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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

Or

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

For the transition period from to

Commission File Number: 000-21088

BRICKELL BIOTECH, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No ☒
As of November 5, 2020, there were 53,515,476 shares of the registrant's common stock outstanding.

BRICKELL BIOTECH, INC.
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FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q ("Quarterly Report"), contains forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this Quarterly Report other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, liquidity, future revenue, projected expenses, results of operations, expectations concerning the timing and our ability to commence and subsequently report data from planned non-clinical studies and clinical trials, prospects, plans and objectives of management are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Unless otherwise mentioned or unless the context requires otherwise, all references in this Quarterly Report to "Brickell," "Brickell Subsidiary," "Company," "we," "us," and "our," or similar references, refer to Brickell Biotech, Inc., and our consolidated subsidiaries.

We based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019, and in Part II, Item 1A. "Risk Factors" in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 2020, and in this Quarterly Report, and under a similar heading in any other annual, periodic or current report we may file with the U.S. Securities and Exchange Commission (the "SEC"), in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

RISK FACTORS SUMMARY

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

- Our business depends on the successful financing, clinical development, regulatory approval, and commercialization of sofpironium bromide.
- We have never conducted a pivotal Phase 3 clinical trial ourselves and may be unable to successfully do so for sofpironium bromide.
- Clinical drug development for sofpironium bromide is very expensive, time-consuming, and uncertain.
- Use of patient-reported outcome assessments and gravimetric assessments in sofpironium bromide clinical trials may delay or adversely impact the development of sofpironium bromide gel or clinical trial results or increase our development costs.
- Sofpironium bromide may cause undesirable side effects or have other unexpected properties that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in post-approval regulatory action.
- Our development partner in Asia, Kaken Pharmaceutical Co., Ltd., 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.
- If we or any partners with which we may collaborate to market and sell sofpironium bromide are unable to achieve and maintain insurance coverage and adequate levels of reimbursement for this compound following regulatory approval and usage by patients, our commercial success may be hindered severely.
- 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.
- Sofpironium bromide, if approved, will face significant competition and its failure to compete effectively may prevent it from achieving significant market penetration.
- We may face generic competition for sofpironium bromide, which could expose us to litigation or adversely affect our business, financial condition, operating results, and prospects.
- If third-party Clinical Research Organizations and other third parties do not meet our requirements or otherwise conduct our sofpironium bromide clinical trials as required or are unable to staff our trials, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, sofpironium bromide.
- 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 will need to raise substantial additional financing in the future to fund our operations, which may not be available to us on favorable terms or at all.

- If the holders of our company's stock options and warrants exercise their rights to purchase our common stock, the ownership of our stockholders will be diluted.
- Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.
- We may never obtain regulatory approval to commercialize any of our product candidates in the U.S., and any products approved for sale will be subject to continued regulatory review and compliance obligations and there could be further restrictions on post-approval activities, including commercialization efforts.
- Major public health issues, and specifically the pandemic caused by the spread of COVID-19, could have an adverse impact on our financial condition and results of operations and other aspects of our business.
- We have sponsored or supported and may in the future sponsor or support clinical trials for our product candidates outside the U.S. and Japan, and the FDA, PMDA, and applicable foreign regulatory authorities may not accept data from such trials.
- We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.
- We may be subject to risks related to pre-approval promotion or off-label use, or unauthorized direct-to-consumer advertising of our product candidates.
- Healthcare reform measures could hinder or prevent the commercial success of our product candidates.
- 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.
- 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, and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of our product candidates.
- Manufacturing and supply of the APIs and other substances and materials used in our product candidates is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality control and assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed.
- We may not be able to obtain, maintain or enforce global patent rights or other intellectual property rights that cover sofpironium bromide and related technologies that are of sufficient breadth.
- We may not be able to protect our intellectual property rights throughout the world.
- If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business. Additionally, these agreements may be subject to disagreement over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology, or increase our financial or other obligations to our licensors.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 20,174	$ 7,232
Marketable securities, available-for-sale	—	4,497
Prepaid expenses and other current assets	6,129	6,240
Total current assets	26,303	17,969
Property and equipment, net	7	16
Operating lease right-of-use asset	94	159
Total assets	$ 26,404	$ 18,144
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,126	$ 2,245
Accrued liabilities	6,042	6,379
Lease liability, current portion	80	78
Deferred revenue	—	1,795
Note payable, current portion	267	—
Total current liabilities	7,515	10,497
Lease liability, net of current portion	7	73
Note payable, net of current portion	170	—
Total liabilities	7,692	10,570
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.01 par value, 100,000,000 and 50,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 31,241,636 and 8,480,968 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	312	85
Additional paid-in capital	116,928	92,497
Accumulated other comprehensive loss	—	(28)
Accumulated deficit	(98,528)	(84,980)
Total stockholders' equity	18,712	7,574
Total liabilities and stockholders' equity	$ 26,404	$ 18,144

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 142	$ 1,183	$ 1,795	$ 7,248
Operating expenses:				
Research and development	1,281	3,337	6,657	13,585
General and administrative	3,211	3,901	8,713	7,290
Total operating expenses	4,492	7,238	15,370	20,875
Loss from operations	(4,350)	(6,055)	(13,575)	(13,627)
Investment and other income, net	24	54	27	64
Gain on extinguishment	—	2,318	—	2,318
Interest expense	—	(1,098)	—	(1,982)
Change in fair value of warrant and derivative liability	—	—	—	212
Net loss	(4,326)	(4,781)	(13,548)	(13,015)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	—	(82)	—	10,274
Net loss attributable to common stockholders	$ (4,326)	$ (4,863)	$ (13,548)	$ (2,741)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.15)	$ (1.65)	$ (0.82)	$ (1.98)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	28,107,785	2,943,896	16,475,843	1,382,592

See accompanying notes to these condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (4,326)	$ (4,781)	$ (13,548)	$ (13,015)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale marketable securities arising during holding period, net of tax benefit of $0	—	(11)	28	(11)
Total comprehensive loss	$ (4,326)	$ (4,792)	$ (13,520)	$ (13,026)

See accompanying notes to these condensed consolidated financial statements.

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

	Series A, B, C & C-1 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In-Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Carrying Value	Shares	Par Value				
Balance, December 31, 2019	—	$ —	8,480,968	$ 85	$ 92,497	$ (28)	$ (84,980)	$ 7,574
Issuance of common stock and common stock purchase warrants, net of issuance costs of $10	—	—	950,000	10	1,980	—	—	1,990
Issuance of common stock upon exercise of warrants	—	—	221,293	2	13	—	—	15
Issuance of common stock upon restricted stock unit settlement, net of shares withheld for taxes	—	—	19,643	—	(13)	—	—	(13)
Stock-based compensation	—	—	—	—	403	—	—	403
Unrealized gain on available-for-sale marketable securities	—	—	—	—	—	28	—	28
Net loss	—	—	—	—	—	—	(4,103)	(4,103)
Balance, March 31, 2020	—	—	9,671,904	97	94,880	—	(89,083)	5,894
Issuance of common stock upon exercise of warrants	—	—	2,202,863	22	(15)	—	—	7
Issuance of common stock upon restricted stock unit settlement, net of shares withheld for taxes	—	—	6,673	—	(4)	—	—	(4)
Common stock and warrants issued, net of issuance costs of $1,443	—	—	14,790,133	148	18,531	—	—	18,679
Stock-based compensation	—	—	—	—	453	—	—	453
Net loss	—	—	—	—	—	—	(5,119)	(5,119)
Balance, June 30, 2020	—	—	26,671,573	267	113,845	—	(94,202)	19,910
Issuance of common stock upon exercise of warrants	—	—	1,113,424	11	(10)	—	—	1
Issuance of common stock upon restricted stock unit settlement, net of shares withheld for taxes	—	—	56,221	—	(22)	—	—	(22)
Common stock issued, net of issuance costs of $261	—	—	3,400,418	34	2,562	—	—	2,596
Stock-based compensation	—	—	—	—	553	—	—	553
Net loss	—	—	—	—	—	—	(4,326)	(4,326)
Balance, September 30, 2020	—	$ —	31,241,636	$ 312	$ 116,928	$ —	$ (98,528)	$ 18,712

	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)
Reduction of redeemable convertible preferred stock to redemption value	—	(10,519)	—	—	—	—	10,519	10,519
Stock-based compensation	—	—	—	—	384	—	—	384
Net loss	—	—	—	—	—	—	(4,580)	(4,580)
Balance, March 31, 2019	1,256,466	47,771	589,001	6	384	—	(65,685)	(65,295)
Stock based compensation	—	—	—	—	299	—	—	299
Accretion of redeemable convertible preferred stock to redemption value	—	163	—	—	(163)	—	—	(163)
Net loss	—	—	—	—	—	—	(3,654)	(3,654)
Balance, June 30, 2019	1,256,466	47,934	589,001	6	520	—	(69,339)	(68,813)
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	—	$ —	7,810,680	$ 78	$ 92,278	$ (11)	$ (74,120)	$ 18,225

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,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (13,548)	$ (13,015)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	9	25
Reduction (accretion) of discount on marketable securities	25	(25)
Non-cash interest expense	—	666
Change in fair value of warrant and derivative liability	—	(212)
Gain on extinguishment	—	(2,318)
Amortization of discounts and financing costs	—	1,043
Stock-based compensation	1,409	1,007
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	112	(2,480)
Accounts payable	(1,119)	(2,776)
Accrued liabilities	(376)	(2,207)
Promissory note	—	5,600
Deferred revenue	(1,795)	(7,248)
Net cash used in operating activities	(15,283)	(21,940)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Maturities of marketable securities	4,500	5,500
Cash and cash equivalents acquired in recapitalization	—	13,017
Capital expenditures	—	(8)
Net cash provided by investing activities	4,500	18,509
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock and warrants, net of issuance costs	23,265	—
Proceeds from the issuance of note payable	437	—
Proceeds from the exercise of warrants	23	—
Proceeds from issuance of convertible promissory notes	—	7,397
Payments of principal of note payable	—	(4,808)
Net cash provided by financing activities	23,725	2,589
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,942	(842)
CASH AND CASH EQUIVALENTS—BEGINNING	7,232	8,067
CASH AND CASH EQUIVALENTS—ENDING	$ 20,174	$ 7,225

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

	Nine Months Ended September 30,	
	2020	**2019**
Supplement Disclosure of Cash Flow Information:		
Interest paid	$ —	$ 319
Supplement Disclosure of Non-Cash Investing and Financing Activities:		
Conversion of redeemable convertible preferred stock and preferred stock dividends to common stock	$ —	$ 48,016
Shares issued in recapitalization	$ —	$ 23,076
Reduction of redeemable convertible preferred stock to redemption value	$ —	$ (10,376)
Warrants to purchase common stock issued with convertible promissory notes	$ —	$ 1,492
Derivative liability issued with convertible promissory notes	$ —	$ 1,442
Warrants to purchase common stock issued with funding agreement	$ —	$ 876
Accretion of redeemable convertible preferred stock issuance costs	$ —	$ 103

See accompanying notes to these condensed consolidated financial statements.

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

NOTE 1. ORGANIZATION AND NATURE OF OPERATIONS

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

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

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

Liquidity and Capital Resources

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The 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, 2020, the Company had a net loss of $13.5 million and net cash used in operating activities of $15.3 million. As of September 30, 2020, the Company had cash and cash equivalents of $20.2 million and an accumulated deficit of $98.5 million.

The Company believes that its cash and cash equivalents as of September 30, 2020, combined with the proceeds received from the subsequent sales of the Company's common stock and warrants (see Note 9. "Subsequent Events"), are sufficient to fund its operations for at least the next 12 months from the issuance of these condensed consolidated financial statements. The Company expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. Additional funding will be required in the future to continue with the Company's planned development and commercial related activities.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Brickell Subsidiary, Inc., and are presented in United States ("U.S.") dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America ("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, 2020 are not necessarily indicative of the results to be expected for the full year ending December 31, 2020, for any other interim period, or for any other future period. The condensed consolidated balance sheet as of December 31, 2019 has been derived from audited financial statements at that date but does not include all of the information required by US GAAP for complete financial statements. All intercompany balances and transactions have been eliminated in consolidation. The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein. The Company's management performed an evaluation of its activities through the date of filing of these financial statements and concluded that there are no subsequent events requiring disclosure, other than as disclosed.

Use of Estimates

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

Risks and Uncertainties

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

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

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

Fair Value Measurements

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

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

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

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

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

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

	Level 1 (1)	
	September 30, 2020	December 31, 2019
Assets:		
Money market funds	$ 19,519	$ 7,232
U.S. treasuries	—	4,497
Total	$ 19,519	$ 11,729

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

Fair Value of Financial Instruments

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

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

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

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

Leases

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

Revenue Recognition

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

To date, the Company has not received approval for any drug candidates from the FDA, and the Company has not generated or recognized any revenue from the sale of products. As described further below, in September 2020, the Company's Japanese development partner received regulatory approval in Japan to manufacture and market sofpironium bromide gel, 5% for the treatment of primary axillary (underarm) hyperhidrosis, and under the agreement with its development partner, the Company is entitled to receive commercial milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide in Japan.

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

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

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

are recognized proportionately with the delivery of drug substance and are accounted for as reductions to research and development expense and are excluded from the transaction price.

In May 2018, the Company entered into an amendment to the Kaken Agreement, pursuant to which the Company received an upfront non-refundable fee of $15.6 million (the "Kaken R&D Payment"), which was initially recorded as deferred revenue, to provide the Company with research and development funds for the sole purpose of conducting certain clinical trials and other such research and development activities required to support the submission of a new drug application for sofpironium bromide. These clinical trials have a benefit to Kaken and have the characteristics of a vendor and customer relationship. The Company has accounted for the Kaken R&D Payment under the provisions of Topic 606. This Kaken R&D Payment is recognized using an input method in proportion to the cost incurred. Upon receipt of the Kaken R&D Payment, on May 31, 2018, a milestone payment originally due upon the first commercial sale in Japan was removed from the Kaken Agreement and all future royalties to the Company under the Kaken Agreement were reduced 150 basis points.

Consequently, during the three months ended September 30, 2020 and 2019, the Company recognized revenue of $0.1 million and $1.2 million, respectively, related to the Kaken R&D Payment. During the nine months ended September 30, 2020 and 2019, the Company recognized revenue of $1.8 million and $7.2 million, respectively, related to the Kaken R&D Payment. As of December 31, 2019, the Company had a deferred revenue balance related to the Kaken R&D Payment of $1.8 million, which is recorded as deferred revenue on the accompanying condensed consolidated balance sheets. As of September 30, 2020, there was no remaining deferred revenue balance related to the Kaken R&D Payment.

Milestones

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

To date, Kaken has paid the Company $10.0 million in milestone payments under the Kaken Agreement.

Royalties

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

Net Income (Loss) per Common Share

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

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

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

	Three and Nine Months Ended September 30,	
	2020	2019
Outstanding warrants	19,556,108	1,632,495
Outstanding options	4,743,537	1,802,895
Unvested restricted stock units	204,233	—
Total	24,503,878	3,435,390

NOTE 3. ACCRUED LIABILITIES

Accrued liabilities consisted of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued contracted research and development services	$ 3,436	$ 4,532
Accrued compensation	1,128	59
Accrued license fee	1,000	—
Accrued professional fees	478	1,788
Total	$ 6,042	$ 6,379

NOTE 4. CONVERTIBLE PROMISSORY NOTES

In March 2019, the Company initiated a convertible promissory notes offering pursuant to which the Company issued unsecured convertible promissory notes (the "Prom Notes"), bearing interest at 12.0% with a maturity of one year. Through August 31, 2019, the Company had raised an aggregate principal amount of $7.4 million in Prom Notes, including $1.7 million from certain of the Company's management and board of directors. On August 31, 2019, immediately prior to the Merger, the Prom Notes and related accrued interest converted into 1,069,740 shares of Private Brickell common stock at a conversion price of $7.54 per share.

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

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

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

During the three months ended 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 12.0%. 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 12.0%. During the three and nine months ended September 30, 2020, no interest expense was recognized.

NOTE 5. NOTE PAYABLE

Loan Agreement with Hercules Capital, Inc.

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

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

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

Paycheck Protection Program

On April 15, 2020, the Company executed an unsecured promissory note to IberiaBank (the "PPP Loan") pursuant to the U.S. Small Business Administration's Paycheck Protection Program (the "PPP") under Division A, Title I of the federal Coronavirus Aid, Relief, and Economic Security ("CARES") Act, which is reported in the condensed consolidated balance sheet as of September 30, 2020 within the current and long-term note payable line items. A PPP loan is for the purpose of helping businesses keep their workforce employed during the Coronavirus (COVID-19) crisis. The Company used the PPP Loan proceeds to cover payroll costs and certain other permitted costs in accordance with the relevant terms and conditions of the CARES Act.

The PPP Loan is in the principal amount of $0.4 million, bears interest at a fixed rate of 1.00% per annum and matures on April 15, 2022. The PPP Loan requires equal monthly payments of principal and interest commencing on November 15, 2020. The PPP Loan may be prepaid by the Company at any time prior to maturity without penalty. As of September 30, 2020, the Company has evaluated the uses of proceeds under the PPP Loan with respect to the relevant terms and conditions of the CARES Act and believes that the full amount of the loan is subject to forgiveness. The Company intends to apply for full forgiveness of the PPP Loan.

NOTE 6. COMMITMENTS AND CONTINGENCIES

Operating Leases

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

The Company recognized a right-of-use asset and corresponding lease liability on January 1, 2019, by calculating the present value of lease payments, discounted at 12.0%, the Company's estimated incremental borrowing rate, over the 2.8 years expected remaining term. As the Company's lease does not provide an implicit rate, the Company estimated the incremental

borrowing rate based on industry peers. Industry peers consist of several public companies in the biotechnology industry with comparable characteristics, including clinical trials progress and therapeutic indications. Amortization of the operating lease right-of-use asset for the Boulder Lease amounted to $19 thousand and $0.1 million for the three and nine months ended September 30, 2020, respectively, which was included in operating expense. As of September 30, 2020, the remaining lease term was 1.1 years.

The terms of the Boulder Lease provide for rental payments on a monthly basis on a graduated scale. Lease expense for the three months ended September 30, 2020 and 2019 was $23 thousand and $22 thousand, respectively. Lease expense for each of the nine months ended September 30, 2020 and 2019 was $0.1 million.

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

Less than 1 year	$	85
1-3 years		8
3-5 years		—
More than 5 years		—
Imputed interest		(6)
Total	$	87

Amended and Restated License Agreement with Bodor

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

The Amended and Restated License Agreement retains with the Company a worldwide, exclusive license to develop, manufacture, market, sell and sublicense products containing the proprietary compound sofpironium bromide based upon the patents referenced in the Amended and Restated License Agreement for a defined field of use. In exchange for entering into the Amended and Restated License Agreement, settling the previously disclosed dispute, and resolving the associated litigation between the Company and Bodor, the Company made an upfront payment of $1.0 million in cash to Bodor following the execution of the Amended and Restated License Agreement and the settlement agreement by and among the Company, Brickell Subsidiary, Inc., and Bodor, dated February 17, 2020. Additionally, under the original License Agreement and the Amended and Restated License Agreement, the Company is required to pay Bodor (i) a royalty on sales of product outside Kaken's territory, including a low single-digit royalty on sales of certain product not covered by the patent estate licensed from Bodor; (ii) a specified percentage of all royalties the Company receives from Kaken for sales of product within its territory; (iii) a percentage of non-royalty sublicensing income the Company receives from Kaken or other sublicensees; and (iv) up to an aggregate of $1.8 million (plus an additional $0.1 million for approvals of additional products) in cash payments and $1.5 million of shares of the Company's common stock upon the achievement of certain development, regulatory and other milestones, including the enrollment of the first patient in the U.S. Phase 3 trials. Based on the foregoing, the Company made a $0.5 million milestone payment to Bodor in June 2020 following the closing of the June 2020 Offering (see Note 7. "Capital Stock"). Additionally, in October 2020, in association with the enrollment of the first patient in its U.S. Phase 3 pivotal program, the Company made a cash payment of $0.5 million and issued $0.5 million, or 480,769 shares, of the Company's common stock to Bodor. As a result, during the nine months ended September 30, 2020, the Company recorded an aggregate of $1.5 million as research and development expense in the condensed consolidated statements of operations.

NOTE 7. CAPITAL STOCK

Common Stock

Under the Company's amended and restated certificate of incorporation, the Company is authorized to issue 100,000,000 shares of common stock with a par value of $0.01 per share. Each share of the Company's common stock is entitled to one vote, and the holders of the Company's common stock are entitled to receive dividends when and as declared or paid by its board of directors. The Company has reserved authorized shares of common stock for future issuance at September 30, 2020 as follows:

	September 30, 2020[1]
Common stock warrants	19,556,109
Common stock options outstanding	4,743,537
Shares available for grant under the Omnibus Plan	1,997,623
Unvested restricted stock units	204,233
Total	26,501,502

(1) In connection with the October 2020 Offering, the Company removed the reservation of the 1,997,623 shares available for grant under the Omnibus Plan.

Public Offering of Common Stock and Warrants

In June 2020, the Company entered into an underwriting agreement with Oppenheimer & Co. Inc. ("Oppenheimer"), as representative of several underwriters, relating to the public offering, issuance and sale of 14,790,133 shares of its common stock, and, to certain investors, pre-funded warrants to purchase 2,709,867 shares of its common stock, and accompanying common stock warrants to purchase up to an aggregate of 17,500,000 shares of its common stock (the "June 2020 Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of common stock. The public offering price of each share of common stock and accompanying common warrant was $1.15 and $1.149 for each pre-funded warrant and accompanying common warrant, respectively. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of common stock. The common warrants were immediately exercisable at a price of $1.25 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The June 2020 Offering resulted in approximately $18.7 million of net proceeds to the Company after deducting underwriting commissions and discounts and other offering expenses of $1.4 million and excluding the proceeds, if any, from the exercise of the warrants. The Company anticipates using the net proceeds from the June 2020 Offering for research and development, including clinical trials, working capital, and general corporate purposes.

Certain officers of the Company participated in the June 2020 Offering by purchasing an aggregate purchase price of $0.2 million of the Company's common stock and warrants.

At Market Issuance Sales Agreement

On April 14, 2020, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with Oppenheimer as the Company's sales agent (the "Agent"). Pursuant to the terms of the ATM Agreement, the Company may sell from time to time through the Agent shares of the Company's common stock having an aggregate offering price of up to $8.0 million (the "Shares"). The Shares are issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the Shares are made by means of ordinary brokers' transactions on the Nasdaq Capital Market at market prices or as otherwise agreed by the Company and the Agent. Under the terms of the ATM Agreement, the Company may also sell the Shares from time to time to the Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the Shares to the Agent as principal would be pursuant to the terms of a separate placement notice between the Company and the Agent. The Company will be significantly limited in its ability to sell shares of its common stock under the ATM Agreement unless and until the number of authorized shares of common stock of the Company is increased, which would require stockholder approval. During the three and nine months ended September 30, 2020, the Company sold 3,400,418 Shares under the ATM Agreement at a weighted-average price of $0.84

per share, for aggregate net proceeds of $2.6 million, after giving effect to a 3% commission to Oppenheimer as Agent plus initial expenses for executing the ATM Agreement.

Private Placement Offerings

On February 17, 2020, the Company and Lincoln Park entered into (i) a securities purchase agreement (the "Securities Purchase Agreement"); (ii) a purchase agreement (the "Purchase Agreement"); and (iii) a registration rights agreement (the "Registration Rights Agreement"). Pursuant to the Securities Purchase Agreement, Lincoln Park purchased, and the Company sold, (i) an aggregate of 950,000 shares of common stock (the "Common Shares"); (ii) a warrant to initially purchase an aggregate of up to 606,420 shares of common stock at an exercise price of $0.01 per share (the "Series A Warrant"); and (iii) a warrant to initially purchase an aggregate of up to 1,556,420 shares of common stock at an exercise price of $1.16 per share (the "Series B Warrant" and together with the Series A Warrant, the "Warrants"). The aggregate gross purchase price for the Common Shares and the Warrants was $2.0 million.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $28.0 million in the aggregate of shares of common stock. Sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's sole discretion, over the 36-month period commencing on August 14, 2020 (the "Commencement Date"). Further, the Company will be significantly limited in its ability to sell shares of its common stock under the Purchase Agreement unless and until the number of authorized shares of common stock of the Company is increased, which would require stockholder approval.

Following the Commencement Date, under the Purchase Agreement, on any business day selected by the Company, the Company may direct Lincoln Park to purchase up to 100,000 shares of common stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 125,000 shares, provided that the closing sale price of the common stock is not below $3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below $5.00 on the purchase date. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The purchase price per share for each such Regular Purchase will be based off of prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, the Company may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, the Company may not sell shares of its common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of common stock. As of September 30, 2020, the Company has not made any sales of its common stock under the Purchase Agreement.

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

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

Preferred Stock

Under the Company's amended and restated certificate of incorporation, the Company's board of directors has the authority to issue up to 5,000,000 shares of preferred stock with a par value of $0.01 per share, at its discretion, in one or more classes or series and to fix the powers, preferences and rights, and the qualifications, limitations, or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, without further vote or action by the Company's stockholders. As of September 30, 2020, the Company had no shares of preferred stock outstanding and had not designated the rights, preferences, or privileges of any class or series of preferred stock.

NOTE 8. STOCK-BASED COMPENSATION

Equity Incentive Plans

2020 Omnibus Plan

On April 20, 2020, the Company's stockholders approved the Omnibus Plan, which replaced, with respect to new award grants, the Company's 2009 Equity Incentive Plan, as amended and restated (the "2009 Plan"), and the Vical Equity Incentive Plan (the "Vical Plan") (collectively, the "Prior Plans") that were previously in effect. Following the approval of the Omnibus Plan on April 20, 2020, no additional grants will be made pursuant to the Prior Plans, but awards outstanding under those plans as of that date remain outstanding in accordance with their terms. On August 31, 2020, the Company's stockholders approved an increase in the number of shares of common stock authorized for issuance under the Omnibus Plan by 4,500,000. At September 30, 2020, 3,347,065 shares were subject to outstanding awards under the Omnibus Plan, and 1,997,623 shares remained available for grant under the Omnibus Plan.

2009 Equity Incentive Plan

The 2009 Plan was replaced by the Omnibus Plan on April 20, 2020 and, as a result, at September 30, 2020, there were no remaining shares available for new grants under the 2009 Plan. However, as of September 30, 2020, 1,319,452 shares were subject to outstanding awards under the 2009 Plan, which awards remain outstanding in accordance with their terms.

Vical Equity Incentive Plan

In connection with the Merger, the Company adopted the Vical Plan, which was replaced by the Omnibus Plan on April 20, 2020. As a result, at September 30, 2020, there were no remaining shares available for new grants under the Vical Plan. However, as of September 30, 2020, 281,253 shares were subject to outstanding awards under the Vical Plan, which awards remain outstanding in accordance with their terms.

Stock-based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 98	$ 81	$ 270	$ 237
General and administrative	455	243	1,139	770
Total stock-based compensation expense	$ 553	$ 324	$ 1,409	$ 1,007

NOTE 9. SUBSEQUENT EVENTS

Public Offering of Common Stock and Warrants

In October 2020, the Company entered into an underwriting agreement with Oppenheimer, as representative of several underwriters, relating to the public offering, issuance and sale of 19,003,510 shares of its common stock, and, to certain investors, pre-funded warrants to purchase 1,829,812 shares of its common stock, and accompanying common stock warrants to purchase up to an aggregate of 20,833,322 shares of its common stock (the "October 2020 Offering"). Each share of common stock and pre-funded warrant to purchase one share of our common stock was sold together with a common warrant to purchase one share of our common stock. The public offering price of each share of the Company's common stock and accompanying common warrant was $0.72 and $0.719 for each pre-funded warrant and accompanying common warrant, respectively. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of the Company's common stock. The common warrants were immediately exercisable at a price of $0.72 per share of the Company's common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The October 2020 Offering resulted in net proceeds of approximately $13.7 million to the Company after deducting underwriting commissions

and discounts and other offering expenses of $1.3 million and excluding the proceeds, if any, from the exercise of the warrants. The Company anticipates using the net proceeds from the October 2020 Offering for research and development, including clinical trials, working capital, and general corporate purposes.

Sales of Shares under the ATM Agreement

Subsequent to September 30, 2020 and through November 12, 2020, the Company sold959,749 Shares under the ATM Agreement at a weighted-average price of $ 0.88 per share, resulting in aggregate net proceeds to the Company of $0.8 million, after giving effect to a 3% commission to Oppenheimer as Agent.

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

Overview

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

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

Hyperhidrosis is a life-altering condition of sweating beyond what is physiologically required to maintain normal thermal regulation. It is believed to be caused by an overactive cholinergic response of the sweat glands and affects an estimated 15.3 million, or 4.8%, of the population of the U.S. According to a 2016 update on the prevalence and severity of hyperhidrosis in the U.S. 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 U.S. or an estimated 10 million individuals.

We and our development partner in Asia, Kaken Pharmaceutical Co., Ltd., ("Kaken"), have conducted multiple clinical trials of sofpironium bromide gel that encompass over 1,300 subjects in the U.S. and Japan. These trials evaluated the potential safety, tolerability, pharmacokinetics (PK), and efficacy of sofpironium bromide gel in adult and pediatric primary axillary hyperhidrosis patients and healthy adult subjects. Under our License, Development and Commercialization Agreement with Kaken, dated March 31, 2015 (as amended, the "Kaken Agreement"), in exchange for paying us an upfront, nonrefundable payment, we granted Kaken the exclusive right to develop, manufacture and commercialize sofpironium bromide in Japan and certain other Asian countries. In March 2019, Kaken completed a Phase 3 trial in patients with primary axillary hyperhidrosis in Japan, achieving statistical significance ($p<0.05$) on all primary and secondary endpoints, upon which Kaken filed for, and in September 2020 received, regulatory approval to manufacture and market in Japan sofpironium bromide gel, 5% under the brand name ECCLOCK® for the treatment of primary axillary (underarm) hyperhidrosis.

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

Recent Clinical and Regulatory Matters

U.S. Phase 3 Clinical Studies

In October 2020, we initiated our first of two pivotal U.S. Phase 3 clinical studies evaluating sofpironium bromide gel, 15% for the treatment for primary axillary (underarm) hyperhidrosis (the "Cardigan I Study"). The Cardigan I Study is expected to enroll up to 350 subjects aged nine years and older with primary axillary hyperhidrosis and is a multicenter, randomized, double-blinded, vehicle (placebo)-controlled Phase 3 study to evaluate the safety and efficacy of topically applied sofpironium bromide gel, 15%. Subjects will apply sofpironium bromide or vehicle once daily at bedtime to their underarms for six consecutive weeks, with a two-week post-treatment follow-up.

The co-primary efficacy endpoints of the Cardigan I Study include the proportion of subjects achieving at least a 2-pointimprovement on the Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) scale, a proprietary and validated patient-reported outcome measure, and change in gravimetric sweat production (GSP), each from baseline to end of treatment (EOT). In addition, safety and tolerability assessments will be performed throughout the study.

We plan to initiate the second of the two pivotal U.S. Phase 3 clinical trials (the "Cardigan II Study") for sofpironium bromide gel, 15% in the fourth quarter of 2020. The Cardigan II Study will evaluate the safety and efficacy of sofpironium bromide gel, 15% versus vehicle in approximately 350 subjects aged nine years and older with primary axillary hyperhidrosis.

We expect to report topline data from both the Cardigan I and II Studies by the end of 2021.

Regulatory Approval by Development Partner in Japan

In September 2020, Kaken received regulatory approval in Japan to manufacture and market sofpironium bromide gel, 5% under the brand name ECCLOCK® for the treatment of primary axillary (underarm) hyperhidrosis. This regulatory approval was based on the results of Kaken's Japanese pivotal Phase 3 registration study of sofpironium bromide gel, 5% in 281 patients with primary axillary hyperhidrosis, in which all primary and secondary efficacy endpoints demonstrated statistically significant differences between sofpironium bromide gel and vehicle. In addition, sofpironium bromide gel, 5% was observed to be safe and generally well tolerated in this study, as well as in the accompanying 52-week long-term safety extension study with 185 patients in Japan. Under the Kaken Agreement, we are entitled to receive commercial milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide in Japan.

Together with Kaken, we were granted by the Japanese Patent Office a composition of matter patent with claims directed to the novel polymorphic, or crystalline, forms of sofpironium bromide that is expected to provide additional protection for these newly developed and distinct forms in Japan through 2040.

Phase 3 Open-Label Long-Term Safety Study

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

AnGes Collaboration Agreement

In September 2020, we entered into a collaboration agreement with AnGes, Inc. ("AnGes") relating to the development and potential commercialization of AnGes' proprietary investigational adjuvanted plasmid DNA vaccine intended to prevent SARS-CoV-2 (COVID-19). Under the terms of the collaboration agreement, AnGes will continue to lead the development of its vaccine candidate in Japan and we will provide information and know-how that could be relevant to such development efforts. If AnGes obtains positive results from its clinical studies in Japan and we are able to satisfy certain conditions, including raising the required development funding, we would have the right to lead the development efforts in the U.S. and certain emerging markets. If ultimately approved for sale in the applicable jurisdictions, AnGes would have commercial rights to the vaccine in Japan and we would have commercial rights in the U.S. and certain emerging markets on terms and conditions to be agreed with AnGes prior to any launch of a vaccine product. AnGes currently is conducting Phase 1/2

clinical studies with its vaccine candidate in Japan, with data readouts expected through the first quarter of 2021. The results from these studies will guide any further development efforts by AnGes and us of this novel vaccine candidate.

Significant Financing and Licensing Arrangements

Public Offerings of Common Stock and Warrants

In October 2020, we entered into an underwriting agreement with Oppenheimer & Co. Inc. ("Oppenheimer"), as representative of several underwriters, relating to the public offering, issuance and sale of 19,003,510 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 1,829,812 shares of our common stock, and accompanying common stock warrants to purchase up to an aggregate of 20,833,322 shares of our common stock (the "October 2020 Offering"). Each share of common stock and pre-funded warrant to purchase one share of common stock was sold together with a common warrant to purchase one share of our common stock. The public offering price of each share of common stock and accompanying common warrant was $0.72 and $0.719 for each pre-funded warrant and accompanying common warrant, respectively. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of common stock. The common warrants were immediately exercisable at a price of $0.72 per share of common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The October 2020 Offering resulted in net proceeds of approximately $13.7 million to the Company after deducting underwriting commissions and discounts and other offering expenses of $1.3 million and excluding the proceeds, if any, from the exercise of the warrants.

In June 2020, we entered into an underwriting agreement with Oppenheimer, as representative of several underwriters, relating to the public offering, issuance and sale of 14,790,133 shares of our common stock, and, to certain investors, pre-funded warrants to purchase 2,709,867 shares of our common stock, and accompanying common warrants to purchase up to an aggregate of 17,500,000 shares of our common stock (the "June 2020 Offering") (and together with the October 2020 Offering, the "2020 Offerings"). Each share of common stock and pre-funded warrant to purchase one share of our common stock was sold together with a common warrant to purchase one share of our common stock. The public offering price of each share of common stock and accompanying common warrant was $1.15 and $1.149 for each pre-funded warrant and accompanying common warrant, respectively. The pre-funded warrants were immediately exercisable at a price of $0.001 per share of our common stock. The common warrants were immediately exercisable at a price of $1.25 per share of our common stock and will expire five years from the date of issuance. The shares of common stock and pre-funded warrants, and the accompanying common warrants, were issued separately and were immediately separable upon issuance. The June 2020 Offering resulted in approximately $18.7 million of net proceeds after deducting underwriting commissions and discounts and other offering expenses of $1.4 million and excluding the proceeds, if any, from the exercise of the warrants.

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

At Market Issuance Sales Agreement

In April 2020, we entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with Oppenheimer as our sales agent (the "Agent"). Pursuant to the terms of the ATM Agreement, we may sell from time to time through the Agent shares of our common stock having an aggregate offering price of up to $8.0 million (the "Shares"). The Shares are issued pursuant to our shelf registration statement on Form S-3 (Registration No. 333-236353). Sales of the Shares are made by means of ordinary brokers' transactions on The Nasdaq Capital Market at market prices or as otherwise agreed by us and the Agent. Under the terms of the ATM Agreement, we may also sell the Shares from time to time to the Agent as principal for its own account at a price to be agreed upon at the time of sale. Any sale of the Shares to the Agent as principal would be pursuant to the terms of a separate placement notice between us and the Agent. We will be significantly limited in our ability to sell shares of our common stock under the ATM Agreement unless and until the number of authorized shares of our common stock is increased, which would require stockholder approval. Through November 12, 2020, aggregate net proceeds of approximately $3.4 million were received from the sale of 4,360,167 Shares at a weighted-average price of $0.85 per share, after giving effect to a 3% commission to Oppenheimer as Agent plus initial expenses for executing the ATM Agreement.

Private Placement Offerings

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

Under the terms and subject to the conditions of the Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to $28.0 million in the aggregate of shares of our common stock. Sales of common stock by us, if any, will be subject to certain limitations, and may occur from time to time, at our sole discretion, over the 36-month period commencing on August 14, 2020 (the "Commencement Date"). Further, we will be significantly limited in our ability to sell shares of our common stock under the Purchase Agreement unless and until the number of authorized shares of our common stock is increased, which would require stockholder approval.

Following the Commencement Date, under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 100,000 shares of our common stock on such business day (each, a "Regular Purchase"), provided, however, that (i) the Regular Purchase may be increased to up to 125,000 shares, provided that the closing sale price of the common stock is not below $3.00 on the purchase date; and (ii) the Regular Purchase may be increased to up to 150,000 shares, provided that the closing sale price of the common stock is not below $5.00 on the purchase date. In each case, Lincoln Park's maximum commitment in any single Regular Purchase may not exceed $1,000,000. The purchase price per share for each such Regular Purchase will be based off of prevailing market prices of common stock immediately preceding the time of sale. In addition to Regular Purchases, we may direct Lincoln Park to purchase other amounts as accelerated purchases or as additional accelerated purchases if the closing sale price of the common stock exceeds certain threshold prices as set forth in the Purchase Agreement. In all instances, we may not sell shares of our common stock to Lincoln Park under the Purchase Agreement if it would result in Lincoln Park beneficially owning more than 9.99% of the outstanding shares of our common stock. As of September 30, 2020, we have not made any sales of our common stock under the Purchase Agreement.

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

Amended and Restated License Agreement with Bodor

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

The Amended and Restated License Agreement retains with us a worldwide, exclusive license to develop, manufacture, market, sell and sublicense products containing the proprietary compound sofpironium bromide based upon the patents referenced in the Amended and Restated License Agreement for a defined field of use. In exchange for entering into the Amended and Restated License Agreement, settling the previously disclosed dispute, and resolving the associated litigation between us and Bodor, we made an upfront payment of $1.0 million in cash to Bodor following the execution of the Amended and Restated License Agreement and the settlement agreement by and among the Company, Brickell Subsidiary, Inc., and Bodor, dated February 17, 2020. Additionally, based on the License Agreement and the Amended and Restated License Agreement, we are required to pay Bodor (i) a royalty on sales of product outside Kaken's territory, including a low single-digit royalty on sales of certain product not covered by the patent estate licensed from Bodor; (ii) a specified percentage of all royalties we receive from Kaken for sales of product within its territory; (iii) a percentage of non-royalty sublicensing income we receive from Kaken or other sublicensees; and (iv) up to an aggregate of $1.8 million (plus an additional $0.1 million for approvals of additional products) in cash payments and $1.5 million of shares of our common stock upon the achievement of certain development, regulatory and other milestones, including the enrollment of the first

patient in the U.S. Phase 3 trials. Based on the foregoing, we made a $0.5 million milestone payment to Bodor in June 2020 following the closing of the June 2020 Offering. Additionally, in October 2020, in association with the enrollment of the first patient in our U.S. Phase 3 pivotal program, we made a cash payment of $0.5 million and issued $0.5 million, or 480,769 shares, of our common stock to Bodor. As a result, during the nine months ended September 30, 2020, we recorded an aggregate of $1.5 million as research and development expense in the condensed consolidated statements of operations.

Corporate History

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

Financial Overview

Our operations to date have been limited to business planning, raising capital, developing our pipeline assets (in particular sofpironium bromide), identifying product candidates, and other research and development. To date, we have financed operations primarily through funds received from the sale of convertible preferred stock, debt, convertible notes, common stock, and warrants, funds received from license and collaboration agreements, and cash and investments acquired in connection with the Merger. We do not have any products approved for sale and have not generated any product sales. Since inception and through September 30, 2020, we have raised or generated an aggregate of $149.6 million to fund our operations, of which $39.1 million was through license and collaboration agreements, $37.0 million was from cash and investments acquired in the Merger, $33.6 million was from the sale of convertible preferred stock, $25.0 million was from the sale of common stock and warrants, $7.5 million was from the sale of debt, and $7.4 million was from the sale of convertible notes. As of September 30, 2020, we had cash and cash equivalents of $20.2 million. As described above, subsequent to September 30, 2020, we received approximately $13.7 million in net proceeds from the October 2020 Offering and $0.8 million in net proceeds from sales under the ATM Agreement.

Since inception, we have incurred operating losses. We recorded a net loss of $4.3 million and $4.8 million for the three months ended September 30, 2020 and 2019, respectively, and $13.5 million and $13.0 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $98.5 million. We expect to continue incurring significant expenses and operating losses for at least the next several years as we:

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

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

Key Components of Operations

Collaboration Revenue

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

Research and Development Expenses

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(in thousands)			
Direct program expenses related to sofpironium bromide	$ 409	$ 2,452	$ 4,140	$ 10,871
Personnel and other expenses				
Salaries, benefits, and stock-based compensation	758	863	2,233	2,518
Regulatory and compliance	79	18	137	158
Other expenses	35	4	147	38
Total research and development expenses	$ 1,281	$ 3,337	$ 6,657	$ 13,585

General and Administrative Expenses

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

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

Total Other Income (Expense)

Investment and Other Income, Net

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

Gain on Extinguishment

Gain on extinguishment consists of the gain realized on the conversion of convertible promissory notes to common stock in August 2019, as described further immediately below.

Interest Expense

Interest expense historically consisted primarily of interest and amortization related to the issuance of $7.4 million of convertible promissory note principal during the nine months ended September 30, 2019 and principal borrowings of $7.5 million provided by the loan and security agreement entered into with Hercules Capital, Inc. on February 18, 2016 (the "Loan Agreement"). In August 2019, the convertible promissory notes were converted and the Loan Agreement was repaid, and therefore, there was no interest expense thereafter related to these agreements.

Change in Fair Value of Warrant and Derivative 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 in the condensed consolidated statements of operations within the "Change in fair value of warrant and derivative liability" line item. The liability was adjusted for changes in fair value through August 2019, and at that time the final warrant liability fair value was reclassified to equity in the condensed consolidated balance sheets and no longer remeasured to fair value each period.

Critical Accounting Policies and Estimates

We have prepared the condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). The preparation of these condensed consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, management evaluates its critical estimates, including those related to revenue recognition, accrued research and development expenses, convertible promissory notes, redeemable convertible preferred stock, warrants, and stock-based compensation. We base our estimates on our historical experience and on assumptions that we believe are reasonable; however, actual results may differ materially from these estimates under different assumptions or conditions.

For the nine months ended September 30, 2020, there have been no material changes in our critical accounting policies and estimates as compared to those disclosed in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 18, 2020.

Recent Accounting Pronouncements

For information on recent accounting pronouncements, whether adopted or to be adopted, that may impact our business, see Note 2 of the notes to the condensed consolidated financial statements included elsewhere in this Quarterly Report. Unless otherwise discussed, we believe that the impact of recently issued guidance to be adopted in the future is not expected to have a material impact on our condensed consolidated financial statements upon adoption.

Results of Operations

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

	Three Months Ended September 30,	
	2020	2019
	(in thousands)	
Collaboration revenue	$ 142	$ 1,183
Research and development expenses	(1,281)	(3,337)
General and administrative expenses	(3,211)	(3,901)
Total other income, net	24	1,274
Net loss	$ (4,326)	$ (4,781)

Collaboration Revenue

Collaboration revenue decreased by $1.0 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. Revenue in both periods was driven by research and development activities related to the Kaken Agreement for which Kaken provided research and development funding. The decrease in revenue recognized was attributable to our Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were ongoing in 2019 but were concluded or winding down by the end of the first quarter of 2020. Conducting these studies is the basis for revenue recognition of a $15.6 million research and development payment received from Kaken in the second quarter of 2018.

Research and Development

Research and development expense decreased by $2.1 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019, which was primarily due to reduced clinical and other related regulatory and compliance costs of the Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were concluded or winding down by the end of the first quarter of 2020.

General and Administrative Expenses

General and administrative expenses decreased by $0.7 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. This decrease was primarily due to lower costs of $1.1 million for professional-related fees associated with the Merger that occurred in the third quarter of 2019 and $0.4 million for other miscellaneous fees, partially offset by higher costs of $0.6 million for stock and other compensation expense that was driven by increased headcount and $0.2 million for directors' and officers' liability insurance due to becoming a public company.

Total Other Income, Net

Total other income, net decreased by $1.3 million for the three months ended September 30, 2020 compared to the three months ended September 30, 2019. The decrease was primarily due to a gain of $2.3 million related to the conversion of the convertible promissory notes in August 2019 and a decrease of $1.1 million in interest expense related to the issuance of convertible promissory notes in 2019 and principal borrowings provided by the Loan Agreement with a former lender, none of which recurred in the 2020 period.

Comparison of the Nine Months Ended September 30, 2020 and 2019

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Collaboration revenue	$ 1,795	$ 7,248
Research and development expenses	(6,657)	(13,585)
General and administrative expenses	(8,713)	(7,290)
Total other income, net	27	612
Net loss	$ (13,548)	$ (13,015)

Collaboration Revenue

Collaboration revenue decreased by $5.5 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. Revenue in both periods was driven by research and development activities related to the Kaken Agreement for which Kaken provided research and development funding. The decrease in revenue recognized was attributable to our Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were ongoing in 2019 but were concluded or winding down by the end of the first quarter of 2020. Conducting these studies is the basis for revenue recognition of a $15.6 million research and development payment received from Kaken in the second quarter of 2018.

Research and Development

Research and development expenses decreased by $6.9 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019, which was primarily due to a decrease in clinical and other related regulatory and compliance costs of the Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were concluded or winding down by the end of the first quarter of 2020. During the nine months ended September 30, 2020, research and development expense of $1.5 million was recorded relating to certain milestone obligations pursuant to the Amended and Restated License Agreement with Bodor.

General and Administrative Expenses

General and administrative expenses increased by $1.4 million for the nine months ended September 30, 2020 compared to the nine months ended September 30, 2019. This increase was primarily due to higher costs of $1.4 million for stock and other compensation expense that was driven by increased headcount and $0.8 million for directors' and officers' liability insurance due to becoming a public company, partially offset by lower costs of $0.8 million for other miscellaneous expenses.

Total Other Income, Net

Total other income, net decreased by $0.6 million for the nine months ended September 30, 2020 compared the nine months ended September 30, 2019. The change was primarily due to a gain of $2.3 million related to the conversion of the convertible promissory notes in August 2019 and a gain of $0.2 million gain resulting from fair value adjustments to warrant liabilities during the nine months ended September 30, 2019, both of which did not recur in 2020. These gains were partially offset by a decrease of $2.0 million in interest expense related to the issuance of convertible promissory notes in 2019 and principal borrowings provided by the Loan Agreement with a former lender.

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, 2020 and 2019, we had a net loss of $13.5 million and $13.0 million, respectively. As of September 30, 2020 and December 31, 2019, we had an accumulated deficit of $98.5 million and $85.0 million, respectively. As of September 30, 2020, we had cash and cash equivalents of $20.2 million. Since inception, we have financed our operations primarily through funds received from the sale of convertible preferred stock, common stock

and warrants, debt, and convertible notes, payments received under strategic license and collaboration agreements, and cash and investments acquired in the Merger.

We believe that our cash and cash equivalents as of September 30, 2020, combined with the proceeds received from the sale of our common stock and warrants in the October 2020 Offering, are sufficient to fund our operations for at least the next 12 months from the issuance of this Quarterly Report. We expect to continue to incur additional substantial losses in the foreseeable future as a result of our research and development activities. Additional funding will be required in the future to continue with our planned development and commercial related activities.

Cash Flows

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

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (15,283)	$ (21,940)
Net cash provided by investing activities	4,500	18,509
Net cash provided by financing activities	23,725	2,589
Net change in cash and cash equivalents	$ 12,942	$ (842)

Operating Activities

Net cash used in operating activities of $15.3 million during the nine months ended September 30, 2020 decreased compared to $21.9 million during the same period in the prior year primarily due to changes in working capital of $6.0 million and an increase of other non-cash net expenses of $1.1 million, partially offset by an increase in net loss of $0.5 million.

Investing Activities

Net cash provided by investing activities of $4.5 million during the nine months ended September 30, 2020 decreased compared to $18.5 million during the same period in the prior year. The $14.0 million decrease was primarily the result of cash received from Vical in the Merger in the 2019 period.

Financing Activities

Net cash provided by financing activities of $23.7 million during the nine months ended September 30, 2020 increased compared to $2.6 million during the same period in the prior year. The increase was primarily related to higher net proceeds received in the 2020 period from the issuance of common stock and warrants of $23.3 million and proceeds from the issuance of a note payable of $0.4 million, compared to net proceeds received in the 2019 period from the issuance of convertible promissory notes of $7.4 million, partially offset by the repayment of principal associated with the Loan Agreement in the 2019 period of $4.8 million.

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the design and operation of our disclosure controls and procedures, as such term is defined in Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act as of the end of the period covered by this Quarterly Report. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective and were operating at a reasonable assurance level as of September 30, 2020.

Changes in Internal Control over Financial Reporting

Management has determined that there were no significant changes in our internal control over financial reporting that occurred during the three months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On September 4, 2020, a confidential binding settlement was reached with Patricia S. Walker, our former President and Chief Scientific Officer, with regard to litigation she brought in the United States District Court for the Central District of California against our company, one of our officers, our Board Chairperson and others, alleging wrongful termination for unspecified damages, and claiming discrimination based on age, gender, and association with a person with a disability. On September 25, 2020, Ms. Walker filed a notice with the court dismissing her action with prejudice. On September 29, 2020, Ms. Walker notified the arbitrator who would have decided the case of the settlement, who has now closed the matter. On October 2, 2020, we made an immaterial payment in consideration of the settlement, and the matter is final.

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

ITEM 1A. RISK FACTORS

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

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

Risks Related to Our Business Operations

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

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

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

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

- ability to commercialize sofpironium bromide successfully in the U.S. 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 pivotal Phase 3 clinical trial ourselves and may be unable to successfully do so for sofpironium bromide.

The conduct of a pivotal Phase 3 clinical trial is a long, expensive, complicated, uncertain, and highly regulated process. Although our employees have conducted successful Phase 2 and Phase 3 clinical trials in the past across many therapeutic areas while employed at other companies, we as a company have not conducted a pivotal Phase 3 clinical trial, and as a result, we may require more time and incur greater costs than we anticipate. We commenced a Phase 3 long-term safety study for sofpironium bromide gel in the third quarter of 2018 and intend to conduct two pivotal Phase 3 clinical trials in subjects with primary axillary hyperhidrosis in the U.S. While we initiated the U.S. Phase 3 pivotal program for sofpironium bromide gel, 15% in the fourth quarter of 2020, we may not be able to complete that program in a reasonable timeframe, or at all. Failure to commence or complete, or delays in, our planned clinical trials would prevent us from, or delay us in, obtaining regulatory approval of and commercializing sofpironium bromide and could prevent us from, or delay us in, receiving development- or regulatory-based milestone payments and commercializing sofpironium bromide gel for the treatment of primary axillary hyperhidrosis, which would adversely impact our financial performance, as well as put us in potential breach of material contracts for the licensing and development of sofpironium bromide, subjecting us to significant contract liabilities, including but not limited to potential loss of rights in and to sofpironium bromide.

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

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

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

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

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

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

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

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

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

****Under our Clinical Supply Agreement with Kaken, we owe an outstanding sum for API for further development of sofpironium bromide, and our inability to obtain such API from Kaken on a timely basis, or Kaken's attempt to immediately collect the outstanding sum in full, could have a material adverse impact on our business.***

On July 30, 2019, we entered into a Clinical Supply Agreement with Kaken (the "Clinical Supply Agreement") under which we made various purchase orders for certain amounts of drug substance and product components for use in non-clinical and clinical studies, as well as for scale-up validation activities. As of September 30, 2020, we owed Kaken approximately $2.8 million. As a result of our non-payment, Kaken could assert a breach or default under the Clinical Supply Agreement and seek damages and/or termination of the Clinical Supply Agreement, among other available remedies. We have entered into a letter agreement with Kaken specifying the terms under which Kaken will ship to us, and we will pay for, a portion of the API, but that letter agreement does not include a waiver of Kaken's rights in respect of our non-payment. If Kaken were to seek the immediate payment of all amounts owed under the Clinical Supply Agreement, and we are unable to secure additional resources, our liquidity and cash position would be impaired, and our ability to meet our other financial obligations as they come due could be materially adversely affected.

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

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

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

In September 2020, Kaken received approval of a new drug application in Japan for the manufacturing and marketing of sofpironium bromide gel, 5% for primary axillary hyperhidrosis. Despite receiving such approval in Japan, we cannot provide any assurance that a new drug application in any other Asian markets will be approved or that regulatory approvals in other Asian countries will occur. We will not receive additional milestone or other payments from Kaken if Kaken is not successful in its development, regulatory or commercial activities.

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

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

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

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In the U.S., although private third-party payors tend to follow Medicare and Medicaid practices, no uniform or consistent policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor as well as

state to state. Consequently, the coverage determination process is often uncertain and a time-consuming and costly process that must be played out across many jurisdictions and different entities and which will require us to provide scientific, clinical and health economics support for the use of sofpironium bromide compared to current alternatives and do so to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained and in what amount or time frame.

Further, we believe that future coverage and reimbursement likely will be subject to increased restrictions both in the U.S. and in international markets, potentially based on changes in law and/or payor practices. Third-party coverage and reimbursement for sofpironium bromide may not be available or adequate in either the U.S. or international markets, which could harm our business, financial condition, operating results, and prospects.

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 U.S., will depend on a number of factors, including but not limited to:

- patient demand for approved products that treat hyperhidrosis;
- our ability to market and sell the drug, including through direct-to-consumer advertising and non-traditional sales strategies;
- our ability to manage the novel Coronavirus ("COVID-19") pandemic to complete necessary clinical trials, supply/manufacture sofpironium bromide for such trials and commercially, and otherwise market and sell sofpironium bromide while the pandemic continues in effect;
- the safety and effectiveness of sofpironium bromide, and ease of use, compared to other available hyperhidrosis therapies, whether approved or used by physicians off-label;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for sofpironium bromide;
- the cost of treatment with sofpironium bromide in relation to alternative hyperhidrosis treatments and willingness to pay for sofpironium bromide, if approved, on the part of patients;
- overcoming physician or patient biases toward particular therapies for the treatment of hyperhidrosis and achieving acceptance by physicians, major operators of clinics and patients of sofpironium bromide as a safe, effective, and economical hyperhidrosis treatment;
- patients' perception of hyperhidrosis as a disease and one for which medical treatment may be appropriate and a prescription therapy may be available;
- insurers' and physicians' willingness to see hyperhidrosis as a disease worth treating and for which reimbursement will be made available for treatment;
- proper administration of sofpironium bromide;
- patient satisfaction with the results and administration of sofpironium bromide and overall treatment experience;
- limitations or contraindications, warnings, precautions, or approved indications for use different than those sought by us that are contained in any final FDA-approved labeling for sofpironium bromide;
- any FDA requirement to undertake a risk evaluation and mitigation strategy, or results from any post-marketing surveillance studies that FDA may require as a condition of product approval;

- the effectiveness of our sales, marketing, pricing, reimbursement and access, government affairs, legal, medical, public relations, compliance, and distribution efforts;
- adverse publicity about sofpironium bromide or favorable publicity about competitive products;
- new government regulations and programs, including price controls and/or public or private institutional limits or prohibitions on ways to commercialize drugs, such as increased scrutiny on direct-to-consumer advertising of pharmaceuticals or restrictions on sales representatives to market pharmaceuticals; and
- potential product liability claims or other product-related litigation or litigation related to licensing and or other commercial matters associated with sofpironium bromide.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Due to less stringent regulatory requirements in certain foreign countries, there are many more dermatological products and procedures available for use in those international markets than are approved for use in the U.S. 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 U.S.

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

Upon expiration of patent protection (including applicable extensions) in the U.S. (and any other countries where patent coverage exists) for sofpironium bromide, we could lose a significant portion of then-existing sales of sofpironium bromide in a short period of time from generic competition, which would reduce existing sales and could expose us to litigation, adversely affecting our business, financial condition, operating results, and prospects. Further, other therapies used for hyperhidrosis that would compete with sofpironium bromide could lose their patent protection at any time, increasing the risk of generic competition, which could reduce existing sales and adversely affect our business, financial condition, operating results, and prospects.

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

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

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

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

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

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

The COVID-19 vaccine candidate that is the subject of our collaboration agreement with AnGes, Inc. is at an early stage, it may not result in a safe and effective product candidate in a timely manner, or at all, there could be supply chain issues for both clinical and commercial contexts, and we may not be able to proceed with related development and commercialization activities. Further, any attention and resources we devote to this vaccine candidate could negatively impact our development program related to sofpironium bromide.

In September 2020, we entered into a collaboration agreement with AnGes relating to the development and potential commercialization of AnGes' proprietary investigational adjuvanted plasmid DNA vaccine intended to prevent SARS-CoV-2 (COVID-19). Under the terms of the collaboration agreement, AnGes will continue to lead the development of its vaccine candidate in Japan and we will provide information and know-how that could be relevant to such development efforts. If AnGes obtains positive results from its clinical studies in Japan and we are able to satisfy certain conditions, including raising the required development funding, we would have the right to lead the development efforts in the U.S. and certain emerging markets. If ultimately approved for sale in the applicable jurisdictions, AnGes would have commercial rights to the vaccine in Japan and we would have commercial rights in the U.S. and certain emerging markets on terms and conditions to be agreed with AnGes prior to any launch of a vaccine product.

AnGes currently is conducting Phase 1/2 clinical studies with its vaccine candidate in Japan, with data readouts expected through the first quarter of 2021. The results from these studies will guide any further development efforts by AnGes and us of this novel vaccine candidate. As such, the work on this vaccine candidate is in the early stages, and it may not develop into an effective and safe vaccine in a timely manner, or at all. All product candidates are prone to significant risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by one or more regulatory authorities. Some regulatory authorities may approve a product candidate while others do not, or may provide approval on different terms or with additional conditions or limitations, or may issue any regulatory approval decisions at very different times. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, costly, and inherently unpredictable, especially for early-stage product candidates. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. The development of any early-stage product candidates may be discontinued at any time for a variety of reasons, including but not limited to safety and efficacy concerns, the appearance of new technologies that make the product obsolete, competition from a competing product, supply chain considerations, intellectual property right impacts, ability to price or changes in or failure to comply with applicable regulatory requirements, or constraints on us or our product sponsor in obtaining additional financing and capital.

In addition, a substantial number of companies, individuals and institutions are working to develop a COVID-19 vaccine, many of which commenced studies much earlier than the studies commenced by AnGes and many of which have substantially greater financial, scientific and other resources than AnGes and us, and another party may be successful in producing a vaccine in a much faster timeframe and producing a safer or more efficacious vaccine or other treatment for COVID-19, or a less costly treatment, which may also lead to the diversion of governmental and quasi-governmental funding toward other companies and better insurance coverage for other COVID-19 treatments, and lead to demand being driven away from any product developed by AnGes or us, or cause AnGes and/or us to cancel or significantly scale back the introduction of a vaccine candidate based on the other available patient options. The rapid expansion of development programs directed at COVID-19 may also generate a scarcity of manufacturing capacity among contract research organizations that provide cGMP materials for development and commercialization of biopharmaceutical products, and/or could make it difficult for those conducting clinical studies to recruit in a timely manner an adequate number of trial participants, especially for companies like AnGes and us which started these studies much later than other companies.

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

Risks Related to Our Financial Operations

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

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

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

Our ability to raise additional funds is uncertain and is limited given our small market capitalization. Even if sufficient funding is available, there can be no assurance that it will be available on terms acceptable to us or our stockholders.

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

Our operating results and liquidity could be affected negatively by global economic conditions generally, both in the U.S. and elsewhere around the world, including but not limited to the ongoing COVID-19 pandemic. The market for discretionary pharmaceutical products, medical devices and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider sofpironium bromide as discretionary, and if full reimbursement for the product is not available, demand for the product may be tied to the discretionary, out-of-pocket cash-spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, or a bear market ensues in the U.S. stock market, including as a result of the recent COVID-19 outbreak, our operating results and liquidity could be affected adversely by those factors in many ways, including weakening demand for sofpironium bromide, making it more difficult for us to raise funds if necessary, and our stock price may decline.

Our stock price and volume of shares traded have been and may continue to be highly volatile, and our common stock may continue to be illiquid.

The market price of our common stock following the Merger has been subject to significant fluctuations. The closing price of our common stock fluctuated from $4.69 per share as of September 3, 2019, the first trading date following the closing of the Merger, to $0.90 per share as of September 30, 2020. Market prices for securities of biotechnology and other life sciences companies historically have been particularly volatile subject even to large daily price swings. In addition, there has been limited liquidity in the trading market for our securities, which may adversely affect stockholders. Some of the factors that may cause the market price of our common stock to continue to fluctuate include, but are not limited to:

- material developments in, or the conclusion of, any litigation to enforce or defend any intellectual property rights or defend against the intellectual property rights of others;
- our inability to increase our share price to at least $1.00 per share for the frequency and duration required by The Nasdaq Capital Market to stay listed on this stock exchange and the impact that this lower price may have on investors;
- the entry into, or termination of, or breach by us or our partners of material agreements, including key commercial partner or licensing agreements, including the Kaken Agreement;
- our ability to obtain timely regulatory approvals for sofpironium bromide or future product candidates, and delays or failures to obtain such approvals;
- failure of sofpironium bromide, if approved, to achieve commercial success;
- issues in manufacturing or the supply chain for sofpironium bromide or future product candidates;
- the results of current and any future clinical trials of sofpironium bromide;
- failure of other product candidates, if approved, to achieve commercial success;
- announcements of any dilutive equity financings;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies or formulations that compete with sofpironium bromide;
- lack of commercial success of competitive products or products treating the same or similar indications;
- failure to elicit meaningful stock analyst coverage and downgrades of our stock by analysts; and
- the loss of key employees and/or inability to recruit the necessary talent for new positions or to replace exiting employees.

Moreover, the stock markets in general have experienced substantial volatility in our industry that has often been unrelated to the operating performance of individual companies or a certain industry segment, such as the ongoing reaction of global markets to the COVID-19 outbreak. These broad market fluctuations may also adversely affect the trading price of our common stock.

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

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

Our operations to date have been limited primarily to researching and developing sofpironium bromide and undertaking preclinical studies and clinical trials of sofpironium bromide. 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, the achievement of sales milestones and royalties under an agreement with Kaken, as well as any potential future collaboration and license agreements and sales of sofpironium bromide or future products, if approved, and our ability to maintain the related license. These up-front and milestone

payments may vary significantly from period to period, and country to country, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict.

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

We qualify as a "smaller reporting company" under Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). As a smaller reporting company, we are entitled to rely on certain exemptions and reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements, in our SEC filings. These exemptions and decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock price may be more volatile. We will remain a "smaller reporting company" under Item 10(f)(1) of SEC Regulation S-K as long as we maintain a public float as defined by that regulation of less than $250.0 million; or we have less than $100.0 million in annual revenues and (i) either no public float, or (ii) a public float of less than $700.0 million.

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

If the holders of our outstanding stock options and warrants exercise their rights to acquire our common stock and service conditions related to restricted stock units are met, the percentage ownership of our stockholders existing prior to the exercise of such rights will be diluted. As of September 30, 2020, we had outstanding warrants to purchase (i) one share of our common stock at an exercise price of $0.07 per share; (ii) 490,683 shares of our common stock at an exercise price of $10.36 per share; (iii) 9,005 shares of our common stock at an exercise price of $33.31 per share; (iv) 1,556,420 shares of our common stock at an exercise price of $1.16 per share; and (v) 17,500,000 shares of our common stock at an exercise price of $1.25 per share. As of September 30, 2020, we also had 4,743,537 options issued and outstanding to purchase our common stock at a weighted average-exercise price of $4.67 per share and 204,233 shares of common stock underlying unvested restricted stock units outstanding. Subsequent to September 30, 2020, we issued additional warrants to purchase 20,833,322 shares of our common stock at an exercise price of $0.72 per share.

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

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

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On August 17, 2020, we received a notice from the Listing Qualifications Department of the Nasdaq informing us that because the closing bid price for our common stock listed on Nasdaq was below $1.00 per share for 30 consecutive business days, we were not in compliance with the minimum closing bid price requirement for continued listing on The Nasdaq Capital Market under Nasdaq Marketplace Rule 5550(a)(2) (the "Rule"). In accordance with Nasdaq's Listing Rules, we have a period of 180 calendar days, or until February 16, 2021, to regain compliance with the Rule. If at any time during this 180-day period, the closing bid price of our common stock is at least $1.00 per share for a minimum of 10 consecutive business days, Nasdaq will provide written confirmation that we have achieved compliance with the Rule.

The notice also disclosed that in the event we do not regain compliance with the Rule by February 16, 2021, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. If we meet these requirements, Nasdaq will inform us that we have been granted an additional 180 calendar days. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting. We intend to continue to monitor the bid price for our common stock between now and February 16, 2021, and will consider available options to resolve the deficiency and regain compliance with the Rule, including seeking stockholder approval of a reverse split of our common stock in order to increase the trading price of our common stock in compliance with The Nasdaq Capital Market rules. There is no assurance, however, that we will be eligible for an additional compliance period or that our common stock will not be delisted from Nasdaq.

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

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

Our current expectation is that we will retain 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.

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

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

subsequent changes in our stock ownership, as a result of offerings of our stock or subsequent shifts in our stock ownership, some of which may be outside of our control. In that case, the ability to use net operating loss carryforwards to offset future taxable income will be limited following any such ownership change, and could be eliminated. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance on our financial statements.

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

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

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

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

Risks Related to Legal, Regulatory and Compliance Matters

We may never obtain regulatory approval to commercialize any of our product candidates in the U.S., and any products approved for sale will be subject to continued regulatory review and compliance obligations and there could be further restrictions on post-approval activities, including commercialization efforts.

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

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

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

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

- impose restrictions on the sale, marketing, advertising, or manufacturing of the product, or amend, suspend, or withdraw product approvals, or revoke necessary licenses;
- mandate modifications to or prohibit promotional and other product-specific materials or require us to provide corrective information to healthcare practitioners and other customers and/or patients, or in our advertising and promotion;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, penalties for noncompliance and, in extreme cases, require an independent compliance monitor to oversee our activities;
- issue warning letters, bring enforcement actions, initiate surprise inspections, issue show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- debar certain healthcare professionals;
- exclude us from participating in or being eligible for government reimbursement and formulary inclusion;
- initiate audits, inspections, accounting and civil investigations or litigation;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;

- impose other civil or criminal penalties;
- suspend or cancel any ongoing clinical trials;
- place restrictions on the kind of promotional activities that can be done;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the U.S.;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- change or restrict our product labeling; or
- seize or detain products or require us or our partners to initiate a product recall.

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

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

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

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

We face an inherent risk of product liability or similar causes of action as a result of the clinical testing (and use) of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and is manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority and notwithstanding that we comply with applicable laws on promotional activity. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in actual or perceived injury to a patient that may or may not be reversible or potentially even cause death. We cannot offer any assurance that we will not face

product liability or other similar suits in the future or that we will be successful in defending them, nor can we assure that our insurance coverage will be sufficient to cover our liability under any such cases.

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

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

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

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

We are exposed to the risk that our employees, officers, directors, independent contractors, principal investigators, other clinical trial staff, consultants, advisors, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal or unethical activity. Misconduct by these persons could include intentional, reckless, gross or negligent misconduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; product sampling; manufacturing

standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; anticorruption laws, anti-kickback and Medicare/Medicaid rules, debarment laws, promotional laws, securities laws, and/or laws that require the true, complete and accurate reporting of financial information or data, books and records. If any such or similar actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative and punitive penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal or state healthcare programs, debarments, contractual damages, reputational harm, diminished profits and future earnings, injunctions, and curtailment or cessation of our operations, any of which could expose us to liability and adversely affect our business, financial condition, operating results, and prospects.

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

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

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

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

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

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

Additionally, in October 2018, the U.S. President proposed to lower Medicare Part B drug prices, in addition to contemplating other measures to lower or prescribe certain mandatory prescription drug prices or drug substitution policies. While these proposals have not yet been enacted, we expect that additional state and federal healthcare reform measures will

be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates if approved or additional pricing pressures.

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

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

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

Risks Related to Strategic Matters

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

One of our strategies is to in-license and acquire product candidates and we may engage in other strategic transactions. Additional potential transactions that we may consider include a variety of different business arrangements, including mergers and acquisitions, spin-offs, strategic partnerships, joint ventures, co-marketing, co-promotion, distributorships, development and co-development, restructurings, divestitures, business combinations and investments on a global basis. Any such transaction(s) may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures, grow and expand rapidly putting pressure on current resources and capabilities, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. Further, any such transaction(s) may require us to obtain additional financing, which may not be available to us on favorable terms or at all. Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could expose us to liability, delays, and implementation obstacles that could harm our business, financial condition, operating results, and prospects. We have no

current commitment or obligation to enter into any transaction described above other than ones to which we are already committed.

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

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

In order to conduct larger or late-stage clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our drug substances and product candidates in larger quantities, more cost-effectively and, in

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, especially if the patent owner does not enforce or use its patents over a protracted period of time. In some cases, the courts will force compulsory licenses on the patent holder even when finding the patentholder’s patents are valid if the court believes it is in the best interests of the country to have widespread access to an essential product covered by the patent. Further, there is no guarantee that any country will not adopt or impose compulsory licensing in the future. In these situations, the royalty the court requires to be paid by the licenseholder receiving the compulsory license may not be calculated at fair market value and can be inconsequential, thereby disaffecting the patentholder’s business. In these countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could also materially diminish the value of those patents. This would limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own

or license, especially in comparison to what we enjoy from enforcing our intellectual property rights in the U.S. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in both U.S. and foreign intellectual property laws, or changes to the policies in various government agencies in these countries, including but not limited to the patent office issuing patents and the health agency issuing pharmaceutical product approvals. For example, in Brazil, pharmaceutical patents require prior initial approval of the Brazilian health agency, ANVISA. Finally, many countries have large backlogs in patent prosecution, and in some countries in Latin America it can take years, even decades, just to get a pharmaceutical patent application reviewed notwithstanding the merits of the application.

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

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

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

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

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

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

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies notwithstanding the patents we may possess. Because some patent applications in the U.S. and other countries may be maintained in confidence until the patents are issued, because patent applications in the U.S. and many foreign jurisdictions are typically not published until eighteen (18) months or some other time after filing, and

because publications in the scientific literature or other public disclosures often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to our technology. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies, which may mean paying significant licensing fees or royalties, or the like. If another party has filed a U.S. patent application on inventions similar to ours, we or the licensor, may have to participate in the U.S. in an interference proceeding to determine priority of invention.

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

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

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

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

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

General Risk Factors

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

We incur significant legal, accounting, and other expenses that Private Brickell did not incur as a private company prior to the Merger and operating as a public company, including costs associated with public company reporting and other SEC requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as rules implemented by the SEC and The Nasdaq Stock Market LLC ("Nasdaq"). These rules

and regulations have, and are expected to continue to, increase our legal and financial compliance costs and to make some activities more time-consuming and costly. These rules and regulations may also make it expensive for us to operate our business.

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

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

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

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

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation, as amended through August 31, 2020 (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on September 1, 2020).	
3.2	Amended and Restated Bylaws, as currently in effect (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2020).	
4.1	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed with the SEC on October 13, 2020).	
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed with the SEC on October 13, 2020).	
4.3	Form of Warrant Agency Agreement (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1 filed with the SEC on October 13, 2020).	
10.1	Form of Indemnification Agreement by and between the Company and its directors and executive officers (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2020).	
10.2	Brickell Biotech, Inc. 2020 Omnibus Long-Term Incentive Plan, as amended through August 31, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 1, 2020).	
10.3†	Letter Agreement, dated as of September 3, 2020, by and between Brickell Biotech, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 filed with the SEC on October 13, 2020).	
10.4	First Amended and Restated Employment Agreement, dated September 1, 2020, by and between Brickell Biotech, Inc. and Deepak Chadha (incorporated by reference to Exhibit 10.17 to the Company's Registration Statement on Form S-1 filed with the SEC on October 13, 2020).	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.	×
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.	×
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	×
101.INS	Inline XBRL Instance Document	×
101.SCH	Inline XBRL Taxonomy Extension Schema Document	×
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	×
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	×
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	×
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	×
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	×

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

× Filed herewith.

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

SIGNATURES

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

Brickell Biotech, Inc.

Date: November 12, 2020

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

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

Exhibit 31.1

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

I, Robert. B. Brown, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2020

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

Exhibit 31.2

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

I, R. Michael Carruthers, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 12, 2020

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

Exhibit 32.1

SECTION 1350 CERTIFICATION

Each of the undersigned, Robert. B. Brown, Chief Executive Officer of Brickell Biotech, Inc., a Delaware corporation (the "Company"), and R. Michael Carruthers, Chief Financial Officer of the Company, do hereby certify, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Robert. B. Brown

Robert B. Brown
Chief Executive Officer
(Principal Executive Officer)
Date: November 12, 2020

/s/ R. Michael Carruthers

R. Michael Carruthers
Chief Financial Officer
(Principal Financial Officer)
Date: November 12, 2020

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