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) August 12, 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 August 12, 2021, Brickell Biotech, Inc. issued a press release reporting, among other things, its financial results for the three and six months ended June 30, 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 August 12, 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: August 12, 2021

Brickell Biotech, Inc.

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

Exhibit 99.1

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

Final patient has completed the Phase 3 pivotal Cardigan I study; Enrollment completed in Phase 3 pivotal Cardigan II study

- - -

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

- - -

Recent $8.1 million capital raise expected to fund operations beyond anticipated NDA submission in mid-2022

BOULDER, CO — **August 12, 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 second quarter ended June 30, 2021 and provided a corporate update.

"We have made tremendous progress this year advancing our Phase 3 clinical development program for sofpironium bromide gel, 15% as a potential treatment option for primary axillary hyperhidrosis, or excessive underarm sweating. Since initiating the Phase 3 Cardigan I and II studies in late 2020, we have completed enrollment in both pivotal studies, and the last enrolled hyperhidrosis patient has completed the Cardigan I study," commented Robert Brown, Chief Executive Officer of Brickell. "We remain on track to announce topline data for both studies concurrently in the fourth quarter of 2021, and if these studies are successful, we expect to proceed towards an NDA submission to the U.S. FDA in mid-2022."

Mr. Brown continued, "Our development partner, Kaken Pharmaceutical, continues to ramp up its commercial launch of sofpironium bromide gel, 5% (ECCLOCK®) in Japan. We are encouraged by Kaken's early sales progress, as well as its continued investment in the commercialization of ECCLOCK, disease state awareness and lifecycle management activities. To this point, Kaken has recently initiated a Phase 1 clinical study to explore the pharmacokinetics (PK), safety and efficacy of sofpironium bromide gel in patients with primary palmoplantar hyperhidrosis, or excessive sweating from the palms and soles. We look forward to seeing the results of this study, which will help us determine next development steps, if any, in this new potential indication for sofpironium bromide gel."

Business and Recent Developments

- Final patient has completed the Phase 3 Cardigan I study and enrollment completed in the Phase 3 Cardigan II study. Each pivotal clinical study is evaluating sofpironium bromide gel, 15% in approximately 350 subjects with primary axillary hyperhidrosis in the U.S.
- Phase 1 clinical study assessing the PK, safety and efficacy of sofpironium bromide gel in patients with primary palmoplantar hyperhidrosis was initiated by Kaken in Japan. 5.3% and 2.8% of the population in Japan are estimated to be affected by primary palmar and plantar hyperhidrosis, respectively[1].
- Following the recent $8.1 million capital raise, the Company believes it has sufficient cash to fund its operations beyond the potential NDA submission to the U.S. FDA, which is anticipated in mid-2022.

Upcoming Milestones

- Final patient expected to complete the Phase 3 Cardigan II study in the third quarter of 2021.
- Expect to concurrently report topline results from the U.S. Cardigan I and II studies in the fourth quarter of 2021.
- Potential NDA submission to the U.S. FDA anticipated in mid-2022, pending the outcome of the ongoing Phase 3 clinical program.
- Kaken to continue ramping up commercialization efforts for ECCLOCK in Japan and evaluating additional hyperhidrosis indications for sofpironium bromide gel.

Financial Results

Second Quarter 2021 Financial Results

The Company reported cash and cash equivalents of $24.4 million as of June 30, 2021, compared to $30.1 million as of December 31, 2020.

Revenue was $0.2 million for the second quarter of 2021 and consisted of royalty revenue recognized from sales of ECCLOCK in Japan by Kaken, which increased from $17 thousand for the first quarter of 2021. Revenue was $0.6 million for the second quarter of 2020, which was driven by collaboration revenue recognized for research and development funding provided by Kaken to Brickell in 2018.

Research and development expenses were $8.8 million for the second quarter of 2021, compared to $2.7 million for the second 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 $2.9 million for the second quarter of 2021, compared to $3.0 million for the second quarter of 2020. The decrease was primarily due to lower costs for professional-related fees associated with capital raising activities that occurred in the second quarter of 2020.

Total other income, net was $0.4 million for the second quarter of 2021, compared to $7 thousand for the second quarter of 2020. The increase was primarily due to a gain on extinguishment of debt of approximately $0.4 million that resulted from the forgiveness of the Paycheck Protection Program Loan in June 2021.

Brickell's net loss was $11.1 million for the second quarter of 2021 compared to $5.1 million for the second 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 #13720599. A live webcast of the conference call can be accessed at http://public.viavid.com/index.php?id=145287 or through the "Investors" tab on the Brickell Biotech website athttps://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 implementation, 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, commercialize and further develop 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] Fujimoto et al. Epidemiological study and considerations of focal hyperhidrosis in Japan. J Dermatol 2013; 40: 886-90.
[2] Doolittle et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 2016; 308: 743-749.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue				
Collaboration revenue	$ —	$ 607	$ —	$ 1,653
Royalty revenue	151	—	168	—
Total revenue	151	607	168	1,653
Operating expenses:				
Research and development	8,838	2,712	14,890	5,376
General and administrative	2,891	3,021	5,858	5,502
Total operating expenses	11,729	5,733	20,748	10,878
Loss from operations	(11,578)	(5,126)	(20,580)	(9,225)
Investment and other income, net	459	7	490	3
Interest expense	(30)	—	(64)	—
Net loss	$ (11,149)	$ (5,119)	$ (20,154)	$ (9,222)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.16)	$ (0.43)	$ (0.31)	$ (0.87)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	68,856,370	11,819,152	64,646,565	10,595,960

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

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 24,408	$ 30,115
Prepaid expenses and other current assets	4,507	3,415
Total assets	29,073	33,634
Total liabilities	6,720	6,499
Total stockholders' equity	22,353	27,135