ii) we terminate the Funding Agreement under circumstances giving rise to a payment obligation to NovaQuest and fail to make the required payment, as described above under "*—If we suspend or terminate the development program for sofpironium bromide under certain circumstances, we will be obligated to pay NovaQuest $25 million plus interest*," (iii) if we fail to comply with a covenant to maintain certain minimum cash balances specified in the Funding Agreement, or (iv) the occurrence of certain insolvency events affecting us or other related entities that are, or become parties to, the Security Agreement. NovaQuest's rights following an event of default include, among other things, foreclosing on our assets in the territory relating to sofpironium bromide and, in certain circumstances, accelerating payment obligations under the Funding Agreement.

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

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

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

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

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

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

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

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

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

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

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

- failure of our manufacturers to follow cGMP or other legal requirements or mishandling of or adulterating product while in production or in preparation for transit;
- inability of our contract suppliers and manufacturers to efficiently and cost-effectively increase and maintain high yields and batch quality, consistency, and stability;
- difficulty in establishing optimal drug delivery substances and techniques, production and storage methods and packaging and shipment processes;
- challenges in designing effective drug delivery substances and techniques especially in light of competitor options;
- transportation and import/export risk, particularly given the global nature of our supply chain;
- delays in analytical results or failure of analytical techniques that we depend on for quality control/assurance and release of a product;

- natural disasters, strikes and labor disputes, war and terrorism, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and

- latent defects that may become apparent after a product has been released and even sold and used and that may result in recall and destruction of the product.

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

Risks Related to Our Financial Operations

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

We will require substantial additional funds to conduct the costly and time-consuming clinical trials necessary to pursue regulatory approval of each potential product candidate and to continue the development of sofpironium bromide in new indications or uses. Our future capital requirements will depend upon a number of factors, including but not limited to: the number and timing of future product candidates in the pipeline; progress with and results from preclinical testing and clinical trials; the ability to manufacture sufficient drug supplies to complete preclinical and clinical trials; the costs involved in preparing, filing, acquiring, prosecuting, maintaining and enforcing patent and other intellectual property claims; compliance with our material contracts including the licensing agreement for sofpironium bromide and resolution of the Bodor Complaint; the time and costs involved in obtaining regulatory approvals and favorable reimbursement or formulary acceptance for such product candidates; and overall stock market conditions and trends. Raising additional capital may be costly or difficult to obtain and could significantly dilute stockholders' ownership interests or inhibit our ability to achieve our business objectives. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interests in our company will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us in one or more countries. Even if we were to obtain sufficient funding, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

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

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

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

The market price of our common stock following the Merger has been subject to significant fluctuations. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. In addition, there has been limited liquidity in the trading market for our securities, which may adversely affect stockholders. Some of the factors that may cause the market price of our common stock to continue to fluctuate include, but are not limited to:

- material developments in, or the conclusion of, any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- the entry into, or termination of, or breach by us or our partners of material agreements, including key commercial partner or licensing agreements, including the License Agreement;
- our ability to obtain timely regulatory approvals for sofpironium bromide or future product candidates, and delays or failures to obtain such approvals;
- failure of sofpironium bromide, if approved, to achieve commercial success;
- issues in manufacturing sofpironium bromide or future product candidates;
- the results of current and any future clinical trials of sofpironium bromide;
- failure of other product candidates, if approved, to achieve commercial success;
- announcements of any dilutive equity financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies or formulations that compete with sofpironium bromide;
- lack of commercial success of competitive products or products treating the same or similar indications;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and/or
- the loss of key employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment. These broad market fluctuations may also adversely affect the trading price of our common stock.

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

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

Our operations to date have been limited primarily to researching and developing sofpironium bromide and undertaking preclinical studies and clinical trials of sofpironium bromide. We (and our partners) have not yet obtained regulatory approvals for sofpironium bromide in any country. Consequently, any predictions you or we make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our revenue and profitability will depend on development funding and the achievement of development and clinical milestones under an agreement with Kaken, as well as any potential future collaboration and license agreements and sales of sofpironium bromide or future products, if approved, and our ability to maintain the related license as part of the Bodor Complaint. These up-front and milestone payments may vary significantly from period to period, and country to country, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we will measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the

magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict.

We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

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

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

We qualify as a "smaller reporting company" under Rule 12b-2 of the Exchange Act. As a smaller reporting company, we are entitled to rely on certain exemptions and reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements, in our SEC filings. These exemptions and decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock price may be more volatile. We will remain a "smaller reporting company" under Item 10(f)(1) of SEC Regulation S-K as long as we maintain a public float as defined by that regulation of less than $250 million; or we have less than $100 million in annual revenues and (i) either no public float, or (ii) a public float of less than $700 million.

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

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

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

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

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

As of September 30, 2019, we have (i) warrants issued and outstanding to purchase 891,582 shares of our common stock at an exercise price of $0.07 per share, 731,908 shares of our common stock at an exercise price of $10.36 and 9,005 shares of our common stock at an exercise price of $33.31; and (ii) we have 1,802,895 options issued and outstanding to purchase our common stock at a weighted average exercise price of $14.99 per share. If the holders of our outstanding stock options and warrants exercise their rights to acquire our common stock, the percentage ownership of our stockholders existing prior to the exercise of rights will be diluted.

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

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

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

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

Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2018, we had approximately $36.5 million of federal and $30.9 million of state operating loss carryforwards available to offset future taxable income, which expire in varying amounts beginning in 2030 for federal and state purposes if unused. It is possible that we will not generate taxable income in time to use these loss carryforwards before their expiration. Our net operating loss carryforwards may also be subject to limitation as a result of prior shifts in equity ownership in connection with the Merger. In addition, we may experience ownership changes in the future as a result of offerings of our stock or subsequent shifts in our stock ownership, some of which are outside of our control. In that case, the ability to use net operating loss carryforwards to offset future taxable income will be limited following any such ownership change.

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

Competitors in the field of dermatologic therapeutics have created a substantial amount of prior art, including scientific publications, abstracts, posters, presentations, patents and patent applications and other public disclosures including on the Internet and various social media. Our ability to obtain and maintain valid and enforceable patents and other intellectual property rights depends on whether the differences between our proprietary technology and the prior art allow our technology to be patentable over the prior art. We do not have outstanding issued patents covering all of the recent developments in our technology and are unsure of the patent protection that we will be successful in obtaining, if any. Even if the patents do issue successfully,

third parties may design around or challenge the validity, enforceability or scope of such issued patents or any other issued patents or intellectual property we own or license, which may result in such patents and/or other intellectual property being narrowed, invalidated, or held unenforceable. If the breadth or strength of protection provided by the patents and other intellectual property we hold or pursue with respect to our product candidates is challenged, regardless of our future success, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize or finance, our product candidates.

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

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

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

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

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

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

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

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

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

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

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, or increase our financial or other obligations to our licensors.

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

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

or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields across many countries, there may be a risk that third parties may allege they have patent or other rights encompassing our product candidates, technologies, or methods.

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

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

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

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

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

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

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

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

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 Commission on September 3, 2019).	
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the Commission on September 3, 2019).	
3.3	Certificate of Merger (incorporated by reference to Exhibit 3.4 to the Company's Current Report on 8-K filed with the Commission on September 3, 2019).	
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed with the Commission on September 10, 2019).	
31.1	Certification of Principal Executive Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.	•
31.2	Certification of Principal Financial Officer pursuant to Rule13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act, as amended.	•
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	•
101.INS**	XBRL Instance Document	•
101.SCH**	XBRL Taxonomy Extension Schema Document	•
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document	•
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document	•
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document	•
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document	•

* 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: November 14, 2019

By: /s/ Robert. B. Brown

Robert B. Brown

Chief Executive Officer
(Principal Executive Officer)

By: /s/ R. Michael Carruthers

R. Michael Carruthers

Chief Financial Officer
(Principal Financial Officer; Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Robert. B. Brown, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2019

By: /s/ Robert. B. Brown

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

Exhibit 31.2

CERTIFICATION

I, R. Michael Carruthers, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2019

By: /s/ R. Michael Carruthers

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

Exhibit 32.1

SECTION 1350 CERTIFICATION

Each of the undersigned, Robert. B. Brown Chief Executive Officer of Brickell Biotech, Inc., a Delaware corporation (the "Company"), and R. Michael Carruthers, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Brickell Biotech, Inc.

By: /s/ Robert. B. Brown

Robert B. Brown
Chief Executive Officer
(Principal Executive Officer)
Date: November 14, 2019

By: /s/ R. Michael Carruthers

R. Michael Carruthers
Chief Financial Officer
(Principal Financial Officer)
Date: November 14, 2019

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.