

# Brickell Biotech Reports Second Quarter 2021 Financial Results and Provides Corporate Update

*Final patient has completed the Phase 3 pivotal Cardigan I study; Enrollment completed in Phase 3 pivotal Cardigan II study*

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*Topline results for Phase 3 pivotal Cardigan I and Cardigan II studies expected to be reported in Q4 2021*

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*Recent \$8.1 million capital raise expected to fund operations beyond anticipated NDA submission in mid-2022*

BOULDER, Colo., Aug. 12, 2021 (GLOBE NEWSWIRE) -- 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 financial results for the second quarter ended June 30, 2021 and provided a corporate update.

"We have made tremendous progress this year advancing our Phase 3 clinical development program for sofipronium bromide gel, 15% as a potential treatment option for primary axillary hyperhidrosis, or excessive underarm sweating. Since initiating the Phase 3 Cardigan I and II studies in late 2020, we have completed enrollment in both pivotal studies, and the last enrolled hyperhidrosis patient has completed the Cardigan I study," commented Robert Brown, Chief Executive Officer of Brickell. "We remain on track to announce topline data for both studies concurrently in the fourth quarter of 2021, and if these studies are successful, we expect to proceed towards an NDA submission to the U.S. FDA in mid-2022."

Mr. Brown continued, "Our development partner, Kaken Pharmaceutical, continues to ramp up its commercial launch of sofipronium bromide gel, 5% (ECCLOCK<sup>®</sup>) in Japan. We are encouraged by Kaken's early sales progress, as well as its continued investment in the commercialization of ECCLOCK, disease state awareness and lifecycle management activities. To this point, Kaken has recently initiated a Phase 1 clinical study to explore the pharmacokinetics (PK), safety and efficacy of sofipronium bromide gel in patients with primary palmo-plantar hyperhidrosis, or excessive sweating from the palms and soles. We look forward to seeing the results of this study, which will help us determine next development steps, if any, in this new potential indication for sofipronium bromide gel."

## Business and Recent Developments

- Final patient has completed the Phase 3 Cardigan I study and enrollment completed in the Phase 3 Cardigan II study. Each pivotal clinical study is evaluating sofipronium bromide gel, 15% in approximately 350 subjects with primary axillary hyperhidrosis in the U.S.

- Phase 1 clinical study assessing the PK, safety and efficacy of sofpironium bromide gel in patients with primary palmo-plantar hyperhidrosis was initiated by Kaken in Japan. 5.3% and 2.8% of the population in Japan are estimated to be affected by primary palmar and plantar hyperhidrosis, respectively<sup>1</sup>.
- Following the recent \$8.1 million capital raise, the Company believes it has sufficient cash to fund its operations beyond the potential NDA submission to the U.S. FDA, which is anticipated in mid-2022.

## **Upcoming Milestones**

- Final patient expected to complete the Phase 3 Cardigan II study in the third quarter of 2021.
- Expect to concurrently report topline results from the U.S. Cardigan I and II studies in the fourth quarter of 2021.
- Potential NDA submission to the U.S. FDA anticipated in mid-2022, pending the outcome of the ongoing Phase 3 clinical program.
- Kaken to continue ramping up commercialization efforts for ECCLOCK in Japan and evaluating additional hyperhidrosis indications for sofpironium bromide gel.

## **Financial Results**

### *Second Quarter 2021 Financial Results*

The Company reported cash and cash equivalents of \$24.4 million as of June 30, 2021, compared to \$30.1 million as of December 31, 2020.

Revenue was \$0.2 million for the second quarter of 2021 and consisted of royalty revenue recognized from sales of ECCLOCK in Japan by Kaken, which increased from \$17 thousand for the first quarter of 2021. Revenue was \$0.6 million for the second quarter of 2020, which was driven by collaboration revenue recognized for research and development funding provided by Kaken to Brickell in 2018.

Research and development expenses were \$8.8 million for the second quarter of 2021, compared to \$2.7 million for the second quarter of 2020. This increase was primarily due to an increase in clinical costs related to the Phase 3 Cardigan studies, which were initiated in the fourth quarter of 2020.

General and administrative expenses were \$2.9 million for the second quarter of 2021, compared to \$3.0 million for the second quarter of 2020. The decrease was primarily due to lower costs for professional-related fees associated with capital raising activities that occurred in the second quarter of 2020.

Total other income, net was \$0.4 million for the second quarter of 2021, compared to \$7 thousand for the second quarter of 2020. The increase was primarily due to a gain on extinguishment of debt of approximately \$0.4 million that resulted from the forgiveness of the Paycheck Protection Program Loan in June 2021.

Brickell's net loss was \$11.1 million for the second quarter of 2021 compared to \$5.1 million for the second quarter of 2020.

### **Conference Call and Webcast Information**

Brickell's management will host a conference call today at 4:30 p.m. ET to discuss the financial results and recent corporate developments. 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 #13720599. A live webcast of the conference call can be accessed at <http://public.viavid.com/index.php?id=145287> or through the "Investors" tab on the Brickell Biotech website at <https://www.brickellbio.com>. A replay will be available on this website shortly after conclusion of the event for 90 days.

### **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 sofpiroonium 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<sup>1,2</sup>. Primary axillary (underarm) hyperhidrosis is the targeted first indication for sofpiroonium 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 sofpiroonium 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<sup>®</sup>, Taltz<sup>®</sup>, Gemzar<sup>®</sup>, Prozac<sup>®</sup>, Cymbalta<sup>®</sup>, and Juvederm<sup>®</sup>. 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 implementation, 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, commercialize and further develop the product in Japan, or obtain or retain adequate pricing or reimbursement, the outcome of Brickell's ongoing U.S. Phase 3 pivotal program on sofipronium bromide gel, 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.

<sup>1</sup> Fujimoto et al. Epidemiological study and considerations of focal hyperhidrosis in Japan. J Dermatol 2013; 40: 886-90.

<sup>2</sup> Doolittle et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 2016; 308: 743-749.

### **Brickell Investor Contact:**

Dan Ferry  
LifeSci Advisors  
(617) 430-7576  
[daniel@lifesciadvisors.com](mailto:daniel@lifesciadvisors.com)

**Brickell Biotech, Inc.**  
**Condensed Consolidated Statements of Operations**  
(in thousands, except share and per share data)  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue				
Collaboration revenue	\$ —	\$ 607	\$ —	\$ 1,653
Royalty revenue	151	—	168	—
Total revenue	151	607	168	1,653
Operating expenses:				
Research and development	8,838	2,712	14,890	5,376
General and administrative	2,891	3,021	5,858	5,502
Total operating expenses	11,729	5,733	20,748	10,878
Loss from operations	(11,578)	(5,126)	(20,580)	(9,225)
Investment and other income, net	459	7	490	3
Interest expense	(30)	—	(64)	—
Net loss	\$ (11,149)	\$ (5,119)	\$ (20,154)	\$ (9,222)
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.16)	\$ (0.43)	\$ (0.31)	\$ (0.87)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	68,856,370	11,819,152	64,646,565	10,595,960

**Brickell Biotech, Inc.**  
**Selected Financial Information**  
**Condensed Consolidated Balance Sheet Data**  
(amounts in thousands)  
(unaudited)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 24,408	\$ 30,115
Prepaid expenses and other current assets	4,507	3,415
Total assets	29,073	33,634
Total liabilities	6,720	6,499
Total stockholders' equity	22,353	27,135



Source: Brickell Biotech, Inc.