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) April 23, 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 April 23, 2021, Brickell Biotech, Inc. (the "Company") issued a press release, which is furnished as Exhibit 99.1 to this report, reporting results from its U.S. Phase 3 open-label, long-term safety study of sofpironium bromide gel as a potential treatment for primary axillary (underarm) hyperhidrosis. An investor presentation that the Company will refer to during a conference call to discuss the results is furnished as Exhibit 99.2 to this report.

The information in this Item 7.01, and Exhibits 99.1 and 99.2 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 April 23, 2021, the Company announced results from its Phase 3 open-label, long-term safety study ("ARGYLE" or "LTSS"). The ARGYLE study assessed the long-term safety and efficacy of topical, once-daily treatment with sofpironium bromide gel, 5% and 15% for 48 weeks in patients nine years and older with primary axillary hyperhidrosis, or excessive underarm sweating.

The study enrolled 300 patients at 30 U.S. sites, and patients were randomized to receive either sofpironium bromide gel, 5% or 15% in a 1:2 ratio. Subjects applied the assigned investigational product once daily at bedtime to both axillae for 48 weeks, followed by a 4-week post-treatment visit. This study was not conducted as a conventional Phase 3 open-label "extension" study where patients from pivotal studies roll over into an open-label extension study. ARGYLE thus provides a more complete clinical data set evaluating treatment-naïve primary axillary hyperhidrosis patients who received sofpironium bromide gel for 48 weeks. 190 patients completed the full study duration of 52 weeks.

The treatment-related treatment-emergent adverse events (TEAEs) for sofpironium bromide gel, 5% (22.5%) and 15% (50.8%) were mostly mild or moderate in severity and transient in nature. The most common and expected treatment-related TEAEs reported were blurred vision (4.9%; 18.8%), dry mouth (8.8%; 16.8%), pruritis (5.9%; 14.7%), pain (3.9%; 14.7%), dermatitis (5.9%; 9.1%), erythema (4.9%; 7.6%), irritation (4.9%; 5.6%), mydriasis (1.0%; 5.1%) and urinary retention (2.9%; 3.6%). The patient discontinuations due to treatment-related TEAEs included blurred vision (2.0%; 7.1%), pruritis (0%; 2.0%), dermatitis (1.0%; 2.0%), dry mouth (0%; 1.5%), pain (0%; 1.5%), erythema (1.0%; 0.5%), irritation (0%; 1.0%), urinary hesitation (1.0%; 0%) and mydriasis (0%; 0.5%). Overall, TEAEs and discontinuations demonstrated decreased incidence over time as patients in the long-term study acclimated to treatment. No treatment-related serious adverse events (SAE) were observed in adult and pediatric patients and no new safety signals emerged.

With respect to studied efficacy, the 5% and 15% gel groups exhibited clinically meaningful improvement in axillary hyperhidrosis severity as measured by the Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax), a proprietary patient-reported outcome scale. For both 5% and 15% dose groups, responders with a 1-point (86.1%; 85.8%) and 2-point (69.4%; 61.9%) improvement on HDSM-Ax PRO scale showed a gradual and continual improvement in sweat severity through the 48 weeks of treatment.

Overall, the safety, tolerability and efficacy results for sofpironium bromide gel, 5% and 15% in ARGYLE were consistent with prior clinical experience and no unexpected safety findings were observed. There were no clinically significant changes in laboratory parameters or vital signs over 48 weeks of treatment.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1	Press release issued by Brickell Biotech, Inc. on April 23, 2021
99.2	Investor presentation dated April 23, 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 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 the Company'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 document, 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 the Company, Kaken or any of the Company's partners, may identify forward-looking statements. The Company 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 the Company'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 the Company as of the date hereof only, and the Company 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: April 23, 2021

Brickell Biotech, Inc.

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

Exhibit 99.1

Brickell Biotech Reports Results from U.S. Phase 3 Open-Label, Long-Term Safety Study on Chronic Use of Sofpironium Bromide Gel as a Potential Treatment for Primary Axillary Hyperhidrosis

Daily treatment with sofpironium bromide gel was generally well-tolerated over 48 weeks of treatment

- - -

Efficacy assessments showed a clinically meaningful and sustained improvement in sweat severity through the 48 weeks of treatment

- - -

Data presented today in a late-breaking oral presentation at AAD VMX 2021

- - -

Management to host an investor call today at 12:00 p.m. EDT

BOULDER, CO — **April 23, 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 results from its Phase 3 open-label, long-term safety study ("ARGYLE" or "LTSS"), which were also presented today in a late-breaking oral presentation at the American Academy of Dermatology's ("AAD") 2021 Virtual Meeting Experience ("VMX"). The ARGYLE study assessed the long-term safety and efficacy of topical, once-daily treatment with sofpironium bromide gel, 5% and 15% for 48 weeks in patients nine years and older with primary axillary hyperhidrosis, or excessive underarm sweating.

"We are pleased that the ARGYLE study results further strengthen the safety, tolerability and efficacy data previously observed in our Phase 2b study of sofpironium bromide gel." said Deepak Chadha, Brickell's Chief Research & Development Officer. "As was observed with earlier clinical studies, the majority of side effects were mild or moderate in severity and transient in nature. Sofpironium bromide gel, 5% and 15% both led to sustained improvements in sweating severity for the majority of patients through the end of 48 weeks of treatment. These data contribute to our understanding of the long-term use of sofpironium bromide gel as a potential novel treatment for the millions of patients suffering from this chronic and debilitating condition."

"In this LTSS study, sofpironium bromide gel was generally well-tolerated with continued efficacy during 48 weeks in patients with primary axillary hyperhidrosis. In addition, we were pleased to see that the incidence of patients with any treatment-emergent adverse events decreased over time, as did the number of discontinuations," commented Stacy Smith, MD, a practicing dermatologist and participating investigator in this study. "Taking into consideration that patients did not have the conventional option to acclimate to treatment prior to enrolling in this standalone long-term safety study, the observed safety profile is even more encouraging."

ARGYLE: Phase 3 Open-Label Long-Term Safety Study Results

The ARGYLE study evaluated the long-term safety and efficacy of sofpironium bromide gel, 5% and 15% for 48 weeks of treatment in patients nine years or older with primary axillary hyperhidrosis. The study enrolled 300 patients at 30 U.S. sites. Patients were randomized to receive either sofpironium bromide gel, 5% or 15% in a 1:2 ratio. Subjects applied the assigned investigational product once daily at bedtime to both axillae for 48 weeks, followed by a 4-week post-treatment visit. This study was not conducted as a conventional Phase 3 open-label "extension" study where patients from pivotal studies roll over into an open-label extension study. ARGYLE thus provides a more complete clinical data set evaluating treatment-naïve primary axillary hyperhidrosis patients who received sofpironium bromide gel for 48 weeks and evaluated for an additional 4 weeks after the end of treatment. 190 patients completed the full study duration of 52 weeks.

The treatment-related treatment-emergent adverse events (TEAEs) for sofpironium bromide gel, 5% (22.5%) and 15% (50.8%) were mostly mild or moderate in severity and transient in nature. The most common and expected treatment-related TEAEs reported were blurred vision (4.9%; 18.8%), dry mouth (8.8%; 16.8%), pruritis (5.9%; 14.7%), pain (3.9%; 14.7%), dermatitis

(5.9%; 9.1%), erythema (4.9%; 7.6%), irritation (4.9%; 5.6%), mydriasis (1.0%; 5.1%) and urinary retention (2.9%; 3.6%). The patient discontinuations due to treatment-related TEAEs included blurred vision (2.0%; 7.1%), pruritis (0%; 2.0%), dermatitis (1.0%; 2.0%), dry mouth (0%; 1.5%), pain (0%; 1.5%), erythema (1.0%; 0.5%), irritation (0%; 1.0%), urinary hesitation (1.0%; 0%) and mydriasis (0%; 0.5%). Overall, TEAEs and discontinuations demonstrated decreased incidence over time as patients in the long-term study acclimated to treatment. No treatment-related serious adverse events (SAE) were observed in adult and pediatric patients and no new safety signals emerged.

With respect to studied efficacy, the 5% and 15% gel groups exhibited clinically meaningful improvement in axillary hyperhidrosis severity as measured by the Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax), a proprietary patient-reported outcome scale. For both 5% and 15% dose groups, responders with a 1-point (86.1%; 85.8%) and 2-point (69.4%; 61.9%) improvement on HDSM-Ax PRO scale showed a gradual and continual improvement in sweat severity through the 48 weeks of treatment.

Overall, the safety, tolerability and efficacy results for sofpironium bromide gel, 5% and 15% in ARGYLE were consistent with prior clinical experience and no unexpected safety findings were observed. There were no clinically significant changes in laboratory parameters or vital signs over 48 weeks of treatment.

Late-Breaking Oral Presentation at AAD VMX 2021

An on-demand video of the virtual late-breaking oral presentation by Dr. Smith will be available to attendees of the AAD VMX 2021 starting at 10:00 a.m. EDT. The presentation is titled, “A Multicenter, Randomized, Open-label, Phase 3 Long-term Safety Study (LTSS) of Topically Applied Sofpironium Bromide Gel, 5% and 15% in Subjects with Axillary Hyperhidrosis.”

Today’s Conference Call and Webcast Information

Brickell’s management will host a conference call geared toward industry and the investment community today at 12:00 p.m. EDT where Dr. Stacy Smith will discuss the ARGYLE study results, followed by a Q&A session. The conference call will be accessible to the public, and 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 #13718742. 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 of the webcast also will be available on Brickell’s website in the Investors tab shortly after conclusion of the call and will be available for approximately 90 days.

U.S. Pivotal Phase 3 Cardigan I and Cardigan II Studies

The Company is currently conducting the U.S. Phase 3 Cardigan I and Cardigan II clinical studies evaluating sofpironium bromide gel, 15% in approximately 350 subjects (per study) aged nine and older with primary axillary hyperhidrosis and expects to announce topline data in the fourth quarter of 2021. If successful, the results from these studies, combined with ARGYLE, are expected to form the basis of a prospective New Drug Application in the U.S. for sofpironium bromide gel, 15% for the treatment of primary axillary hyperhidrosis. Additional details of the Cardigan I and II studies can be found on https://clinicaltrials.gov under identifiers NCT03836287 and NCT03948646, respectively.

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 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] 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.

Brickell Investor Contact:
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daniel@lifesciadvisors.com

Exhibit 99.2

BrickellBio

NASDAQ: BBI

ARGYLE: U.S. Phase 3 Open-Label, Long-Term Safety Study

Making Fresh Tracks in Dermatology®

Investor Call | April 23, 2021

Forward-Looking Statements

- This presentation contains forward-looking statements that involve substantial risk and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation other than statements of historical fact, including, but not limited to, statements regarding our strategy; our ongoing and future clinical and non-clinical trials including timing and ability to complete and later report data therefrom; future operations and attendant results; ability to supply material and products; future financial position; liquidity; future revenue; projected expenses; prospects; and staffing, plans and objectives of management are forward-looking statements. The words "believe," "could," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "look forward," "opportunity," "goals," or "should," and similar expressions and their variants, as they relate to Brickell Biotech, Inc., or any of our business partners, are intended to identify forward-looking statements. Such statements are based on Brickell's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors.

- Statements regarding the following subjects, among others, may be forward-looking: Expectations regarding the successful development, regulatory approval and commercialization of sofpironium bromide and our other product candidates; expectations regarding our intellectual property rights and that of our partners; expectations regarding the results and timing of results of clinical trials for sofpironium bromide and our other product candidates; expectations regarding the potential market size, opportunity and growth potential for sofpironium bromide and our other product candidates; expectations regarding the degree of physician and patient adoption and reimbursement, funding and use of sofpironium bromide following regulatory approval in countries like Japan where it has been obtained and in other countries, if received; our relationship with, and expectations of, our product development partners; our cash (and equity) position and ability to obtain adequate financing in the future on satisfactory terms or at all; our expenses and capital requirements; the timing or likelihood of regulatory filings and approvals; the implementation of our business model, strategic plans for our business, product candidates and technology; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; and developments relating to our competitors; and our business development efforts to enhance the Brickell product pipeline.

- These forward-looking statements are based largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, legal compliance, business strategy, short-term and long-term operations and objectives. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (the "SEC"), in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our Company to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

A Multicenter, Randomized, Open-Label, Phase 3 Long-Term Safety Study (Argyle) of Topically Applied Sofpironium Bromide (SB) Gel, 5% and 15%, in Subjects with Primary Axillary Hyperhidrosis

Brandon M Kirsch, MD[1], Stacy Smith, MD[2], Joel Cohen, MD[3], Janet DuBois, MD[4], Adelaide Hebert, MD[5], Tory Sullivan, MD[6], Lawrence Green, MD[7], Neal Bhatia, MD[8], David Pariser, MD[9], Ping-Yu Liu, PhD[10], Deepak Chadha, MS, MBA, RAC[11]

[1]Kirsch Dermatology, Naples, FL, [2]California Dermatology and Clinical Research Institute, Encinitas, CA, [3]AboutSkin Dermatology and DermSurgery, Greenwood Village, CO; Department of Dermatology, University of California, Irvine, CA, [4]DermResearch, Inc., Austin, TX, [5]Department of Dermatology, The University of Texas Health Science Center, Houston, TX, [6]Sullivan Dermatology, North Miami Beach, FL, [7]Department of Dermatology, George Washington University School of Medicine, Washington, DC, [8]Therapeutic Dermatology, San Diego, CA, [9]Pariser Dermatology, Norfolk, VA, [10]Fred Hutchinson Cancer Research Center, Seattle, WA, [11]Brickell Biotech, Inc., Boulder, CO, USA

Disclosures

- Funding/Support
  - The following clinical trial was supported by Brickell Biotech, Inc.
- Financial Disclosures
  - Stacy Smith, MD, Joel Cohen, MD, Janet DuBois, MD, Tory Sullivan, MD, Lawrence Green, MD, Neal Bhatia, MD, and David Pariser, MD were study investigators and received payment from Brickell Biotech, Inc. for their services. Adelaide Hebert, MD was a study investigator but did not receive direct payment from Brickell Biotech, Inc. Research funding was paid to the University of Texas Health Science Center. Deepak Chadha, MS, MBA, RAC is an employee of Brickell Biotech, Inc. Brandon Kirsch, MD and Ping-Yu Liu, PhD are consultants to Brickell Biotech, Inc.
- Regulatory Statement
  - Sofpironium bromide is an investigational agent in the United States. Sofpironium bromide gel, 5% is approved in Japan for the treatment of axillary hyperhidrosis (ECCLOCK® Gel 5%) .
- Disclaimer
  - The product related statements contained in this presentation are based on preclinical and clinical trial data. Development of this investigational medicinal product is ongoing; the efficacy and safety of sofpironium bromide have not yet been established by the FDA. There is no guarantee that this investigational product will receive approval for use in the United States or become commercially available.

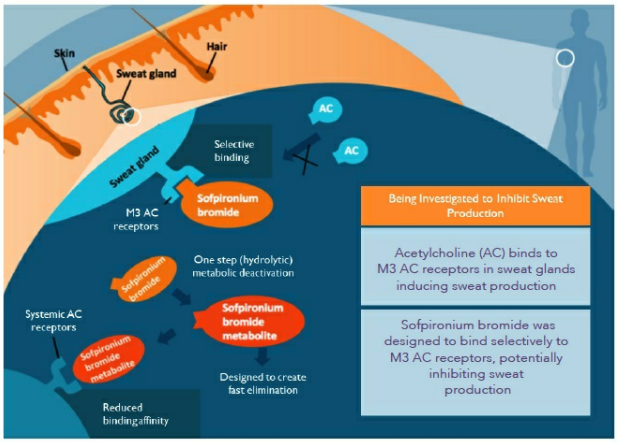
Hyperhidrosis Background

- Hyperhidrosis affects 4.8% of U.S. or >15M individuals[1]
- Over 10 million individuals in the U.S. suffer from axillary hyperhidrosis (AHH)[1]
- 75% of HH sufferers report a profoundly negative impact on their social life, wellbeing, emotional and mental health[1]
- Long-term treatment is often necessary given the chronic nature of primary axillary hyperhidrosis

[1]Hyperhidrosis: An update on prevalence and severity of hyperhidrosis in the United States, Doolittle, James, October 2016

Topical Retrometabolic Anticholinergic Agent

MECHANISM OF ACTION



- **Sofpironium bromide** is an analog of glycopyrrolate (an anticholinergic agent). It is an investigational drug in the United States, intended for the topical treatment of primary axillary hyperhidrosis.
- **Retrometabolic** molecules are designed such that they undergo rapid metabolism into less active moieties following absorption after topical application and therefore have a short systemic half-life.

Study Objectives, Design and Methods

In this open-label trial, the long-term safety, tolerability and efficacy of SB gel was evaluated in adult and pediatric subjects (300 total) with primary axillary hyperhidrosis*

OBJECTIVES	To evaluate the long-term safety, local tolerability and efficacy of sofpironium bromide gel, 5% and 15% when applied topically to subjects with AHH
TREATMENT DURATION	48-week treatment with a 4-week follow-up
RANDOMIZATION	Subjects were randomized 1:2 to receive either sofpironium bromide gel, 5% or 15%
KEY INCLUSION CRITERIA	Subjects ≥9 year of age with AHH of ≥6 months duration Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) scores of 3 or 4 (scale, 0 - 4)
STUDY ASSESSMENTS	Efficacy Assessments: HDSM-Ax, DLQI, PGI-S, PGI-C, HidroQOL; GSP was not measured Safety Assessments: Physical Exams, Adverse Events, Local Tolerability, Clinical Laboratories

*This was NOT a rollover study

Subject Disposition

A total of 190 subjects completed this long-term open-label safety study

	Total	SB gel, 5% n=103 (%)	SB gel, 15% n=197 (%)
Safety Population	299	102[1]	197
Early Terminations	110	31 (30.4)	79 (40.1)
Due to Non-AEs	73	26 (25.5)	47 (23.9)
Due to AEs	37	5 (4.9)	32 (16.2)
Completed 52 Weeks (EOS)	190	72 (70.6)	118 (59.9)

NOTE: SB gel, 15% discontinuations due to AEs (16.2%) were comparable to those observed in the 6-week Phase 2b dose-finding study (12.5%) (Kirsch, Brandon, et al. "Efficacy and safety of topical sofpironium bromide gel for the treatment of axillary hyperhidrosis: A phase II, randomized, controlled, double-blinded trial." Journal of the American Academy of Dermatology 82.6 (2020): 1321-1327)

[1]The number of subjects in the Safety Population for the 5% gel is 102 instead of 103 because one subject was randomized but never applied study product.

Safety Summary at Week 48 End of Treatment

SB gel safety results were consistent with a prior Phase 2b dose-finding study[1]
Majority of the AEs were mild or moderate in severity and transient in nature

TEAE = Treatment-Emergent Adverse Event	SB gel, 5% n=102 (%)	SB gel, 15% n=197 (%)
Any TEAE, n (%)	58 (56.9)	131 (66.5)
Treatment-Related TEAE	23 (22.5)	100 (50.8)
Treatment-Related TEAE by Severity		
Mild	11 (10.8)	48 (24.4)
Moderate	11 (10.8)	40 (20.3)
Severe	1 (1.0)	12 (6.1)
Serious Adverse Events (SAE)[2]	1 (1.0)	4 (2.0)

[1]Kirsch, Brandon, et al. "Efficacy and safety of topical sofpironium bromide gel for the treatment of axillary hyperhidrosis: A phase II, randomized, controlled, double-blinded trial." Journal of the American Academy of Dermatology 82.6 (2020): 1321-1327. [2]No SAEs observed in this study were treatment-related (3020-006 [5%], Pneumonia/septic shock; 3001-016 [15%], Cardiac myxoma; 3014-022 [15%], Suicide attempt; 3027-007 [15%], Depression; 3028-012 [15%], Pulmonary embolism). **Note**: Subjects who experienced one or more AEs are counted once for the closest relationship to investigational product and for the worst (or maximum) severity. Treatment-related includes the following categories: definitely related, probably related, or possibly related.

Incidence of Treatment-Related TEAEs Occurring in ≥5% of Subjects

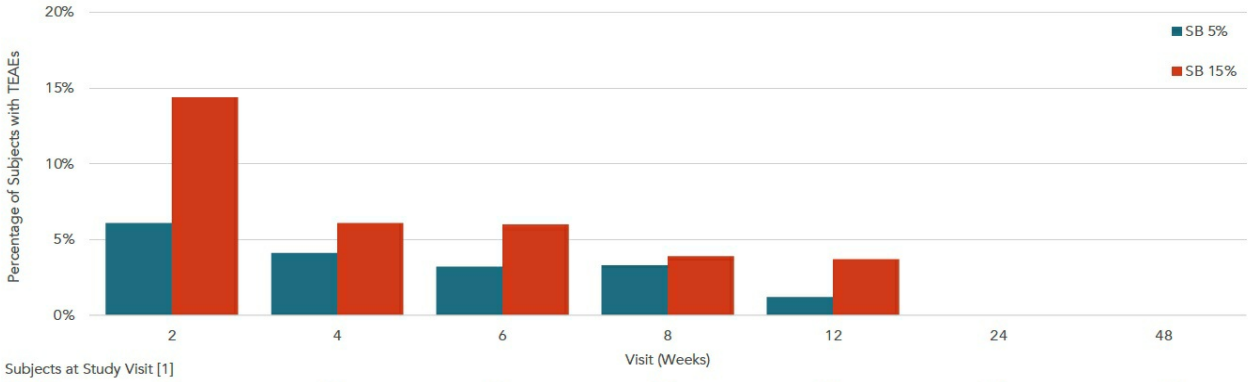
Long-term (48 weeks) daily topical application of sofpironium bromide gel was generally well tolerated

Preferred Term[1]	SB gel, 5% (N = 102)	SB gel, 15% (N=197)
Anticholinergic AEs		
Blurred Vision	4.9%	18.8%
Dry Mouth	8.8%	16.8%
Mydriasis	1.0%	5.1%
Application Site AEs		
Pruritis	5.9%	14.7%
Pain	3.9%	14.7%
Dermatitis	5.9%	9.1%
Erythema	4.9%	7.6%
Irritation	4.9%	5.6%
Infections and Infestations		
Upper respiratory tract infection	8.8%	4.1%

[1]*Adverse events depicted here were present in at least one treatment group at ≥5%*

Percentage of Subjects with Treatment-Related TEAEs Over Time

The incidence of subjects with any TEAEs tended to decrease over time as remaining subjects acclimated to treatment

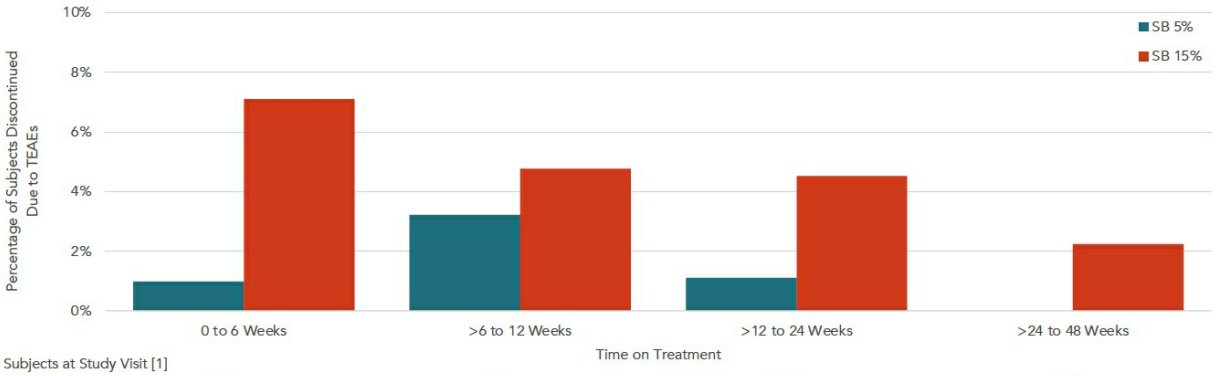


Subjects at Study Visit [1]							
SB 5%	98	98	93	90	84	72	72
SB 15%	188	179	168	155	134	118	118

[1] Subjects at Study Visit are subjects with a visit corresponding to the week shown (i.e., still enrolled and receiving treatment at a given timepoint).

Percentage of Subjects Discontinued Due to TEAEs Over Time

The incidence of discontinuations due to TEAEs tended to decrease over time as remaining subjects acclimated to treatment



Subjects at Study Visit [1]				
SB 5%	102	93	90	84
SB 15%	197	168	155	134

[1] Subjects at Study Visit are subjects with a visit corresponding to the first week of the range shown (i.e., still enrolled and receiving treatment at a given timepoint).

Summary of Anticholinergic AEs

For both concentrations, the observed anticholinergic adverse events were mostly mild or moderate in severity and transient in nature

PREFERRED TERM	SB gel, 5% n = 102 (%)	SB gel, 15% n = 197 (%)
All Anticholinergic	16 (15.7)	56 (28.4)
Blurred Vision	5 (4.9)[1]	37 (18.8)[2]
Dry Mouth	9 (8.8)	33 (16.8)
Mydriasis	1 (1.0)	10 (5.1)
Urinary Retention	3 (2.9)	7 (3.6)
Dry Eye	1 (1.0)	7 (3.6)

[1]The severity was 3 subjects mild, 2 subjects moderate and 0 subjects severe. [2]The severity was 20 subjects mild, 12 subjects moderate and 5 subjects severe.
Note: A severe AE is not a SAE per FDA and ICH adverse event definitions. **Note:** If a subject experienced more than one episode of an adverse event, the subject is counted once for that Preferred Term.

Discontinuation Due to Anticholinergic AEs

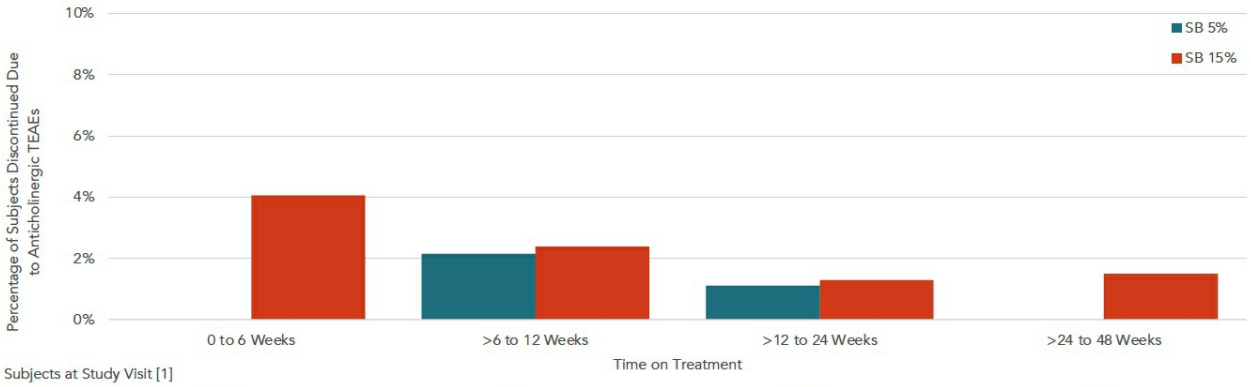
There were few anticholinergic TEAEs leading to study discontinuation

PREFERRED TERM	SB gel, 5% n = 102 (%)	SB gel, 15% n = 197 (%)
All Anticholinergic	3 (3.0)	16 (8.1)
Blurred Vision[1]	2 (2.0)	14 (7.1)
Dry Mouth	0	1 (0.5)
Mydriasis	0	1 (0.5)
Urinary Retention	1 (1.0)	0
Dry Eye	0	0

[1]The severity of blurred vision for those who discontinued from the SB gel, 15% group was evenly distributed: 4 subjects mild, 5 subjects moderate, 5 subjects severe. For the SB gel, 5% group, the severity of blurred vision for both subjects who discontinued was moderate.

Percentage of Subjects Discontinued Due to Anticholinergic TEAEs Over Time

The incidence of discontinuations due to anticholinergic TEAEs tended to decrease over time as remaining subjects acclimated to treatment

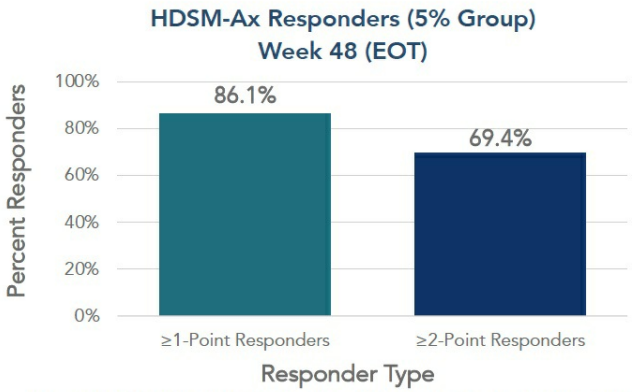


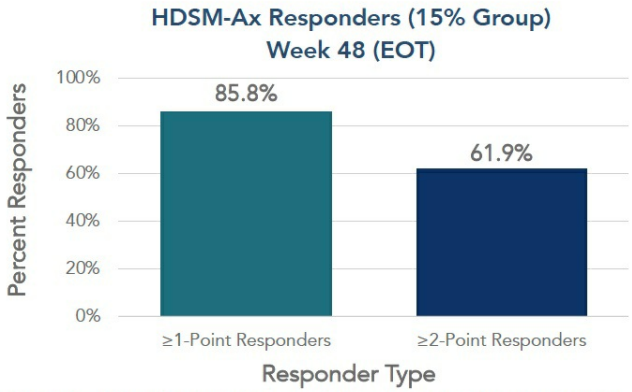
Subjects at Study Visit [1]				
SB 5%	102	93	90	84
SB 15%	197	168	155	134

[1] Subjects at Study Visit are subjects with a visit corresponding to the first week of the range shown (i.e., still enrolled and receiving treatment at a given timepoint).

Efficacy Assessment: HDSM-Ax Responder Analysis

1- and 2-point responders on the HDSM-Ax scale at end of treatment Week 48 suggests clinically meaningful improvement of sweat severity





Note: The HDSM-Ax is defined as the mean of the items in Section 1 and questions 2a through 2e of the HDSM-Ax questionnaire. The mean is derived by taking the total score and dividing by the number of questions answered. Subjects must answer all 7 sub-items to be evaluable for the total score.
The denominator is defined as the number of subjects in each treatment group at the end of treatment (Week 48).

Efficacy Assessment: HDSM-Ax Response Over Time

There appears to be efficacy over 48 weeks of treatment as measured by ≥2-point improvement in HDSM-Ax

Subjects at Study Visit [1]

	WK 2	WK 4	WK 6	WK 8	WK 12	WK 16	WK 20	WK 24	WK 28	WK 32	WK 36	WK 40	WK 44	WK 48	WK 52
SB 5%	97	96	93	92	86	86	84	83	80	81	77	73	72	72	69
SB 15%	186	178	166	167	152	140	133	133	129	125	123	117	112	113	116

[1] Subjects at Study Visit are subjects with a visit corresponding to the week shown (i.e., still enrolled and receiving treatment at a given timepoint).

Note: The proportions shown are the number of subjects in each treatment group meeting the criteria at each visit out of the number of subjects in each treatment group at each visit. The denominator is defined as the number of subjects in each treatment group at each visit, is displayed

Conclusion

Safety of long-term daily topical application of SB gel, 5% and 15% was consistent with prior clinical experience. Both concentrations led to measurable improvements in sweating severity for the majority of subjects

- For both concentrations, observed TEAEs and anticholinergic adverse events were mostly mild or moderate in severity and transient in nature.
- The most common and expected anticholinergic treatment-related adverse events reported were blurred vision, mydriasis and dry mouth.
- No treatment-related SAEs were observed. No new safety signals emerged.
- TEAEs demonstrated decreased incidence over time and infrequently led to discontinuation.
- Clinically meaningful reductions in sweat severity as measured by HDSM-Ax were observed.

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Q&A

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