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) September 25, 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 7.01. Regulation FD Disclosure.

On September 25, 2020, Brickell Biotech, Inc. (the "Company") issued a press release, which is furnished as Exhibit 99.1 to this report, announcing that its Japanese development partner, Kaken Pharmaceutical Co., Ltd. ("Kaken"), received approval to manufacture and market sofpironium bromide gel, 5% in Japan for the treatment of primary axillary (underarm) hyperhidrosis.

The information in this Item 7.01, 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 8.01. Other Events.

On September 25, 2020, the Company announced that its Japanese development partner, Kaken, received approval to manufacture and market sofpironium bromide gel, 5% under the brand name ECCLOCK® in Japan for the treatment of primary axillary (underarm) hyperhidrosis.

This regulatory approval is based on the results of the Japanese Phase 3 pivotal registration study of sofpironium bromide gel, 5% in 281 patients with primary axillary hyperhidrosis, in which all primary and secondary efficacy endpoints demonstrated statistically significant differences between sofpironium bromide gel and vehicle (placebo). In addition, sofpironium bromide gel was deemed to be safe and generally well tolerated in this study, as well as in the accompanying 52-week long-term safety extension study in Japan.

Under the sublicense agreement with Kaken, the Company is entitled to receive sales-based milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide gel in Japan.

Sofpironium bromide is currently being developed by the Company in the U.S. for the treatment of primary axillary hyperhidrosis. The Company intends to initiate its pivotal Phase 3 program in the U.S. for sofpironium bromide gel, 15% during the fourth quarter of 2020, which will ultimately be comprised of two pivotal Phase 3 trials to evaluate sofpironium bromide gel compared to vehicle in approximately 350 subjects (per trial) with primary axillary hyperhidrosis.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Brickell Biotech, Inc. on September 25, 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: September 25, 2020

Brickell Biotech, Inc.

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

Brickell Biotech Announces Approval of Sofpironium Bromide Gel, 5% in Japan for Treatment of Primary Axillary Hyperhidrosis Received by its Development Partner, Kaken Pharmaceutical

Japan is the first country to approve sofpironium bromide with commercial launch expected later this year

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Brickell is on track to initiate its U.S. pivotal Phase 3 program for sofpironium bromide in Q4 2020

BOULDER, CO — **September 25, 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, announced today that its Japanese development partner, Kaken Pharmaceutical Co., Ltd. ("Kaken"), received approval to manufacture and market sofpironium bromide gel, 5% under the brand name ECCLOCK® in Japan for the treatment of primary axillary (underarm) hyperhidrosis.

"We are thrilled with the Japanese approval of sofpironium bromide, which is the first topical prescription product to be approved in Japan for the treatment of primary axillary hyperhidrosis," commented Robert Brown, Chief Executive Officer of Brickell. "This is a significant milestone for Brickell and Kaken, as Kaken can now focus its efforts on the commercial launch of sofpironium bromide gel in Japan, which is expected to occur later this year. Most importantly, this novel, first-in-class therapy will soon be available to help improve the quality of life for Japanese patients suffering from this debilitating condition."

This regulatory approval is based on the results of the Japanese Phase 3 pivotal registration study of sofpironium bromide gel, 5% in 281 patients with primary axillary hyperhidrosis, in which all primary and secondary efficacy endpoints demonstrated statistically significant differences between sofpironium bromide gel and vehicle (placebo). In addition, sofpironium bromide gel was deemed to be safe and generally well tolerated in this study, as well as in the accompanying 52-week long-term safety extension study in Japan.

Under the sublicense agreement with Kaken, Brickell is entitled to receive sales-based milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide gel in Japan. Importantly, Kaken has rights to develop and commercialize sofpironium bromide in Korea, China and certain other Asian countries, and will now turn its attention to these markets.

Sofpironium bromide is currently being developed by Brickell in the U.S. for the treatment of primary axillary hyperhidrosis. Brickell is on track to initiate its pivotal Phase 3 program in the U.S. for sofpironium bromide gel, 15% during the fourth quarter of 2020, which will ultimately be comprised of two pivotal Phase 3 trials to evaluate sofpironium bromide gel compared to vehicle in approximately 350 subjects (per trial) with primary axillary hyperhidrosis.

About Sofpironium Bromide

Sofpironium bromide is a proprietary 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 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 12.7% 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[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 https://www.brickellbio.com**.**

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this press release relating to future financial, legal, 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, 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" 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, ability to maintain and enforce intellectual property rights, potential delays for any reason in product development, regulatory changes, unsuccessful clinical trials, unanticipated demands on cash resources, any disruption to our business caused by the current COVID-19 pandemic, interruptions, disruption or inability to launch and commercialize the product by Kaken in Japan, or obtain adequate pricing approval, 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 http://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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