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) June 15, 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 June 15, 2020, Brickell Biotech, Inc. (the "Company") issued a press release, which is furnished as Exhibit 99.1 to this report, announcing the results of a Phase 3 pivotal study for sofpironium bromide conducted by Kaken Pharmaceutical Co., Ltd. ("Kaken").

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 June 12, 2020, Kaken, the Company's development partner in Japan, presented the positive results of its Phase 3 pivotal study for sofpironium bromide at the Late-Breaking Research Program during the American Academy of Dermatology (AAD) Virtual Meeting Experience.

The Phase 3 pivotal study evaluated a total of 281 Japanese subjects at 22 sites. Subjects were randomized 1:1 to apply sofpironium bromide gel, 5% ("SB") or vehicle gel (placebo) once daily to the axillae for 42 days. All subjects had Hyperhidrosis Disease Severity Scale ("HDSS") scores ≥ 3, Hyperhidrosis Disease Severity Measure-Axillary ("HDSM-Ax") scores ≥ 2 and ≥ 50 mg/5 min gravimetric sweat production ("GSP") in each axilla at baseline.

All primary, secondary and exploratory efficacy endpoints were met and demonstrated statistically significant differences between sofpironium bromide and vehicle, with safety and tolerability, as follows:

Primary Endpoint:

- Proportion of subjects whose HDSS was improved to a score of 1 or 2 at the end of treatment ("EOT") and > 50% reduction in GSP at EOT was 53.9% (SB) versus 36.4% (vehicle); p-value = 0.003

Key Secondary Endpoints:

- Proportion of subjects whose HDSS was improved to a score of 1 or 2 at the EOT was 60.3% (SB) versus 47.9% (vehicle); p=0.036
- Change in the total GSP mean value for both axillae from baseline to EOT was -157.6 mg (SB) versus -127.6 mg (vehicle); p=0.015[1]
- Change in the HDSM-Ax-11 score from baseline to EOT was -1.41 (SB) versus -0.93 (vehicle); p=0.001
- Proportion of subjects with ≥50% reduction in the rate of GSP from baseline to EOT was 77.3% (SB) versus 66.4% (vehicle); p=0.042

Exploratory Endpoint:

- Proportion of subjects with ≥2 point reduction in HDSM-Ax-7 score from baseline to EOT was 27.0% (SB) versus 11.4% (vehicle); p=.0010

Safety and Tolerability:

- Common adverse events (incidence ≥5%) in SB group were nasopharyngitis (14.2%), dermatitis at the application site (8.5%), and erythema at the application site (5.7%). The severity of adverse events was predominantly mild.
- 2.8% of SB-treated subjects experienced any anticholinergic-class side effects; dry mouth (1.4%), constipation (0.7%) and mydriasis (0.7%).

[1] Co-primary efficacy endpoints required by the U.S. Food and Drug Administration for the Company's prospective U.S. Phase 3 pivotal trials of sofpironium bromide gel, 15%. While the Kaken Phase 3 pivotal study met each of its efficacy endpoints, no inference should be drawn with respect to the efficacy outcomes of the Company's prospective U.S. Phase 3 pivotal studies due to differences in the design, patient population and product utilized in the studies.

- No serious adverse events related to SB were reported in the study.

Earlier this year, Kaken announced submission of a new drug application for approval in Japan of manufacturing and marketing of sofpironium bromide gel for primary axillary hyperhidrosis based on these data. In addition to Japan, Kaken has rights to develop and commercialize sofpironium bromide in Korea, China and certain other Asian countries. Under the sublicense agreement with Kaken, the Company is due royalties and sales-based milestone payments under certain events, which events may not occur.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Brickell Biotech, Inc. on June 15, 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: June 15, 2020

Brickell Biotech, Inc.

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

Exhibit 99.1

Brickell Biotech Announces Positive Phase 3 Pivotal Study Results for Sofpironium Bromide in Japan Released by Development Partner, Kaken Pharmaceutical

Data based on registration study in Japan of sofpironium bromide gel, 5% in patients with primary axillary hyperhidrosis

All primary and secondary endpoints were met and achieved statistical significance

BOULDER, Colo., June 15, 2020 (GLOBE NEWSWIRE) -- 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 the release of positive Phase 3 pivotal study results from its development partner, Kaken Pharmaceutical Co. Ltd., in Japan. All primary and secondary efficacy endpoints of the study were met. The results were presented as part of the Late-Breaking Research Program during the American Academy of Dermatology (AAD) Virtual Meeting Experience. The presentation is titled "A Phase 3, Randomized, Double-Blinded, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Topically Applied Sofpironium Bromide Gel, 5% in Japanese Patients with Primary Axillary Hyperhidrosis." Earlier this year, Kaken announced submission of a new drug application for approval in Japan of manufacturing and marketing of sofpironium bromide gel for primary axillary hyperhidrosis based on these data.

"We are encouraged by these positive results and are pleased by the filing of the Japanese New Drug Application based on this Phase 3 study by Kaken," said Deepak Chadha, Brickell's Chief Research & Development Officer. "We believe there is growing interest from the global medical community for novel therapeutic options for the treatment of primary axillary hyperhidrosis and think these data provide additional clinical support for sofpironium bromide to be a potential best-in-class treatment."

The Phase 3 pivotal study evaluated a total of 281 Japanese subjects randomized 1:1 to apply sofpironium bromide gel, 5% ("SB") or vehicle gel (placebo) to the axillae for 42 days. All subjects had Hyperhidrosis Disease Severity Scale (HDSS) scores ≥ 3 and ≥ 50 mg/5 min gravimetric sweat production (GSP) in each axilla at baseline.

All primary and secondary efficacy endpoints demonstrated statistically significant differences between sofpironium bromide and vehicle, with safety and tolerability, as follows:

Primary Endpoint:

- Proportion of subjects whose HDSS was improved to a score of 1 or 2 at the end of treatment (EOT)*and* $\geq$ 50% reduction in GSP at EOT was 53.9% (SB) versus 36.4% (vehicle); p-value = 0.003

Key Secondary Endpoints:

- Proportion of subjects whose HDSS was improved to a score of 1 or 2 at the EOT was 60.3% (SB) versus 47.9% (vehicle); p=0.036

- Change in the total GSP mean value for both axillae from baseline to EOT was -157.6 mg (SB) versus -127.6 mg (vehicle); p=0.015[1]
- Change in the HDSM-Ax score from baseline to EOT was -1.41 (SB) versus -0.93 (vehicle); p=0.001
- Proportion of subjects with ≥50% reduction in the rate of GSP from baseline to EOT was 77.3% (SB) versus 66.4% (vehicle); p=0.042

Safety and Tolerability:

- Common adverse events (incidence ≥5%) in SB group were nasopharyngitis (14.2%), dermatitis at the application site (8.5%), and erythema at the application site (5.7%). The severity of adverse events was predominantly mild.
- 2.8% of SB-treated subjects experienced any anticholinergic-class side effects; dry mouth (1.4%), constipation (0.7%) and mydriasis (0.7%).
- No serious adverse events related to SB were reported in the study

In addition to Japan, Kaken has rights to develop and commercialize sofpironium bromide in Korea, China and certain other Asian countries. Under the sublicense agreement with Kaken there are royalties and sales-based milestone payments due to Brickell.

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[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 or 10 million individuals and an estimated 45% of patients with hyperhidrosis in Japan or 7.2 million individuals[2,3]. Additional information can be found on the International Hyperhidrosis Society website: https://www.sweathelp.org/.

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[1] Change in the total GSP mean value for both axillae from baseline to EOT is one of the co-primary efficacy endpoints required by FDA for Brickell's prospective U.S. Phase 3 pivotal trials

[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

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.

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