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) March 9, 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 March 9, 2021, Brickell Biotech, Inc. issued a press release reporting, among other things, its financial results for the three months and year ended December 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 March 9, 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: March 9, 2021

Brickell Biotech, Inc.

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

Brickell Biotech Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update

Initiated U.S. pivotal Phase 3 clinical program (Cardigan I and II studies) evaluating sofpironium bromide gel, 15% for the treatment of primary axillary (underarm) hyperhidrosis

- - -

Cardigan I study exceeds 50% enrollment with topline results from both studies anticipated in the fourth quarter of 2021

- - -

Commercial launch of sofpironium bromide gel, 5% (ECCLOCK®) underway in Japan by development partner, Kaken Pharmaceutical Co., Ltd. (Kaken)

BOULDER, CO — **March 9, 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 fourth quarter and full year ended December 31, 2020 and provided a corporate update.

"Over the last several months, we achieved a number of important milestones – including the initiation of the U.S. pivotal Phase 3 clinical program – that have enabled us to continue developing sofpironium bromide as a potential best-in-class treatment option for the more than 10 million people in the U.S. suffering with primary axillary hyperhidrosis," commented Robert Brown, Chief Executive Officer of Brickell. "This momentum is carrying over into 2021, as we have already exceeded 50% enrollment for the Cardigan I study and remain on track to announce topline data from both the Cardigan I and II studies by the end of the year. If successful, we expect the data from these studies to form the basis of an NDA submission to the FDA."

Mr. Brown continued, "In addition to the great progress we've made in the last quarter at Brickell, our Japanese development partner, Kaken, was successful in executing its clinical development program for ECCLOCK®. This progress is highlighted by the approval, placement on Japan's National Health Insurance reimbursement price list, and recent commercial launch of ECCLOCK® in Japan. Of note, Japan is the first country to approve sofpironium bromide, which also represents the first topical prescription product to be marketed for the treatment of primary axillary hyperhidrosis in the country. Kaken has proven to be a valuable partner, and we look forward to seeing the ramp up of their commercialization program for ECCLOCK®, which will provide Brickell with royalties and potential sales-based milestone payments per our sublicense agreement."

Business and Recent Developments

- Completed an equity financing in October 2020 resulting in net proceeds of approximately $13.7 million that strengthened the Company's balance sheet and is expected to fully fund its operations through topline results of the U.S. pivotal Phase 3 program for sofpironium bromide gel, 15%. In addition, recent aggregate net proceeds of $10.5 million from warrant exercises and sales of shares under a previously filed At-The-Market ("ATM") Equity Offering Program have further strengthened the Company's financial position.

- Initiated enrollment in the U.S. Phase 3 Cardigan I (October 2020) and Cardigan II (December 2020) studies evaluating sofpironium bromide gel, 15% in approximately 350 subjects (per study) aged nine and older with primary axillary hyperhidrosis.

- Exceeded 50% enrollment for the Cardigan I study, and all investigational sites are activated and enrollment is underway for the Cardigan II study.

- Kaken launched ECCLOCK® in Japan for the once-daily treatment of primary axillary hyperhidrosis in November 2020.

- Efficacy and safety results from the Japan pivotal Phase 3 study conducted by Kaken were published in the peer-reviewed Journal of Dermatology[i].

- AnGes, Inc. completed a Phase 1/2 study with its investigational COVID-19 vaccine candidate and initiated a Phase 2/3 study in Japan. If the development process continues, a larger Phase 3 registration study will be required for any approval.

Upcoming Milestones

- On track to complete enrollment for the Cardigan I and II pivotal studies by end of third quarter of 2021.
- Expect to report topline data from the Cardigan I and II pivotal studies in the fourth quarter of 2021.
- Hosting a KOL webinar event on March 26th highlighting hyperhidrosis disease insights and market opportunity.

Financial Results

Fourth Quarter 2020 Financial Results

The Company reported cash and cash equivalents and marketable securities of $30.1 million as of December 31, 2020, compared to $11.7 million as of December 31, 2019. In addition, as of December 31, 2020, Brickell had $2.3 million in prepaids to third-party clinical research organizations as part of conducting its U.S. pivotal Phase 3 clinical trials of sofpironium bromide gel, 15%. During the fourth quarter of 2020, the Company completed a public equity offering resulting in net proceeds of approximately $13.7 million. Subsequent to the end of the fourth quarter, the Company received aggregate net proceeds of $10.5 million from warrant exercises and sales of shares under a previously filed ATM Equity Offering Program.

Revenue was approximately $27 thousand for the fourth quarter of 2020, compared to $0.7 million for the fourth quarter of 2019. Revenue in 2020 was driven by royalty income from sales of ECCLOCK® in Japan by Kaken, while revenue in 2019 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. The decrease in revenue recognized was attributable to Brickell's 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 was the basis for revenue recognition over time, through the third quarter of 2020, of a $15.6 million research and development payment received from Kaken in the second quarter of 2018. In late 2020, Brickell began recognizing royalty revenue earned on a percentage of net sales of sofpironium bromide in Japan in the fourth quarter.

Research and development expenses were $4.6 million for the fourth quarter of 2020, compared to $6.6 million for the fourth quarter of 2019. This decrease 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. Brickell began incurring greater research and development costs upon the initiation of its Phase 3 Cardigan Studies in the fourth quarter of 2020.

General and administrative expenses were $2.9 million for the fourth quarter of 2020, compared to $4.9 million for the fourth quarter of 2019. This decrease was primarily due to lower costs of $1.4 million for professional-related fees associated with the merger with Vical Incorporated that occurred in the third quarter of 2019 as well as reduced impairment expense of $0.8 million and other miscellaneous expenses of $0.4 million, partially offset by higher costs of $0.6 million for compensation-related expense.

Brickell's net loss was $7.4 million for the fourth quarter of 2020 compared to $10.9 million for the fourth quarter of 2019.

Full Year 2020 Financial Results

Revenue was $1.8 million for the year ended December 31, 2020, compared to $7.9 million for the year ended December 31, 2019. Revenue in both periods was driven primarily by collaboration revenue recognized for research and development activities related to a license agreement with Kaken for which Kaken provided research and development funding to Brickell. The decrease in revenue recognized was attributable to Brickell's 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 was the basis for revenue recognition over time, through the third quarter of 2020, of a $15.6 million research and development payment received from Kaken in the second quarter of 2018. In late 2020, Brickell began recognizing royalty revenue earned on a percentage of net sales of sofpironium bromide in Japan, which amounted to approximately $27 thousand in the fourth quarter.

Research and development expenses were $11.2 million for the year ended December 31, 2020, compared to $20.2 million for the year ended December 31, 2019, which was driven primarily by a decrease in clinical and other related regulatory and compliance costs related to sofpironium bromide. The Company's Phase 3, open-label, long-term safety study of sofpironium bromide gel and other ancillary clinical studies were ongoing in 2019 but were concluded or winding down by the end of the first quarter of 2020. Brickell began incurring greater research and development costs upon the initiation of its Phase 3 Cardigan Studies in the fourth quarter of 2020.

General and administrative expenses were $11.6 million for the year ended December 31, 2020, compared to $12.2 million for the year ended December 31, 2019. This decrease was primarily due to reduced professional fees of $1.8 million resulting from legal and other fees incurred in 2019 related to the merger with Vical that did not recur in 2020, as well as reduced impairment expense of $0.8 million in 2020 compared to 2019. These reduced expenses were partially offset by higher costs in 2020 of $2.0 million for compensation-related expense and $0.8 million for directors' and officers' liability insurance due to becoming a public company.

Total other income, net was $0.1 million for the year ended December 31, 2020, compared to $0.6 million for the year ended December 31, 2019. The decrease of $0.5 million 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 resulting from fair value adjustments to warrant liabilities during the year ended December 31, 2019, both of which did not recur in 2020. These gains were partially offset by a decrease of $2.1 million in interest expense related to the issuance of convertible promissory notes in 2019 and principal borrowings provided by a loan agreement with a former lender.

Brickell's net loss was $20.9 million for the year ended December 31, 2020, compared to $23.9 million for the year ended December 31, 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 1-877-705-6003 for domestic participants and 1-201-493-6725 for international participants, with Conference ID #13715394. 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 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[2,3]. 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, AnGes 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, 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] The Journal of Dermatology is the official peer-reviewed publication of the Japanese Dermatological Association and the Asian Dermatological Association.
[2] Doolittle et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 2016; 308: 743-749.
[3] 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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Revenue				
Collaboration revenue	$ —	$ 669	$ 1,795	$ 7,917
Royalty revenue	27	—	27	—
Total revenue	27	669	1,822	7,917
Operating expenses:				
Research and development	4,559	6,629	11,216	20,214
General and administrative	2,869	4,881	11,582	12,171
Total operating expenses	7,428	11,510	22,798	32,385
Loss from operations	(7,401)	(10,841)	(20,976)	(24,468)
Investment and other income, net	36	93	63	157
Gain on extinguishment	—	—	—	2,318
Interest expense	—	(114)	—	(2,096)
Change in fair value of warrant and derivative liability	—	—	—	212
Net loss	(7,365)	(10,862)	(20,913)	(23,877)
Reduction of redeemable convertible preferred stock to redemption value	—	—	—	10,274
Net loss attributable to common stockholders	$ (7,365)	$ (10,862)	$ (20,913)	$ (13,603)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.15)	$ (1.38)	$ (0.85)	$ (4.50)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	48,454,350	7,890,823	24,514,157	3,023,023

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

	December 31,	
	2020	2019
Cash and cash equivalents	$ 30,115	$ 7,232
Marketable securities, available-for-sale	—	4,497
Prepaid expenses and other current assets	3,415	6,240
Total assets	33,634	18,144
Total liabilities	6,499	10,570
Total stockholders' equity	27,135	7,574