August 12, 2020

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

Positive data from the Sofpironium Bromide Phase 3 pivotal study in Japan presented in Q2 2020 by development partner, Kaken

Kaken to receive regulatory decision in Japan for sofpironium bromide gel as early as the fourth quarter of 2020

Brickell plans to initiate its U.S. pivotal Phase 3 program in the fourth quarter of 2020

BOULDER, Colo., Aug. 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 second quarter ended June 30, 2020 and provided a corporate update.

“We announced several milestones during the first half of 2020 that strengthened our ability to execute our strategy to develop sofpironium bromide as a treatment for primary axillary hyperhidrosis in the U.S. and in Japan. Most notable are the successful completion of our U.S. Phase 3 long-term safety study, the positive Phase 3 pivotal study results in Japan for sofpironium bromide presented in June by our Japanese development partner, Kaken Pharmaceutical Co., Ltd. (“Kaken”), and an equity financing for net proceeds of $18.7 million,” commented Robert Brown, Chief Executive Officer of Brickell. “These important achievements position us well to move towards the anticipated initiation of our U.S. Phase 3 pivotal program in the fourth quarter of 2020. We continue to be excited by the prospects of sofpironium bromide as a potential best-in-class treatment for primary axillary hyperhidrosis and look forward to keeping our shareholders updated on our R&D progress.”

Business and Recent Developments

- In July 2020, Brickell completed the analysis of its 12-month Phase 3 open-label long-term safety study, in 300 subjects 9 years and older with primary axillary hyperhidrosis, sofpironium bromide gel, 5% and 15%. 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. Brickell expects to release additional details at an upcoming scientific forum.

- In June 2020, Brickell announced positive Phase 3 pivotal study results in Japan from Kaken. All primary and secondary efficacy endpoints of the study were achieved and sofpironium bromide was safe and generally well tolerated. The study evaluated a total of 281 Japanese patients randomized 1:1 to apply sofpironium bromide gel, 5% (SB) or

vehicle gel (placebo) to the axillae (i.e., underarm) for 42 days. These study results were presented as part of the Late-Breaking Research Program during the American Academy of Dermatology (AAD) Virtual Meeting Experience.

- In January 2020, Kaken announced submission of a new drug application in Japan requesting approval to manufacture and market sofpironium bromide gel, 5% for primary axillary hyperhidrosis based on the positive Phase 3 data.

- In June 2020, Brickell completed an equity offering resulting in net proceeds of approximately $18.7 million. The Company anticipates using the proceeds from the offering for research and development, including clinical trials, working capital, and general corporate purposes.

Upcoming Milestones

- Plan to initiate the U.S. Phase 3 pivotal program for sofpironium bromide gel, 15% in the fourth quarter of 2020. The planned program will be comprised of two pivotal Phase 3 trials to evaluate approximately 350 subjects per trial with primary axillary hyperhidrosis in the U.S. The first Phase 3 study is expected to begin in the fourth quarter of 2020.

- Expect Kaken to receive regulatory decision for sofpironium bromide gel, 5% in Japan, as early as the fourth quarter of 2020. Under the agreement with Kaken, Brickell is entitled to receive commercial milestone payments, as well as tiered royalties based on a percentage of net sales of sofpironium bromide in Japan.

Financial Results

The Company reported cash and cash equivalents and marketable securities of $21.6 million as of June 30, 2020 compared to $11.7 million as of December 31, 2019. In addition, Brickell has prepaid $4.6 million to third-party clinical research organizations in anticipation of commencing Phase 3 pivotal clinical trials of sofpironium bromide in the U.S. later this year.

Revenue was $0.6 million for the second quarter of 2020 compared to $2.6 million for the second 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 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 for a $15.6 million research and development payment received from Kaken in the second quarter of 2018.

Research and development expenses were $2.7 million for the second quarter of 2020 compared to $4.2 million for the second quarter of 2019. This decrease was primarily due to reduced clinical and other related regulatory and administrative costs of the Phase 3 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. Expenses in the second quarter of 2020 included $1.5 million in paid or accrued milestone payments to the licensor of sofpironium bromide. Research and development expenses are expected to increase

following the initiation of the Phase 3 program for sofpironium bromide.

General and administrative expenses were $3.0 million for the second quarter of 2020 compared to $1.3 million for the second quarter of 2019. This increase was primarily due to higher costs of $0.9 million for professional-related fees related to capital-raising activities and additional expenses incurred for operating as a public company, $0.6 million for stock and other compensation expense, and $0.3 million for directors' and officers' liability insurance fees due to becoming a public company.

Total other income, net was $7.0 thousand for the second quarter of 2020 compared to total other expense, net of $0.7 million for the second quarter of 2019. The change was primarily due to a decrease of $0.7 million in interest expense related to the issuance of convertible promissory notes in 2019 and principal borrowings provided by a loan agreement with a former lender.

Brickell's net loss was $5.1 million for the second quarter of 2020 compared to $3.7 million for the second 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 #13706625. A live webcast of the conference call can be accessed through the "Investors" tab on the Brickell Biotech website at http://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 new molecular 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. This proposed mechanism of action may allow for highly effective doses to be used while limiting systemic side effects. 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. Sofpironium bromide is not approved for use in any country at this time.

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 more than 16 million people, or 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 or 10 million individuals and an estimated 45% of patients with hyperhidrosis in Japan or 7.2 million individuals[1,2]. 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 http://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 future clinical trials, the expected timing and/or results of regulatory approvals and prospects for commercializing any of Brickell's product candidates, 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" and similar expressions and their variants, as they relate to Brickell, 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 (including the U.S. Phase 3 pivotal program for sofpironium bromide), potential delays for any reason in product development, regulatory changes, unanticipated demands on cash resources, any disruption to its business caused by the current COVID-19 pandemic, interruptions, delays or negative determinations on Kaken's new drug application under review, and other risks associated with developing, and obtaining regulatory approval for and commercializing novel therapeutics.

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 http://www.sec.gov (or at http://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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue	$ 607	$ 2,573	$ 1,653	$ 6,065
Operating expenses:				
Research and development	2,712	4,229	5,376	10,248
General and administrative	3,021	1,323	5,502	3,389
Total operating expenses	5,733	5,552	10,878	13,637
Loss from operations	(5,126)	(2,979)	(9,225)	(7,572)
Investment and other income, net	7	4	3	10
Interest expense	—	(660)	—	(884)
Change in fair value of derivative liability	—	(11)	—	(11)
Change in fair value of warrant liability	—	(8)	—	223
Net loss	(5,119)	(3,654)	(9,222)	(8,234)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	—	(163)	—	10,356
Net income (loss) attributable to common stockholders	$ (5,119)	$ (3,817)	$ (9,222)	$ 2,122
Net income (loss) per common share attributable to common stockholders, basic	$ (0.43)	$ (6.48)	$ (0.87)	$ 3.60
Net loss per common share attributable to common stockholders, diluted	$ (0.43)	$ (6.48)	$ (0.87)	$ (4.46)
Weighted-average shares used to compute net income (loss) per share attributable to common stockholders, basic	11,819,152	589,001	10,595,960	589,001
Weighted-average shares used to compute net loss per share attributable to common stockholders, diluted	11,819,152	589,001	10,595,960	1,845,467

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

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$ 21,570	$ 7,232
Marketable securities, available-for-sale	—	4,497
Prepaid expenses and other current assets	5,736	6,240
Total assets	27,430	18,144
Total liabilities	7,520	10,570
Total stockholders' equity	19,910	7,574

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Source: Brickell Biotech, Inc.