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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest reported) November 13, 2019

BRICKELL BIOTECH, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**000-21088**	**93-0948554**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5777 Central Avenue
Suite 102
Boulder, CO 80301
(Address of Principal Executive Offices)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 13, 2019, Brickell Biotech, Inc., issued a press release announcing, among other things, its unaudited financial results for the three and nine months ended September 30, 2019. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Brickell Biotech, Inc., on November 13, 2019.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 13, 2019 **Brickell Biotech, Inc.**

By:	/s/ Robert B. Brown
Name:	Robert B. Brown
Title:	Chief Executive Officer

Exhibit 99.1

Brickell Bio Announces Third Quarter 2019 Financial Results and Provides Corporate Update

BOULDER, CO — **November 13, 2019** —Brickell Biotech, Inc. ("Brickell") (Nasdaq: BBI), a clinical-stage pharmaceutical company focused on developing innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases, today announced financial results for the third quarter ended September 30, 2019 and provided a corporate update.

"Becoming a publicly listed company earlier this year was a transformative milestone for Brickell and we remain confident about the potential of our lead asset, sofpironium bromide, for primary axillary hyperhidrosis," commented Robert Brown, Chief Executive Officer of Brickell. "Ten million people in the United States suffer from this disease which can have a negative impact on a patient's social life, well-being, emotional and mental health."

Business and Recent Developments

- In September 2019, Brickell announced completion of its merger with Vical Incorporated ("Vical"), following approval by Vical's shareholders, and commenced trading on The Nasdaq Capital Market under the ticker symbol "BBI". Vical contributed approximately $35 million to the combined company in addition to an R&D financing arrangement entered into with NovaQuest Capital Management that provides up to $25 million in funding.

- The long-term safety study for sofpironium bromide is fully enrolled with 300 subjects and is on track to be completed in the first quarter of 2020. Earlier this year, Brickell's development partner, Kaken Pharmaceutical Co. Ltd. ("Kaken"), achieved positive pivotal Phase 3 results in its clinical study conducted in Japan. To date there have been 19 clinical studies conducted by Brickell and Kaken of sofpironium bromide gel that encompass over 1,200 subjects.

- On October 23, 2019, Bodor Laboratories, Inc. and Nicholas S. Bodor (collectively, "Bodor") filed a complaint against Brickell disputing certain aspects of the license agreement between the parties with respect to sofpironium bromide ("Complaint"). As a result, NovaQuest notified the Company that additional development funding for sofpironium bromide was suspended temporarily. Subsequently, Brickell filed a motion to dismiss the Complaint, initiated arbitration proceedings against Bodor and asserted claims against Bodor for tortious interference and material breach of the license agreement by Bodor.

- The sofpironium bromide pivotal Phase 3 studies in axillary hyperhidrosis are ready to commence in the United States, pending developments in the ongoing dispute resolution process with Bodor.

Financial Results

Cash, cash equivalents, and short-term investments were $25.7 million as of September 30, 2019 compared to $8.1 million as of September 30, 2018.

Revenue was $1.2 million for the third quarter of 2019 compared to $3.0 million for the third quarter of 2018. The decrease is due primarily to the completion of certain research and development activities during the three months ended September 30, 2019 for which funding is provided under a license and collaboration agreement with Kaken.

Research and development expenses were $3.3 million for the third quarter of 2019 compared to $4.1 million for the third quarter of 2018. The decrease in research and development expenses is primarily due to a decrease in clinical studies costs associated with sofpironium bromide following the completion of certain clinical trials.

General and administrative expenses were $3.9 million for the third quarter of 2019 compared to $1.2 million for the third quarter of 2018. The increase in general and administrative expenses is primarily due to an increase in professional fees for legal, accounting, and auditing services, including merger-related costs.

The Company's net loss was $4.8 million for the third quarter of 2019, and $13.0 million for the nine months ended September 30, 2019, compared to $2.5 million for the third quarter of 2018, and $5.6 million for the nine months ended September 30, 2018.

About Sofpironium Bromide

Sofpironium bromide, is a proprietary new molecular entity that belongs to a class of medications called anticholinergics. Anticholinergics block the action of acetylcholine, a chemical that transmits signals within the nervous system that are responsible for a range of bodily functions, including activation of the sweat glands. Sofpironium bromide was retrometabolically designed. Retrometabolic drugs are designed to exert their action 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.

About Hyperhidrosis

Hyperhidrosis is a life-altering medical condition where a person sweats more than the body requires to regulate its temperature. More than 15 million people, or 4.8% of the population of the United States, are believed to suffer from hyperhidrosis. Axillary (underarm) hyperhidrosis is the targeted first indication for sofpironium bromide and is the most common occurrence of hyperhidrosis, affecting an estimated 65% of patients in the United States or 10 million individuals. Doolittle et al. Arch Dermatol Res (2016).

About Brickell

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on developing innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. Brickell's pipeline consists of potential novel therapeutics for hyperhidrosis, cutaneous T-cell lymphoma, psoriasis, and other prevalent dermatological conditions. Brickell's 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®. Brickell's strategy is to leverage this experience to in-license, acquire, develop and commercialize innovative products that Brickell believes can be successful in the currently underserved dermatology global marketplace. For more information, visit www.brickellbio.com**.**

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this press release relating to future financial, business and/or research and clinical performance, conditions, plans, prospects, trends, or strategies and other such matters, including without limitation, the anticipated timing, scope, design and/or results of future clinical trials and prospects for commercializing any of Brickell's product candidates are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Brickell, may identify forward-looking statements. Brickell cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time, often quickly and in unanticipated ways. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation, whether Brickell prevails in arbitration and/or litigation relating to its license agreement with Bodor, whether NovaQuest will resume development payments under the funding agreement or take any other actions related to the funding agreement, the costs associated with, and the management time associated with arbitration and/or litigation, potential delays in product development, regulatory or law changes, unanticipated demands on cash resources, risks associated with developing, and obtaining regulatory approval for and commercializing novel therapeutics.

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained Brickell's filings with the United States Securities and Exchange Commission (SEC), which are available at www.sec.gov (or at www.brickellbio.com). The forward-looking statements represent the estimates of Brickell as of the date hereof only, and Brickell specifically disclaims any duty or obligation to update forward-looking statements.

Brickell Investor Contact:

Patti Bank
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Brickell Biotech, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

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

Brickell Biotech, Inc.
Selected Financial Information
Condensed Consolidated Balance Sheet Data
(amounts in thousands)
(unaudited)

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 7,225	$ 8,067
Marketable securities, available-for-sale	18,473	—
Total assets	31,369	8,749
Note payable	—	4,639
Total liabilities	13,144	22,077
Total stockholders' equity (deficit)	18,225	(71,618)