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, 2021

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, 2021, Brickell Biotech, Inc. issued a press release reporting, among other things, its financial results for the three months and three months ended March 31, 2021. 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, 2021

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, 2021

Brickell Biotech, Inc.

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

Brickell Biotech Reports First Quarter 2021 Financial Results and Provides Corporate Update

Completed enrollment in Phase 3 pivotal Cardigan I study and exceeded 70% enrollment in Phase 3 pivotal Cardigan II study

- - -

Topline results for Phase 3 pivotal Cardigan I and Cardigan II studies expected in Q4 2021

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Presented results from Phase 3 open-label, long-term safety study of sofpironium bromide gel, 5% & 15% at AAD VMX 2021

BOULDER, CO — **May 13, 2021** — Brickell Biotech, Inc. ("Brickell" or the "Company") (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, 2021 and provided a corporate update.

"The beginning of 2021 has been a very productive period for the Brickell team, as we continue to execute against our development strategy for sofpironium bromide gel, 15% as a potential best-in-class treatment option for primary axillary hyperhidrosis," commented Robert Brown, Chief Executive Officer of Brickell. "Most importantly, we continue to see patient enrollment in our Phase 3 pivotal clinical studies meet expectations, with enrollment completed last month in the Cardigan I study, and 70% enrollment surpassed in the Cardigan II study. As a result, we are on track to announce topline data from both studies in the fourth quarter of 2021. If these studies are successful, we expect to proceed towards an NDA submission to the U.S. FDA in 2022."

Mr. Brown continued, "In April 2021, we were pleased to highlight data from the ARGYLE study, our Phase 3 open-label, long-term safety study of sofpironium bromide gel, as part of the late-breaking research program at the American Academy of Dermatology's Virtual Meeting Experience 2021. In this study, sofpironium bromide gel was generally well-tolerated with continued efficacy during 48 weeks in patients with primary axillary hyperhidrosis. These data further contribute to our understanding of the long-term use of sofpironium bromide gel as a potential novel treatment for the millions of patients suffering from this chronic and debilitating condition."

Business and Recent Developments

- Completed enrollment in the Phase 3 Cardigan I study and exceeded 70% enrollment in the Phase 3 Cardigan II study. Both randomized, double-blinded, placebo-controlled pivotal studies are evaluating sofpironium bromide gel, 15% *vs.* placebo (1:1 ratio) in approximately 350 subjects (per study) aged nine and older with primary axillary hyperhidrosis.
- Presented results from the Phase 3 open-label, long-term safety study of sofpironium bromide gel, 5% and 15% in a late-breaking oral presentation at the American Academy of Dermatology's Virtual Meeting Experience 2021 ("AAD VMX 2021"), in which the safety, tolerability, and efficacy results for sofpironium bromide gel, 5% and 15% were consistent with prior clinical experience and no unexpected safety findings were observed.
- Published validation results from the Company's proprietary patient reported outcome scale, the Hyperhidrosis Disease Severity Measure-Axillary© (HDSM-Ax), in the peer-reviewed Journal of Drugs in Dermatology. The published results conclude that the HDSM-AX scale is a well-defined and reliable measure of primary axillary hyperhidrosis.
- Hosted a KOL event in March with leading dermatologists to discuss hyperhidrosis through both the eyes of a patient and diagnosing clinician, as well as the unmet need that exists in hyperhidrosis, the current treatment landscape, and the negative quality of life impacts experienced by both pediatric and adult patients.
- Japanese development partner, Kaken Pharmaceutical Co., Ltd. ("Kaken"), continued to ramp up commercialization efforts for sofpironium bromide gel, 5% (ECCLOCK®) in Japan.
- Strengthened the Company's balance sheet to $34.8 million in cash and cash equivalents at the end of the first quarter of 2021, which includes aggregate net proceeds of $10.6 million from warrant exercises and the sale of shares under a previously filed At-The-Market Equity Offering Program during the first quarter of 2021.

Upcoming Milestones

- On track to complete enrollment for the Cardigan II pivotal study in the third quarter of 2021.
- Expect to report topline results from the Cardigan I and II pivotal studies in the fourth quarter of 2021.

Financial Results

First Quarter 2021 Financial Results

The Company reported cash and cash equivalents of $34.8 million as of March 31, 2021, compared to $30.1 million as of December 31, 2020.

Revenue was approximately $17 thousand for the first quarter of 2021, compared to $1.0 million for the first quarter of 2020. Revenue in 2021 consisted of royalty revenue recognized related to sales of ECCLOCK® in Japan by Kaken, while revenue in 2020 was driven by collaboration revenue recognized for research and development activities related to a license agreement with Kaken pursuant to which Kaken provided research and development funding to Brickell.

Research and development expenses were $6.1 million for the first quarter of 2021, compared to $2.7 million for the first quarter of 2020. This increase was primarily due to an increase in clinical costs related to the Phase 3 Cardigan studies, which were initiated in the fourth quarter of 2020.

General and administrative expenses were $3.0 million for the first quarter of 2021, compared to $2.5 million for the first quarter of 2020. The increase was primarily due to increases in compensation-related expense and professional fees.

Brickell's net loss was $9.0 million for the first quarter of 2021 compared to $4.1 million for the first quarter of 2020.

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 1-877-705-6003 for domestic participants and 1-201-493-6725 for international participants, with Conference ID #13718897. A live webcast of the conference call can be accessed through the "Investors" tab on the Brickell Biotech website at https://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 Brickell's lead investigational product candidate and is a new chemical 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 intended to exert their action locally and are potentially rapidly metabolized into a less active metabolite once absorbed into the blood. Sofpironium bromide gel, 15% is currently being evaluated in a U.S. pivotal Phase 3 clinical program for the treatment of primary axillary hyperhidrosis, and sofpironium bromide gel, 5% is approved in Japan for the same indication under the brand name ECCLOCK®. 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.

About Hyperhidrosis

Hyperhidrosis is a debilitating, life-altering medical condition where a person sweats beyond what is physiologically required for thermoregulation of the body. More than 15 million people, or 4.8% of the population of the United States, and 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. 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 the development of innovative and differentiated prescription therapeutics for debilitating skin diseases with a focus on its lead asset sofpironium bromide for the treatment of hyperhidrosis. 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 and differentiated pharmaceutical products that Brickell believes can be successful in the marketplace and transform lives by solving currently unmet patient needs. For more information, visit https://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 ongoing and future clinical trials, intellectual property rights, including the validity, term and enforceability of such, the expected timing and/or results of regulatory approvals and prospects for commercializing any of Brickell's product candidates, or research collaborations with its partners, 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," "potential," "look forward" and similar expressions and their variants, as they relate to Brickell, Kaken or any of Brickell's partners, 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, ability to maintain and enforce intellectual property rights, potential delays for any reason in product development and clinical trial enrollment, regulatory changes, supply chain disruptions, unanticipated demands on cash resources, any disruption to its business caused by the current COVID-19 pandemic, interruptions, disruption or inability by Kaken to supply and commercialize the product in Japan, or obtain or retain adequate pricing or reimbursement, the outcome of Brickell's ongoing U.S. Phase 3 pivotal program on sofpironium bromide gel, and other risks associated with developing and obtaining regulatory approval for and commercializing product candidates.

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 https://www.sec.gov (or at https://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.

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue		
Collaboration revenue	$ —	$ 1,046
Royalty revenue	17	—
Total revenue	17	1,046
Operating expenses:		
Research and development	6,052	2,664
General and administrative	2,967	2,481
Total operating expenses	9,019	5,145
Loss from operations	(9,002)	(4,099)
Investment and other income (loss), net	31	(4)
Interest expense	(34)	—
Net loss	$ (9,005)	$ (4,103)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.15)	$ (0.45)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	61,163,581	9,106,209

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

	March 31, 2021	**December 31, 2020**
Cash and cash equivalents	$ 34,781	$ 30,115
Prepaid expenses and other current assets	3,997	3,489
Total assets	38,851	33,634
Total liabilities	9,707	6,499
Total stockholders' equity	29,144	27,135