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 event reported) May 13, 2020

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) (Zip Code)

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 communications 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 Stock Market LLC**

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 May 13, 2020, Brickell Biotech, Inc. issued a press release announcing, among other things, its unaudited financial results for the three months ended March 31, 2020. 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 May 13, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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: May 13, 2020

Brickell Biotech, Inc.

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

Exhibit 99.1

Brickell Biotech Reports First Quarter 2020 Financial Results and Provides Corporate Update

Announces top-line results from 12-month, Phase 3, long-term safety study

BOULDER, CO — **May 13, 2020** —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 first quarter ended March 31, 2020 and provided a corporate update.

"Brickell has continued to make progress during the first quarter of 2020, and we remain committed to advancing sofpironium bromide into Phase 3 clinical studies in the U.S.," commented Robert Brown, Chief Executive Officer of Brickell. "As we continue to prepare for the initiation of our pivotal studies, we are encouraged by the top-line results of our recently completed Phase 3 long-term safety study. Furthermore, the Japanese Phase 3 pivotal study data that we expect to be presented by our Asian development partner, Kaken Pharmaceutical Co. Ltd. ("Kaken"), next month further strengthens our enthusiasm of sofpironium bromide's potential to be a best-in-class therapy for hyperhidrosis."

Business and Recent Developments

- Today, Brickell announced that, based on a preliminary review of the top-line results from the 12-month Phase 3 open-label long-term safety study, in 300 subjects >9 years old with primary axillary hyperhidrosis, sofpironium bromide gel, 5% and 15% was safe and generally well tolerated, which was consistent with the earlier Phase 2 clinical trial results. No treatment-related serious adverse events were observed.

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

- On February 20, 2020, Brickell announced that positive results from its Phase 2b study with sofpironium bromide in patients with primary axillary hyperhidrosis were published in the peer-reviewed *Journal of the American Academy of Dermatology* ("JAAD"). In this Phase 2b dose-finding study, sofpironium bromide elicited clinically meaningful and statistically significant sustained reductions in sweating severity and was well tolerated. The paper, entitled "Efficacy and Safety of Topical Sofpironium Bromide Gel for the Treatment of Axillary Hyperhidrosis: A Phase II, Randomized, Controlled, Double-Blinded Trial," is available online (https://doi.org/10.1016/j.jaad.2020.02.016) and will be published in volume 82, Issue 6 (2020) pp.1320-1327 in the June 2020 print edition of JAAD.

- On February 18, 2020, Brickell announced that Brickell, Bodor Laboratories, Inc. and Dr. Nicholas S. Bodor entered into a binding settlement agreement and an amended license agreement, concluding all litigation related thereto and allowing Brickell to continue development of sofpironium bromide for the treatment of hyperhidrosis.

- On February 18, 2020, Brickell announced entry into a purchase agreement with Lincoln Park Capital Fund, LLC ("LPC"), a long-only Chicago-based institutional investor, whereby LPC purchased $2.0 million in Brickell common stock and warrants. Additionally, Brickell and LPC entered into a separate purchase agreement whereby Brickell, for up to a 36-month period, will have the right, in its sole discretion subject to satisfaction of certain conditions, to sell up to an additional $28 million of its common stock to LPC. This agreement is intended to augment the various potential sources of capital the Company may have access to as Brickell develops sofpironium bromide for the treatment of axillary hyperhidrosis.

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

- On January 10, 2020, Brickell announced that Kaken submitted a new drug application for approval with the Pharmaceuticals and Medical Devices Agency in Japan for the manufacturing and marketing of sofpironium bromide gel for primary axillary hyperhidrosis.

Financial Results

Cash, cash equivalents, and marketable securities were $7.1 million as of March 31, 2020 compared to $11.7 million as of December 31, 2019. In addition, Brickell has prepaid $4.6 million to third-party clinical research organizations in anticipation of commencing Phase 3 pivotal clinical trials of sofpironium bromide in the U.S.

Revenue was $1.0 million for the first quarter of 2020 compared to $3.5 million for the first quarter of 2019. The decrease in revenue recognized was attributable to the Phase 3 long-term safety study of sofpironium bromide gel and other ancillary studies that were ongoing in 2019 but were concluded or winding down by the first quarter of 2020. Conducting these studies is the basis for revenue recognition for a $15.6 million R&D payment that was received from Kaken in the second quarter of 2018.

Research and development expenses were $2.7 million for the first quarter of 2020 compared to $6.0 million for the first quarter of 2019. This decrease was primarily due to a decrease in clinical study and other related regulatory and administrative costs of the Phase 3 long-term safety study of sofpironium bromide gel and other ancillary studies that were ongoing in 2019, but were concluded or winding down by the first quarter of 2020.

General and administrative expenses were $2.5 million for the first quarter of 2020 compared to $2.1 million for the first quarter of 2019. This increase was primarily due to $0.3 million in higher fees for directors' and officers' liability insurance as a public company.

Brickell's net loss was $4.1 million for the first quarter of 2020 compared to $4.6 million for the first quarter of 2019.

Conference Call and Webcast Information

Brickell's management will host a conference call today at 4:30 p.m. ET to discuss the financial results and recent corporate developments. The dial-in number for the conference call is 1-855-327-6837 for domestic participants and 1-631-891-4304 for international participants, with Conference ID #10009475. A live webcast of the conference call can be accessed through the "Investors" tab on the Brickell Biotech website at http://www.brickellbio.com. A replay will be available on this website shortly after conclusion of the event for 90 days.

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 into a less active metabolite once absorbed into the blood. This proposed mechanism of action may allow for highly effective doses to be used while limiting systemic side effects. Sofpironium bromide was discovered at Bodor Laboratories, Inc. by Dr. Nicholas Bodor D.Sc., d.h.c. (multi), HoF, Graduate Research Professor Emeritus, University of Florida. Sofpironium bromide is not approved for use in any country at this time.

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, and more than 16 million people, or 12.76% of the population in Japan, are believed to suffer from hyperhidrosis[1,2]. Primary axillary (underarm) hyperhidrosis is the targeted first indication for sofpironium bromide and is the most common site of occurrence of hyperhidrosis, affecting an estimated 65% of patients with hyperhidrosis in the United States or 10 million individuals and an estimated 45% of patients with hyperhidrosis in Japan or 7.2 million individuals[1,2]. Additional information can be found on the International Hyperhidrosis Society website: https://www.sweathelp.org/.

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 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 http://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, including in Japan, the United States or any other country, are forward-looking statements within the meaning of the U.S. 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, ability to obtain adequate financing to advance product development, potential delays for any reason in product development, regulatory changes, unanticipated demands on cash resources, any disruption to our business caused by the current COVID-19 pandemic, and 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 in Brickell's filings with the United States Securities and Exchange Commission (SEC), which are available at http://www.sec.gov (or at http://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.

[1]Doolittle et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 2016; 308: 743-749.
[2] Fujimoto et al. Epidemiological study and considerations of focal hyperhidrosis in Japan. J Dermatol 2013; 40: 886-90.

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

	Three Months Ended March 31,	
	2020	**2019**
Collaboration revenue	$ 1,046	$ 3,492
Operating expenses:		
Research and development	2,664	6,019
General and administrative	2,481	2,066
Total operating expenses	5,145	8,085
Loss from operations	(4,099)	(4,593)
Investment and other income (loss), net	(4)	6
Interest expense	—	(224)
Change in fair value of warrant liability	—	231
Net loss	(4,103)	(4,580)
Reduction of redeemable convertible preferred stock to redemption value	—	10,519
Net income (loss) attributable to common stockholders	$ (4,103)	$ 5,939
Net income (loss) per common share attributable to common stockholders, basic	$ (0.45)	$ 10.08
Net loss per common share attributable to common stockholders, diluted	$ (0.45)	$ (2.48)
Weighted-average shares used to compute net income (loss) per share attributable to common stockholders, basic	9,106,209	589,001
Weighted-average shares used to compute net loss per share attributable to common stockholders, diluted	9,106,209	1,845,467

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 7,127	$ 7,232
Marketable securities, available-for-sale	—	4,497
Prepaid expenses and other current assets	5,765	6,240
Total assets	13,038	18,144
Total liabilities	7,144	10,570
Total stockholders' equity	5,894	7,574

Brickell Investor Contact:

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