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) October 7, 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 7.01. Regulation FD Disclosure.

On October 7, 2021, Brickell Biotech, Inc. (the "Company") issued a press release, which is furnished as Exhibit 99.1 to this report, reporting positive topline results, achieving statistical significance on all primary and secondary endpoints, from its U.S. Phase 3 pivotal Cardigan I and Cardigan II clinical studies of sofpironium bromide gel, 15% in primary axillary (underarm) hyperhidrosis patients. In the Cardigan I and II studies, sofpironium bromide gel, 15% was generally well-tolerated.

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 October 7, 2021, the Company announced positive topline results, achieving statistical significance on all primary and secondary endpoints, from its U.S. Phase 3 pivotal Cardigan I and Cardigan II clinical studies, which evaluated sofpironium bromide gel, 15% as a once daily topical formulation in patients with primary axillary hyperhidrosis (excessive underarm sweating). The U.S. Phase 3 pivotal clinical program for sofpironium bromide gel, 15% was comprised of two pivotal clinical studies. The Cardigan I and Cardigan II studies enrolled 350 subjects and 351 subjects, respectively, who were nine years of age and older with primary axillary hyperhidrosis. The studies were multicenter, randomized, double-blinded, vehicle (placebo)-controlled, evaluating the efficacy and safety of topically applied sofpironium bromide gel, 15%. Subjects applied sofpironium bromide gel, 15% or placebo to their underarms once daily at bedtime for six consecutive weeks, with a two-week post-treatment follow-up.

The Company expects that the results from the Cardigan I and Cardigan II studies, along with all previously completed clinical studies, will form the basis for a U.S. New Drug Application for sofpironium bromide gel, 15%, that it anticipates it will submit to the U.S. Food and Drug Administration in mid-2022.

All primary and secondary efficacy endpoints of the Cardigan I and Cardigan II studies demonstrated statistically significant differences between sofpironium bromide gel, 15% (SB) and vehicle (or placebo), as follows:

Cardigan I and II Efficacy Results[*]

Co-Primary Efficacy Endpoints	**Cardigan I**			**Cardigan II**		
	SB (n=173)	**Vehicle (n=177)**	**p-value**	**SB (n=180)**	**Vehicle (n=171)**	**p-value**
• Proportion of subjects achieving at least a 2-point improvement in the HDSM-Ax[1] score from baseline to EOT[2]	49.3%	29.4%	p<0.001	63.9%	47.0%	p=0.003
• Change in GSP[3] from baseline to EOT (in mg)	-129.5	-99.3	p=0.002	-145.9	-131.7	p=0.030

Secondary Efficacy Endpoints	**Cardigan I**			**Cardigan II**		
	SB (n=173)	**Vehicle (n=177)**	**p-value**	**SB (n=180)**	**Vehicle (n=171)**	**p-value**
• Proportion of subjects achieving at least a 1-point improvement in the HDSM-Ax score from baseline to EOT	82.8%	69.5%	p=0.005	89.9%	80.8%	p=0.020
• Proportion of subjects achieving at least a 2-point improvement in the HDSM-Ax score and at least a 70% reduction in GSP from baseline to EOT	32.1%	10.2%	p<0.0001	35.5%	21.4%	p=0.006
• Proportion of subjects achieving at least a 1-point improvement in the HDSM-Ax score and at least a 50% reduction in GSP from baseline to EOT	54.3%	33.3%	p<0.001	68.7%	54.6%	p=0.014

[*] Intent-to-Treat analysis population
[1] HDSM-Ax = Hyperhidrosis Disease Severity Measure–Axillary, a proprietary and validated patient-reported outcome measure
[2] EOT = End of treatment
[3] GSP = gravimetric sweat production

Cardigan I and II Safety Results

In the Cardigan I and II studies, sofpironium bromide gel, 15% was generally well-tolerated. The Treatment-Emergent Adverse Events ("TEAEs") were mild or moderate in severity and transient in nature. Overall, 89% of patients who were randomized to sofpironium gel, 15% in the studies completed the full six weeks of treatment. Common adverse events (incidence ≥2%) observed in the sofpironium bromide gel, 15% treatment group in the Cardigan I and II studies were dry mouth (11.6%, 17.2%), blurred vision (5.2%, 11.7%), application site pain (6.4%, 10.0%), application site erythema (5.2%, 7.8%), mydriasis (7.5%, 5.0%), application site pruritis (6.4%, 2.2%), application site dermatitis (5.8%, 5.6%), urinary retention (1.2%, 3.3%), application site irritation (1.2%, 3.3%), dry eye (0.6%, 3.3%), headache (1.2%, 2.2%), constipation (0.6%, 2.2%) and urinary hesitation (0.6%, 2.2%), respectively. Five (2.9%) and nine (5.0%) subjects who received sofpironium bromide gel, 15%, discontinued the Cardigan I and II studies, respectively, due to a TEAE. No treatment-related Serious Adverse Events were reported.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release issued by Brickell Biotech, Inc. on October 7, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this document and its attachment 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 pre-clinical and clinical trials, intellectual property rights, including the validity, term and enforceability of such, the expected timing and/or results of regulatory applications and approvals, and size and prospects for commercializing any of Brickell's product candidates, or research collaborations with its partners, including in Japan, Korea, 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 document and its attachment, the words "may," "could," "would," "should," "might," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "look forward" and similar expressions and their variants, as they relate to Brickell 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 or events to differ materially from what are discussed in the forward-looking statements or known by historical experience include risks and uncertainties, including without limitation, research results and data that do not meet targets or expectations, ability to obtain adequate financing for product development, regulatory submissions and any commercialization, ability to maintain and enforce intellectual property rights, potential delays or alterations for any reason in product development and regulatory submission and reviews, changes in law or policy, regulatory agency feedback or requests, 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 Brickell or its partners to supply and commercialize research material and/or the product anywhere in the world, or obtain or retain adequate pricing or reimbursement, the outcome of Brickell's current and planned preclinical and clinical trials, 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.

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: October 7, 2021

Brickell Biotech, Inc.

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

Exhibit 99.1

Brickell Biotech Announces Positive Topline Results, Achieving Statistical Significance on all Primary and Secondary Endpoints, from Both U.S. Phase 3 Pivotal Clinical Studies of Sofpironium Bromide Gel, 15% in Primary Axillary Hyperhidrosis Patients

Sofpironium bromide gel, 15% was generally well-tolerated

Plan to submit a New Drug Application (NDA) to the FDA in mid-2022

Management to host webcast and conference call today at 8:30 a.m. ET to present the topline results

BOULDER, Colo., October 7, 2021(GLOBE NEWSWIRE) – Brickell Biotech, Inc. ("Brickell") (Nasdaq: BBI), a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of dermatologic, autoimmune and other debilitating diseases, today announced positive topline results from the Phase 3 pivotal Cardigan I and Cardigan II studies, which evaluated sofpironium bromide gel, 15% as a once daily topical formulation in patients with primary axillary hyperhidrosis (excessive underarm sweating).

"We are excited to report the positive topline results from our pivotal Phase 3 clinical studies. These data are highly encouraging and further reinforce our belief that sofpironium bromide gel, 15% has the potential to become a best-in-class treatment option for the millions of patients suffering from primary axillary hyperhidrosis," said Robert Brown, Chief Executive Officer of Brickell. "The results from the Cardigan I and Cardigan II studies, along with all previously completed clinical studies, will form the basis for a U.S. NDA for sofpironium bromide gel, 15%, which we expect to submit to the FDA in mid-2022. We are tremendously appreciative of the collaborative and diligent efforts of our patients, study investigators, partners and employees who participated in or contributed to these studies. This was a huge team effort, and we are thankful to all of those involved in making our Phase 3 program a success."

"These data demonstrate that once-daily topical sofpironium bromide gel, 15% achieved early, sustained and significant improvements in primary axillary hyperhidrosis signs and symptoms consistent across all efficacy measures and was generally well-tolerated over six weeks of treatment," commented Stacy Smith, MD, a practicing dermatologist. "I feel privileged to have served as a principal investigator in the U.S. pivotal Phase 3 program. There is a real need for new and improved hyperhidrosis treatment options, and the results from these pivotal Phase 3 studies further support the potential for sofpironium bromide gel, 15% to become a first-line therapy of choice for patients with primary axillary hyperhidrosis."

The U.S. Phase 3 pivotal clinical program for sofpironium bromide gel, 15% was comprised of two pivotal clinical studies. The Cardigan I and Cardigan II studies enrolled 350 subjects and 351 subjects, respectively, who were nine years of age and older with primary axillary hyperhidrosis. The studies were multicenter, randomized, double-blinded, vehicle (placebo)-controlled, evaluating the efficacy and safety of topically applied sofpironium bromide gel, 15%. Subjects applied sofpironium bromide gel, 15% or placebo to their underarms once daily at bedtime for six consecutive weeks, with a two-week post-treatment follow-up. Additional details of the Cardigan I and II studies can be found on https://clinicaltrials.gov under identifiers NCT03836287 and NCT03948646, respectively.

All primary and secondary efficacy endpoints demonstrated statistically significant differences between sofpironium bromide gel, 15% (SB) and vehicle, as follows:

Cardigan I and II Efficacy Results*

Co-Primary Efficacy Endpoints	Cardigan I			Cardigan II		
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Conference Call and Webcast Information

Brickell's management will host a webcast and conference call today at 8:30 a.m. ET to discuss the topline data announced in this release. 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 #13723931. A live webcast of the conference call can be accessed here (http://public.viavid.com/index.php?id=146847) 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 approximately 90 days.

About Sofpironium Bromide

Sofpironium bromide 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% has completed 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 striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of dermatologic, autoimmune and other debilitating diseases. Brickell's pipeline combines a potential best-in-class, late clinical-stage program for hyperhidrosis with a novel, cutting-edge platform and development stage candidates with broad potential in autoimmune and neuroinflammatory disorders. 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 meaningfully benefit patients who are suffering from chronic debilitating diseases that are underserved by available therapies. 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 pre-clinical and clinical trials, intellectual property rights, including the validity, term and enforceability of such, the expected timing and/or results of regulatory applications and approvals, and size and prospects for commercializing any of Brickell's product candidates, or research collaborations with its partners, including in Japan, Korea, 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," "would," "should," "might," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "look forward" and similar expressions and their variants, as they relate to Brickell 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 or events to differ materially from what are discussed in the forward-looking statements or known by historical experience include risks and uncertainties, including without limitation, research results and data that do not meet targets or expectations, ability to obtain adequate financing for product development, regulatory submissions and any commercialization , ability to maintain and enforce intellectual property rights, potential delays or alterations for any reason in product development and regulatory submission and reviews, changes in law or policy, regulatory agency feedback or requests, 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 Brickell or its partners to supply and commercialize research material and/or the product anywhere in the world, or obtain or retain adequate pricing or reimbursement, the outcome of Brickell's current and planned preclinical and clinical trials, 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.

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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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