November 12, 2020

Brickell Biotech Reports Third Quarter 2020 Financial Results and Provides Corporate Update

Recently completed capital raise expected to fully fund U.S. pivotal Phase 3 program, with topline results anticipated in Q4 2021

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Initiated the Cardigan I study, the first of two U.S. pivotal Phase 3 clinical studies evaluating sofpironium bromide gel, 15% as a potential treatment for primary axillary hyperhidrosis

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On track to initiate the Cardigan II study, the second U.S. pivotal Phase 3 clinical study, later this year

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Planned commercial launch of ECCLOCK® in Japan by development partner, Kaken, expected by the end of 2020, which follows regulatory approval received in the third quarter

BOULDER, Colo., Nov. 12, 2020 (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 third quarter ended September 30, 2020 and provided a corporate update.

"I am proud of the focus, drive and determination that the Brickell team has shown in 2020, which has allowed us to execute against our corporate goals. As a result, we are now well-positioned to continue executing our strategy to develop sofpironium bromide as a potentially best-in-class treatment option for the more than 10 million people in the U.S. suffering with primary axillary hyperhidrosis," commented Robert Brown, Chief Executive Officer of Brickell. "Last month, we initiated the Cardigan I registration trial and completed an equity financing, which provided us with additional capital needed to initiate the Cardigan II second registration trial later this year and is expected to allow us to complete the U.S. pivotal Phase 3 program, with topline results anticipated in the fourth quarter of 2021."

"The third quarter was a productive period for our Japanese development partner, Kaken, who recently received regulatory approval for ECCLOCK® (sofpironium bromide gel, 5%) in Japan for the treatment of primary axillary hyperhidrosis. Japan is the first country to approve sofpironium bromide for any indication and Kaken remains on target for commercial launch later this year. We are thrilled with the progress that both Brickell and Kaken have made and look forward to providing updates on the advancement of our U.S. pivotal Phase 3 program, as well as Kaken's launch efforts in Japan, over the coming months," concluded Mr. Brown.

Business and Recent Developments

- Completed an equity financing in October 2020 resulting in net proceeds of

approximately $13.7 million that strengthened the Company's balance sheet and is expected to fully fund its operations through topline results of the U.S. pivotal Phase 3 program.

- Initiated the U.S. Phase 3 Cardigan I clinical trial, a multicenter, randomized, double-blinded, vehicle (placebo)-controlled study to evaluate the safety and efficacy of topically applied sofpironium bromide gel, 15% for the treatment of primary axillary (underarm) hyperhidrosis. Subjects will apply sofpironium bromide or vehicle once daily at bedtime to their underarms for six consecutive weeks, with a two-week post-treatment follow-up. The study is expected to enroll up to 350 subjects aged nine years and older with primary axillary hyperhidrosis.

- Japanese development partner, Kaken Pharmaceutical, Co., Ltd. ("Kaken"), received regulatory approval in Japan to manufacture and market sofpironium bromide gel, 5% for the treatment of primary axillary hyperhidrosis. This approval was based on the results of Kaken's Japanese pivotal Phase 3 registration study of sofpironium bromide gel, 5% in 281 patients with primary axillary hyperhidrosis, in which all primary and secondary efficacy endpoints demonstrated statistically significant differences between sofpironium bromide gel and vehicle. In addition, sofpironium bromide gel, 5% was observed to be safe and generally well tolerated in this study, as well as in the accompanying 52-week long-term safety extension study with 185 patients in Japan.

- Kaken and Brickell were granted by the Japanese Patent Office a composition of matter patent with claims directed to the novel polymorphic, or crystalline, forms of sofpironium bromide that is expected to provide additional protection for these newly developed and distinct forms in Japan through 2040.

- Completed the 12-month Phase 3 open-label long-term safety study evaluating sofpironium bromide gel, 5% and 15% in 300 subjects nine years and older with primary axillary hyperhidrosis. The study results confirmed that sofpironium bromide gel, at both concentrations, was safe and generally well tolerated, which was consistent with the earlier Phase 2 clinical trial results. No treatment-related serious adverse events were observed. The Company expects to release additional details at an upcoming scientific forum.

- Entered into a collaboration agreement with AnGes, Inc ("AnGes") through which the Company has certain rights to develop AnGes' proprietary investigational adjuvanted plasmid DNA vaccine intended to prevent SARS-CoV-2 (COVID-19) in the U.S., South America and certain other emerging markets. AnGes is currently conducting Phase 1/2 clinical studies with its vaccine candidate in Japan.

Upcoming Milestones

- Plan to initiate the Cardigan II study, the second U.S. pivotal Phase 3 clinical trial, prior to year end. The Cardigan II study will evaluate the safety and efficacy of sofpironium bromide gel, 15% versus vehicle in approximately 350 subjects aged nine years and older with primary axillary hyperhidrosis.

- Expect Kaken to launch ECCLOCK® commercially in Japan by the end of 2020. Under

our agreement with Kaken, Brickell is entitled to receive commercial milestone payments, as well as tiered royalties based on a percentage of net sales in Japan.

- Expect to report topline data from both the Cardigan I and II U.S. pivotal Phase 3 clinical studies by the end of 2021.

- Expect to receive results from the Phase 1/2 clinical studies with AnGes' COVID-19 vaccine candidate in Japan through the first quarter of 2021. The results from these studies will guide AnGes' and Brickell's global development efforts of this novel vaccine candidate.

Financial Results

The Company reported cash and cash equivalents and marketable securities of $20.2 million as of September 30, 2020 compared to $11.7 million as of December 31, 2019. In addition, Brickell has prepaid $4.2 million to third-party clinical research organizations as part of conducting the U.S. pivotal Phase 3 clinical trials of sofpironium bromide. Subsequent to the end of the third quarter, the Company completed a public equity offering resulting in net proceeds of approximately $13.7 million.

Revenue was $0.1 million for the third quarter of 2020 compared to $1.2 million for the third quarter of 2019. Revenue in both periods was driven by research and development activities related to the agreement with Kaken pursuant to which Kaken provided research and development funding to Brickell. The decrease in revenue recognized was attributable to Brickell's Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were ongoing in 2019 but were concluded or winding down by the end of the first quarter of 2020. Conducting these studies is the basis for revenue recognition of a $15.6 million research and development payment received from Kaken in the second quarter of 2018.

Research and development expenses were $1.3 million for the third quarter of 2020 compared to $3.3 million for the third quarter of 2019. This decrease was primarily due to reduced clinical and other related regulatory and compliance costs of the Phase 3 open-label long-term safety study of sofpironium bromide gel and other ancillary clinical studies that were concluded or winding down by the end of the first quarter of 2020.

General and administrative expenses were $3.2 million for the third quarter of 2020 compared to $3.9 million for the third quarter of 2019. This decrease was primarily due to lower costs of $1.1 million for professional-related fees associated with the merger with Vical Incorporated that occurred in the third quarter of 2019 and $0.4 million for other miscellaneous fees, partially offset by higher costs of $0.6 million for stock and other compensation expense that was driven by increased headcount and $0.2 million for directors' and officers' liability insurance due to becoming a public company.

Brickell's net loss was $4.3 million for the third quarter of 2020 compared to $4.8 million for the third quarter of 2019.

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 #13708850. 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 will be available on this website shortly after conclusion of the event for 90 days.

About Sofpironium Bromide

Sofpironium bromide is a proprietary investigational 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 designed to exert their action topically and are potentially rapidly metabolized into a less active metabolite once absorbed into the blood. 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 life-altering medical condition where a person sweats more than the body requires to regulate its temperature. More than 15 million people, or 4.8% of the population of the United States, and 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 developing innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. Brickell's pipeline consists of potential novel therapeutics for hyperhidrosis and other prevalent dermatological conditions. Brickell's executive management team and board of directors bring extensive experience in product development and global commercialization, having served in leadership roles at large global pharmaceutical companies and biotechs that have developed and/or launched successful products, including several that were first-in-class and/or achieved iconic status, such as Cialis®, Taltz®, Gemzar®, Prozac®, Cymbalta® and Juvederm®. Brickell's strategy is to leverage this experience to in-license, acquire, develop and commercialize innovative products that Brickell believes can be successful in the currently underserved dermatology global marketplace. For more information, visit 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, AnGes 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, 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, launch and commercialize the product in Japan, or obtain adequate pricing, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**

Collaboration revenue	$ 142	$ 1,183	$ 1,795	$ 7,248
Operating expenses:				
Research and development	1,281	3,337	6,657	13,585
General and administrative	3,211	3,901	8,713	7,290
Total operating expenses	4,492	7,238	15,370	20,875
Loss from operations	(4,350)	(6,055)	(13,575)	(13,627)
Investment and other income, net	24	54	27	64
Gain on extinguishment	—	2,318	—	2,318
Interest expense	—	(1,098)	—	(1,982)
Change in fair value of warrant and derivative liability	—	—	—	212
Net loss	(4,326)	(4,781)	(13,548)	(13,015)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	—	(82)	—	10,274
Net loss attributable to common stockholders	$ (4,326)	$ (4,863)	$ (13,548)	$ (2,741)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.15)	$ (1.65)	$ (0.82)	$ (1.98)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	28,107,785	2,943,896	16,475,843	1,382,592

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

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 20,174	$ 7,232
Marketable securities, available-for-sale	—	4,497
Prepaid expenses and other current assets	6,129	6,240
Total assets	26,404	18,144
Total liabilities	7,692	10,570

Total stockholders' equity	18,712	7,574

Source: Brickell Biotech, Inc.