**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.**

Brickell Biotech, Inc. (the "Company") plans to hold a conference call and webcast on October 7, 2021, to discuss the 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. An investor presentation that the Company will refer to during the conference call is furnished as Exhibit 99.1 to this report.

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 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

| | |
|---|---|
| 99.1 | Investor presentation dated 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

BrickellBio

NASDAQ: BBI

# Sofpironium Bromide U.S. Phase 3 Pivotal Program Topline Results

Making Fresh Tracks® in Medicine

October 7, 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 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. The words "believe," "could," "might," "would," "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 including those for autoimmune and neuroinflammatory; 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 approved and in other countries, if received, or any of our future products; our relationship with, and expectations of, our product development partners, suppliers and vendors; our cash (and equity) positions 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; our ability to launch solely or with help or via others; and our business development efforts to enhance the Brickell product pipeline.

- These forward-looking statements are based largely on our current expectations/projections about future events and trends that we believe may affect our financial condition, results of operations, legal compliance, business strategy, short- 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 II, Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the period ended June 30, 2021, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission. 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 Brickell Biotech, Inc. 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.

## Highlights from Today's Announcement

**Brickell announces positive topline results from two U.S. Phase 3 pivotal clinical studies of sofpironium bromide gel, 15% in primary axillary hyperhidrosis patients***

| | |
|---|---|
| **EFFICACY OVERVIEW** | All primary and secondary endpoints were met and achieved statistical significance |
| **SAFETY OVERVIEW** | Sofpironium bromide gel, 15% was generally well-tolerated |
| **NEXT STEPS** | Plan to submit a New Drug Application to the FDA in mid-2022 |

**Sofpironium bromide gel, 15% is not approved by U.S. FDA or any other regulatory authority for any use*

# U.S. Phase 3 Pivotal Program Overview (Cardigan I & Cardigan II)

| | |
|---|---|
| **STUDY TITLE** | • Multicenter, randomized, double-blinded, vehicle-controlled studies to evaluate the safety and efficacy of topically applied sofpironium bromide gel, 15% in subjects with primary axillary hyperhidrosis |
| **STUDY DESIGN** | • In each study, ~350 subjects 9 years of age or older were randomized to receive sofpironium bromide gel, 15% or vehicle (1:1) for 6 weeks of treatment with a 2-week follow-up |
| **CO-PRIMARY EFFICACY ENDPOINTS AGREED WITH FDA** | • The proportion of subjects achieving at least a 2-point improvement in Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax-7) from baseline to end of treatment (EOT)<br>• The change in gravimetric sweat production (GSP) from baseline to EOT |
| **STUDY POWER CALCULATIONS** | • The studies were powered to demonstrate a statistically significant treatment effect ($p<0.05$) for both co-primary endpoints of ~0.90 (>0.95 for HDSM-Ax and 0.95 for GSP) |

# U.S. Phase 3 Pivotal Program: Subject Disposition

**Overall, 89% of subjects receiving sofpironium bromide (SB) gel, 15% completed 6 weeks of treatment in the Phase 3 pivotal program**

| | CARDIGAN I | | | CARDIGAN II | | |
|---|---|---|---|---|---|---|
| | Total | SB Gel, 15% (n = 173)[2] | Vehicle (Placebo Gel) (n = 177)[2] | Total | SB Gel, 15% (n = 180)[2] | Vehicle (Placebo Gel) (n = 171)[2] |
| **Safety Population** | 349 | 173 | 176 | 351 | 180 | 171 |
| **Early Terminations** | 38 | 23 (*13.3%*) | 15 (*8.5%*) | 36 | 20 (*11.1%*) | 16 (*9.4%*) |
| Due to non-TEAEs[1] | 33 | 18 (*10.4%*) | 15 (*8.5%*) | 27 | 11 (*6.1%*) | 16 (*9.4%*) |
| Due to TEAEs | 5 | 5 (*2.9%*) | 0 | 9 | 9 (*5.0%*) | 0 |
| **Completed 6 weeks of treatment (EOT)** | 320 | 154 (*89.0%*) | 166 (*93.8%*) | 319 | 161 (*89.4%*) | 158 (*92.4%*) |

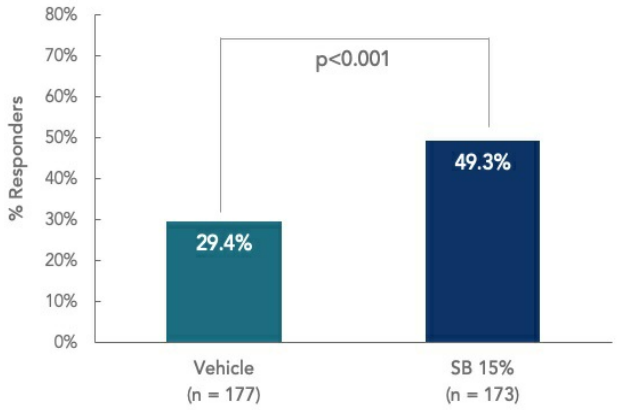
[1] TEAE = Treatment-Emergent Adverse Event; [2] 'n' represents number of subjects in the ITT population;
Source Tables 14.1.1.1.1 and 14.3.1.8.7

# Co-Primary Efficacy Endpoint: ≥2 Point Improvement in HDSM-Ax-7

**Sofpironium bromide (SB) gel, 15% demonstrated statistically significant HDSM-Ax-7 responses from baseline to EOT**

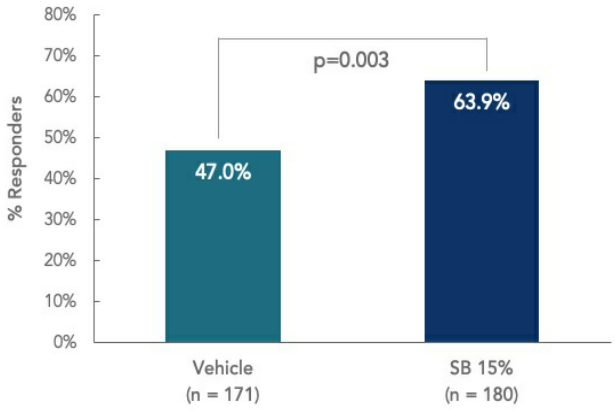
**CARDIGAN I**

≥2 point improvement in HDSM-Ax-7 from baseline to EOT[1]




**CARDIGAN II**

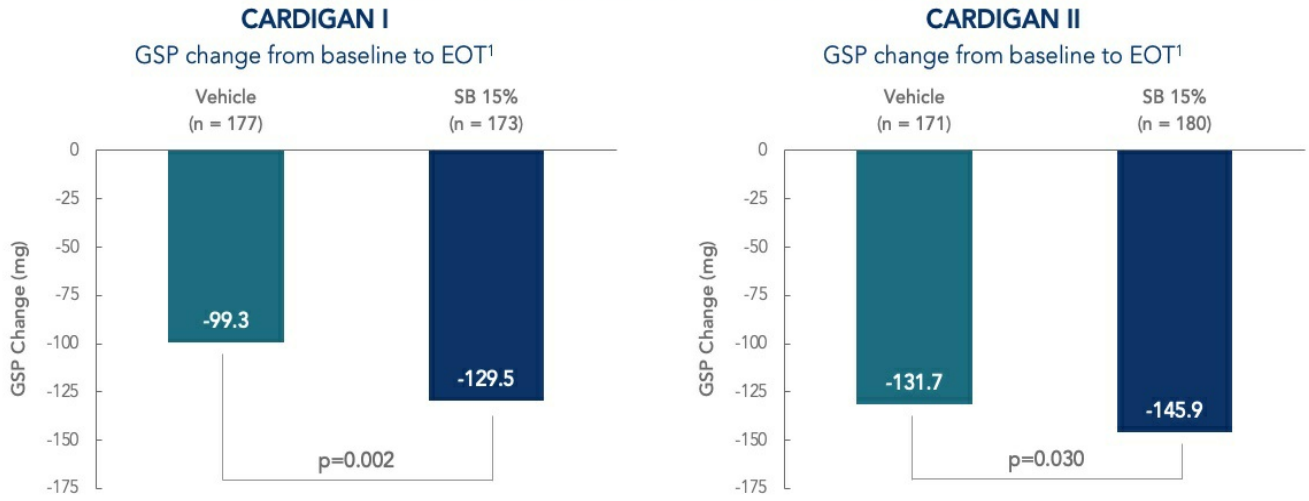
≥2 point improvement in HDSM-Ax-7 from baseline to EOT[1]




[1] Data are based on multiple imputations for missing values
'n' represents number of subjects in the ITT population; EOT = end of treatment
Source Tables 14.2.1.1.1

# Co-Primary Efficacy Endpoint: Change in GSP

**Sofpironium bromide (SB) gel, 15% demonstrated statistically significant responses compared to vehicle for change in GSP from baseline to EOT**



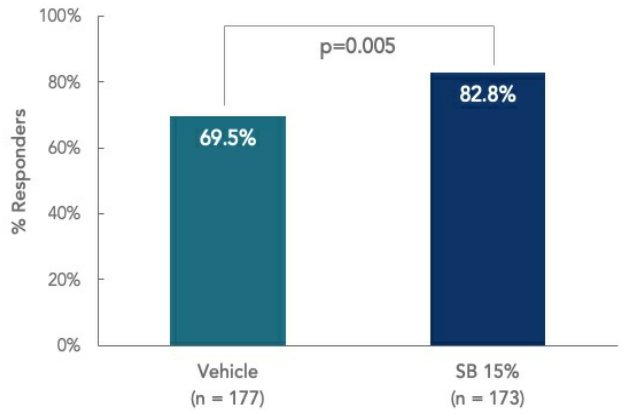

[1] Data are based on observed continuous GSP values and p-values are based on ranked value analysis with multiple imputations for missing data
'n' represents number of subjects in the ITT population; **GSP** = gravimetric sweat production; **EOT** = end of treatment
Source Tables 14.2.3.41 and 14.2.1.1.4

# Secondary Efficacy Endpoint: ≥1 Point Improvement in HDSM-Ax-7

**Sofpironium bromide (SB) gel, 15% demonstrated statistically significant HDSM-Ax-7 responses from baseline to EOT**

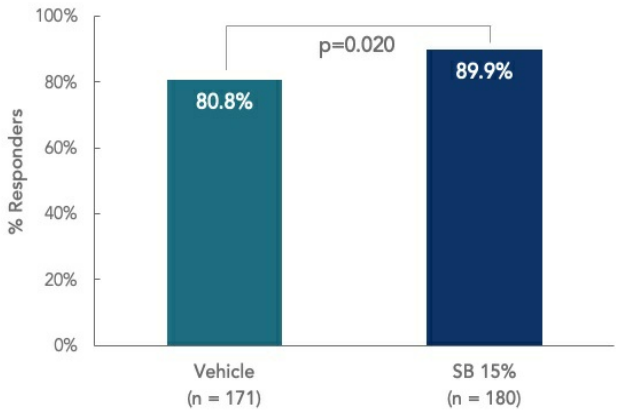
## CARDIGAN I

HDSM-Ax-7 reduction (≥1 point improvement) from baseline to EOT[1]




## CARDIGAN II

HDSM-Ax-7 reduction (≥1 point improvement) from baseline to EOT[1]




[1] Data are based on multiple imputations for missing values
'n' represents number of subjects in the ITT population; EOT = end of treatment
Source Tables 14.2.2.1

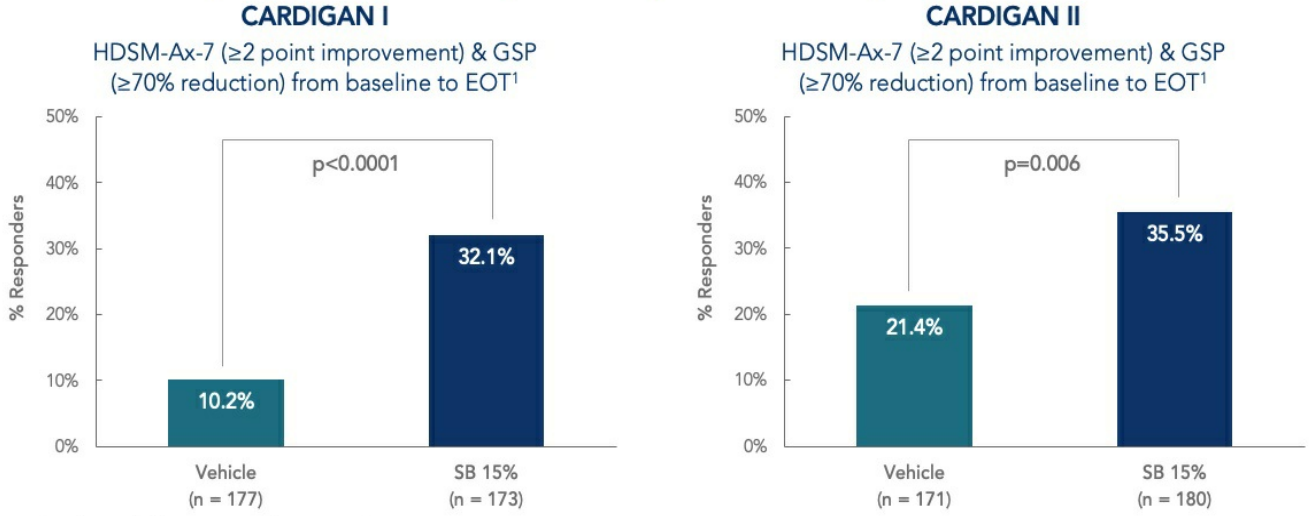




BrickellBio

# Secondary Efficacy Endpoint: Combined HDSM-Ax-7 & GSP Analysis

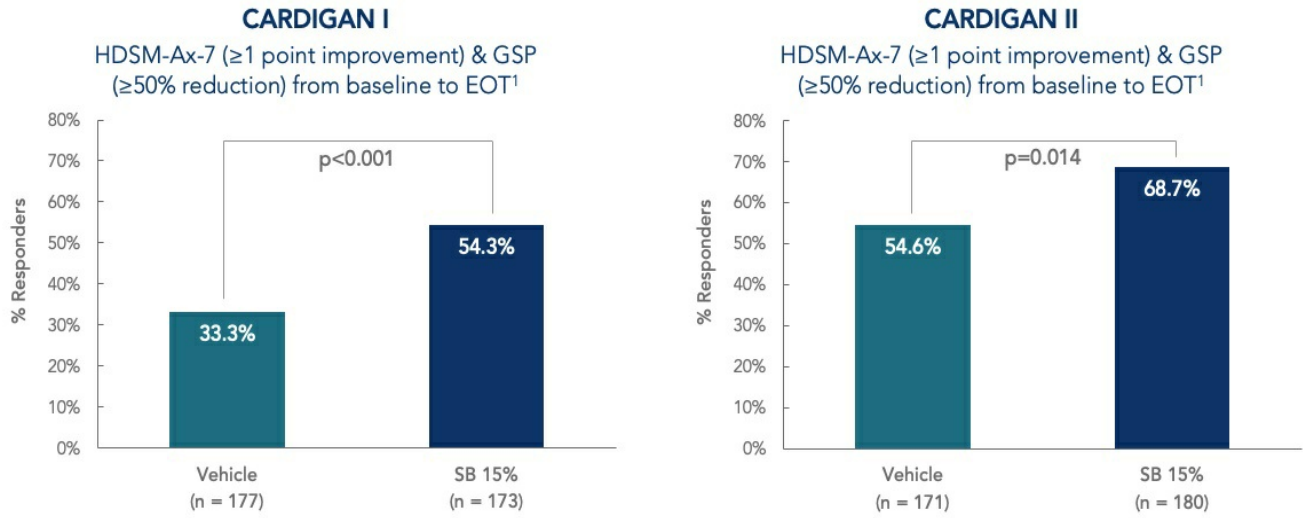
**Sofpironium bromide (SB) gel, 15% demonstrated statistically significant responses in a combined HDSM-Ax-7 (≥2 point improvement) and GSP (≥70% reduction) analysis from baseline to EOT**




[1] Data are based on multiple imputations for missing values
'n' represents number of subjects in the ITT population; GSP = gravimetric sweat production; EOT = end of treatment
Source Tables 14.2.2.4

# Secondary Efficacy Endpoint: Combined HDSM-Ax-7 & GSP Analysis

**Sofpironium bromide (SB) gel, 15% demonstrated statistically significant responses in a combined HDSM-Ax-7 (≥1 point improvement) and GSP (≥50% reduction) analysis from baseline to EOT**




[1] Data are based on multiple imputations for missing values
'n' represents number of subjects in the ITT population; GSP = gravimetric sweat production; EOT = end of treatment
Source Tables 14.2.2.7

# U.S. Phase 3 Pivotal Program: Safety Summary

## Majority of treatment-emergent adverse events (TEAEs) were mild or moderate in severity and transient in nature

| | CARDIGAN I | | CARDIGAN II | |
|---|---|---|---|---|
| | SB Gel, 15% (n = 173) | Vehicle (Placebo Gel) (n = 176) | SB Gel, 15% (n = 180) | Vehicle (Placebo Gel) (n = 171) |
| **Any TEAE, n (%)** | 62 (35.8%) | 23 (13.1%) | 81 (45.0%) | 23 (13.5%) |
| **Treatment-Related TEAE** | 51 (29.5%) | 9 (5.1%) | 63 (35.0%) | 9 (5.3%) |
| **Treatment-Related TEAE by Severity** | | | | |
| Mild | 26 (15.0%) | 8 (4.5%) | 27 (15.0%) | 7 (4.1%) |
| Moderate | 22 (12.7%) | 1 (0.6%) | 32 (17.8%) | 1 (0.6%) |
| Severe | 3 (1.7%) | 0 | 4 (2.2%) | 0 |
| **Serious AEs[1,2]** | 1 (0.6%) | 0 | 1 (0.6%) | 0 |

[1] Cardigan I Serious AE (bowel obstruction) was not treatment-related; [2] Cardigan II Serious AE (appendicitis) was not treatment-related
'n' represents number of subjects in the Safety population; Subjects who experienced one or more AEs are counted once for the worst severity
Source Tables 14.3.1.1 and 14.3.1.7.4

# Incidence of Treatment-Emergent Adverse Events (≥2% of Subjects)

**Sofpironium bromide (SB) gel, 15% was observed to be generally well tolerated and adverse events were predominantly mild or moderate in severity**

| | CARDIGAN I | | CARDIGAN II | |
|---|---|---|---|---|
| | SB Gel, 15% (n = 173) | Vehicle (Placebo Gel) (n = 176) | SB Gel, 15% (n = 180) | Vehicle (Placebo Gel) (n = 171) |
| Dry mouth | 20 (11.6%) | 0 | 31 (17.2%) | 2 (1.2%) |
| Blurred vision | 9 (5.2%) | 0 | 21 (11.7%) | 1 (0.6%) |
| Application Site Pain | 11 (6.4%) | 3 (1.7%) | 18 (10.0%) | 2 (1.2%) |
| Application Site Erythema | 9 (5.2%) | 1 (0.6%) | 14 (7.8%) | 0 |
| Mydriasis | 13 (7.5%) | 0 | 9 (5.0%) | 0 |
| Application Site Pruritis | 11 (6.4%) | 1 (0.6%) | 4 (2.2%) | 1 (0.6%) |
| Application Site Dermatitis | 10 (5.8%) | 1 (0.6%) | 10 (5.6%) | 0 |
| Urinary Retention | 2 (1.2%) | 0 | 6 (3.3%) | 0 |
| Application Site Irritation | 2 (1.2%) | 0 | 6 (3.3%) | 1 (0.6%) |
| Dry Eye | 1 (0.6%) | 0 | 6 (3.3%) | 0 |
| Headache | 2 (1.2%) | 2 (1.1%) | 4 (2.2%) | 0 |
| Constipation | 1 (0.6%) | 2 (1.1%) | 4 (2.2%) | 2 (1.2%) |
| Urinary Hesitation | 1 (0.6%) | 0 | 4 (2.2%) | 0 |

'n' represents number of subjects in the Safety population; AEs depicted above were present in at least 2% of subjects in at least one treatment group
Source Table 14.3.1.7.1

# U.S. Phase 3 Pivotal Program: Conclusions

**Cardigan I and Cardigan II results support submission of an NDA to the FDA for sofpironium bromide gel, 15%**

**CO-PRIMARY EFFICACY ENDPOINTS**

- Sofpironium bromide gel, 15% resulted in a statistically significant greater proportion of subjects achieving at least a 2-point improvement in HDSM-Ax from baseline to EOT compared to vehicle
- Sofpironium bromide gel, 15% resulted in a statistically significant greater reduction in GSP from baseline to EOT compared to vehicle

**SECONDARY EFFICACY ENDPOINTS**

- All 3 secondary efficacy endpoints showed statistically significant results favoring sofpironium bromide gel, 15% over vehicle

**SAFETY AND TOLERABILITY**

- Sofpironium bromide gel, 15% was generally well tolerated
- Majority of treatment-emergent AEs in sofpironium bromide gel, 15% treatment group were mild or moderate in severity and transient in nature
- No treatment-related serious AEs were reported

HDSM-Ax = Hyperhidrosis Disease Severity Measure–Axillary, a proprietary and validated patient reported outcome measure; GSP = gravimetric sweat production; EOT = end of treatment


BrickellBio
Corporate Highlights

# Brickell Biotech, Inc. (NASDAQ: BBI)

**Striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of dermatologic, autoimmune and other debilitating diseases**

## Potential Best-in-Class Hyperhidrosis Product

- **Sofpironium bromide gel, 15%** is a novel topical potential treatment for primary axillary hyperhidrosis
- **Achieved positive US Phase 3 topline results** in Q4 2021
- **US NDA submission** expected in **mid-2022**
- **Commercial launch of SB gel, 5% (ECCLOCK®) underway in Japan** by Kaken Pharmaceutical

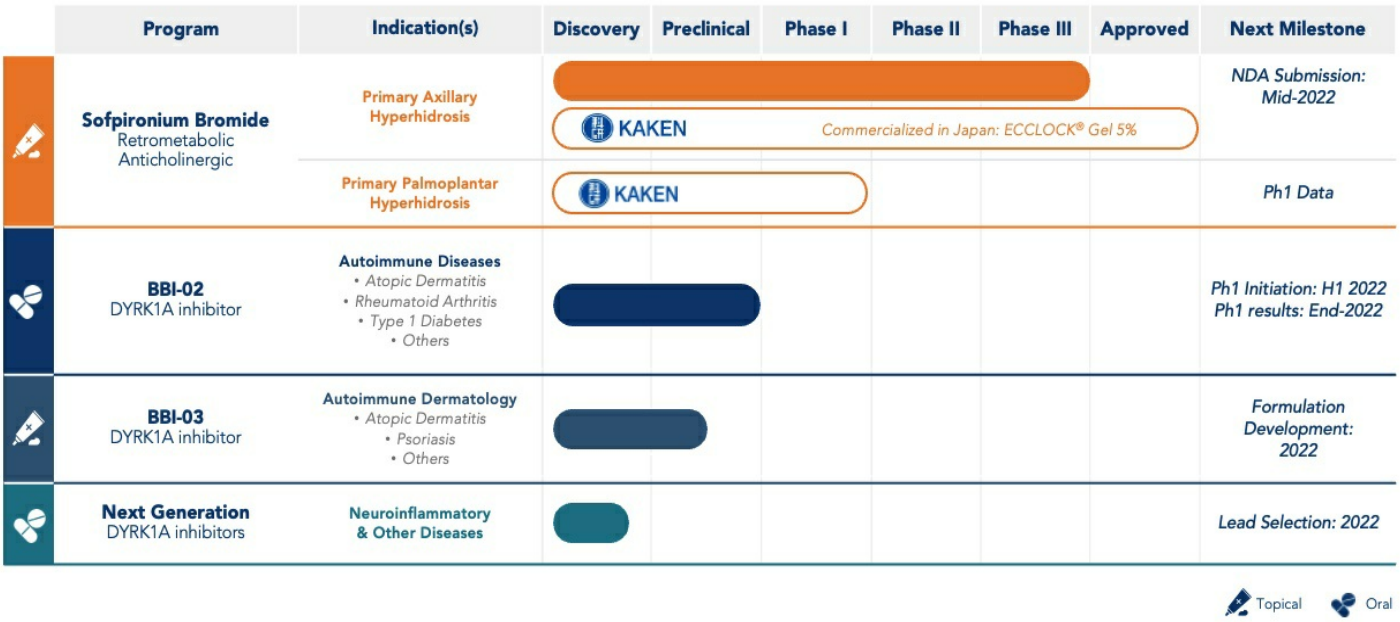
## Cutting-edge Autoimmune Platform

- **BBI-02** is a **Phase 1-ready** potential first-in-class oral DYRK1A inhibitor with **strong nonclinical validation in multiple autoimmune disorders**
- **First-in-human study initiation** planned for BBI-02 **in H1 2022, with Phase 1 topline results expected by end of 2022**
- Extensive next generation compound library offers **opportunity to explore neuroinflammation**

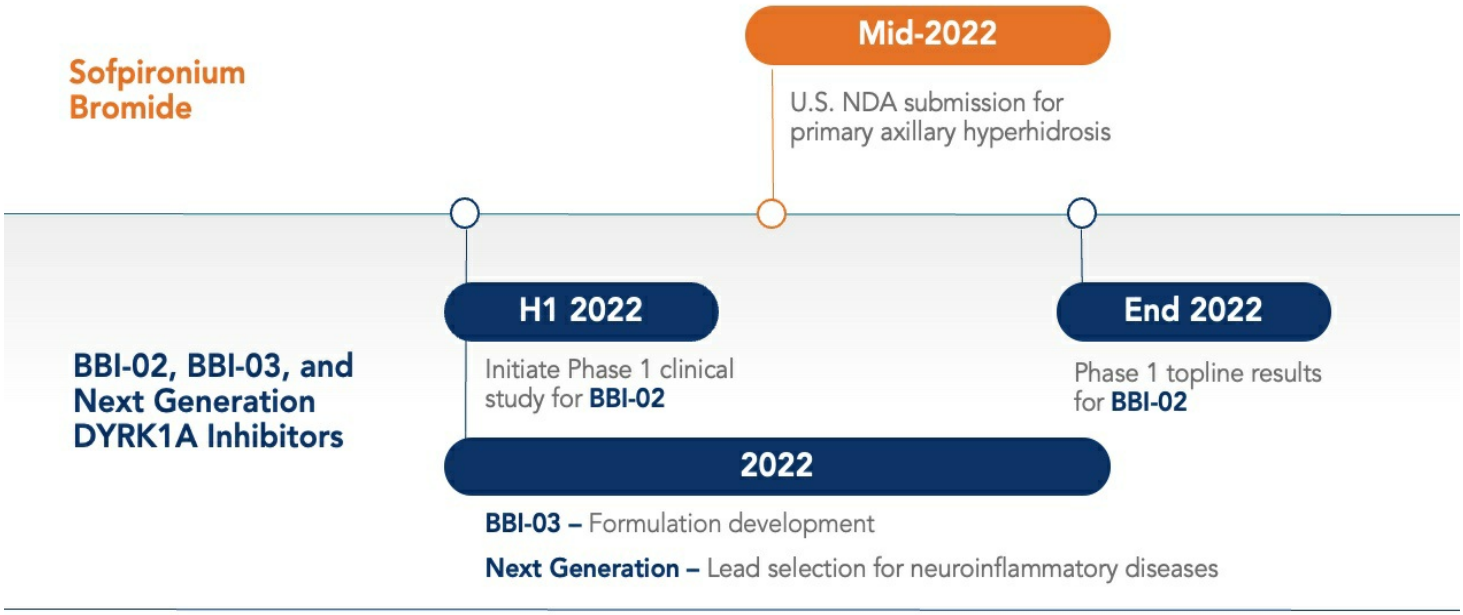
## Experienced Leadership

- **Executive team with proven track record**
- **History of successful development and launch** of numerous products achieving first-in-class and/or iconic status

# Pipeline of NCEs with Multiple Near-Term Value Inflection Points



# Key Upcoming Milestones for BBI



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# Thank You!

Contact: IR@brickellbio.com

Making Fresh Tracks® in Medicine

October 7, 2021