March 18, 2020

Brickell Biotech Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

BOULDER, Colo., March 18, 2020 (GLOBE NEWSWIRE) -- Brickell Biotech, Inc. ("Brickell") (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 fourth quarter and full year ended December 31, 2019 and provided a corporate update.

"Becoming a public company through the listing on the Nasdaq was a significant milestone for the Company this past year," commented Robert Brown, Chief Executive Officer of Brickell. "We remain enthusiastic about the potential for sofpironium bromide as a drug candidate to potentially improve the quality of life of the 10 million U.S. patients that suffer from primary axillary hyperhidrosis."

Business and Recent Developments

- On March 4, 2020, Brickell announced that positive results from its Asian development partner, Kaken Pharmaceutical Co. Ltd.'s ("Kaken") Phase 3 pivotal study in Japan were selected for oral presentation at the Late-Breaking Research Program during the American Academy of Dermatology (AAD) Annual Meeting on March 21, 2020, in Denver, CO. Due to concerns related to the novel coronavirus, the AAD canceled the conference and it is expected that there will be a forum to release the data in the near future. The presentation is expected to include the first public disclosure of efficacy and safety results from Kaken's Phase 3 pivotal study of sofpironium bromide gel. Additionally, on January 10, 2020, Brickell announced that Kaken submitted a new drug application for approval in Japan of manufacturing and marketing for sofpironium bromide gel for primary axillary hyperhidrosis based on the positive results from this study.

- On February 20, 2020, Brickell announced that positive results from its Phase 2b study with sofpironium bromide in patients with primary axillary hyperhidrosis were published in the peer-reviewed *Journal of the American Academy of Dermatology* (JAAD). The paper, entitled "Efficacy and Safety of Topical Sofpironium Bromide Gel for the Treatment of Axillary Hyperhidrosis: A Phase 2, Randomized, Controlled, Double-Blinded Trial," is now available online at (https://doi.org/10.1016/j.jaad.2020.02.016) and is expected to be published in a future print edition of JAAD.

- On February 18, 2020, Brickell announced that Brickell, Bodor Laboratories, Inc. and Dr. Nicholas S. Bodor (collectively "Bodor") entered into a settlement agreement and an amended license agreement. This resolved the litigation dispute disclosed on October 23, 2019 related to the sofpironium bromide license agreement and allows Brickell to continue its efforts to develop sofpironium bromide for the treatment of hyperhidrosis.

- On February 18, 2020, Brickell announced entry into a purchase agreement with Lincoln Park Capital Fund, LLC ("LPC"), a long-only Chicago-based institutional investor, whereby LPC purchased $2.0 million in Brickell common stock and warrants. Additionally, Brickell and LPC entered into a separate purchase agreement whereby Brickell, for up to a 36-month period, will have the right, in its sole discretion subject to satisfaction of certain conditions, to sell up to an additional $28 million of its common stock to LPC.

- In January 2020, the last patient completed the Phase 3 long-term safety study for sofpironium bromide. Brickell remains on track to report top-line results in the second quarter of 2020. To date, there have been 19 clinical studies conducted by Brickell and Kaken of sofpironium bromide gel that encompass over 1,300 subjects.

- On January 19, 2020, Brickell presented the results from pharmacokinetics and long-term safety extension trials with sofpironium bromide gel, 15% in pediatric patients (ages 9 to <17) with primary axillary hyperhidrosis at the Dermatology, Aesthetic & Surgical Conference. Pharmacokinetic analysis of sofpironium bromide did not show any evidence of drug or major metabolite accumulation. Pharmacokinetic findings were consistent with previous investigational evaluations in adults in which systemic sofpironium and its major metabolite concentrations were also variable, sporadic, and minimal. Sofpironium bromide was safe and well-tolerated in over 24 weeks of treatment in this clinical trial. The majority of pediatric subjects had no treatment-emergent

adverse events, and there were no severe or serious adverse events. Additionally, while not designed as an efficacy study, clinically meaningful improvement, i.e., change of -1.00 point on a 5-point patient-reported outcome measures; Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax), were reported as early as Day 8 and improved through week 24 in this pediatric patient population. The median change in the HDSM-Ax from baseline to week 24 of was -2.10 (mean: -1.91; standard deviation: 1.038).

Financial Results

Fourth Quarter 2019 Financial Results

Cash, cash equivalents, and marketable securities were $11.7 million as of December 31, 2019 compared to $8.1 million as of December 31, 2018. In addition, Brickell has prepaid third-party clinical research organizations $4.9 million in anticipation of commencing the pivotal Phase 3 clinical trials of sofpironium bromide.

Revenue was $0.7 million for the fourth quarter of 2019 compared to $2.5 million for the fourth quarter of 2018. The decrease is primarily due to the completion of certain research and development activities by the first half of 2019 for which funding was provided under the license agreement with Kaken.

Research and development expenses were $6.6 million for the fourth quarter of 2019 compared to $4.4 million for the fourth quarter of 2018. This increase is primarily due to the additional clinical study activities and drug supply costs associated with sofpironium bromide.

General and administrative expenses were $4.9 million for the fourth quarter of 2019 compared to $1.7 million for the fourth quarter of 2018. This increase includes $1.0 million in legal settlement accrual, $0.7 million in added fees for accounting, auditing, and legal services, including litigation-related costs, $0.7 million in impairment expense, $0.5 million in insurance and rent expense, and $0.3 million in stock compensation expense and increased headcount.

Brickell's net loss was $10.9 million for the fourth quarter of 2019 compared to $3.7 million for the fourth quarter of 2018.

Full Year 2019 Financial Results

Revenue was $7.9 million for the year ended December 31, 2019 compared to $10.9 million for the year ended December 31, 2018. The decrease is primarily due to the recognition in 2018 of a $5.0 million payment from Kaken.

Research and development expenses were $20.2 million for the year ended December 31, 2019 compared to $13.0 million for the year ended December 31, 2018. This increase is primarily due to the additional clinical study activities, including the Phase 3 long-term safety study, and drug supply costs associated with sofpironium bromide.

General and administrative expenses were $12.2 million for the year ended December 31, 2019 compared to $6.4 million for the year ended December 31, 2018. This increase includes $4.1 million in added fees for accounting, auditing, and legal services, including Merger-related costs, $1.0 million in stock compensation expense and increased headcount, $1.0 million in legal settlement accrual, and $0.7 million in impairment expense, partially offset by a decrease of $1.0 million in sub-licensing fees.

Brickell's net loss was $23.9 million for the year ended December 31, 2019 compared to $9.2 million for the year ended December 31, 2018.

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 #13700118. A live webcast of the conference call can be accessed through the "Investors" tab on the Brickell Biotech website athttp://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].

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 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, potential delays for any reason in product development, regulatory changes, unanticipated demands on cash resources and 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018

	(unaudited)			
Collaboration revenue	$ 669	$ 2,473	$ 7,917	$ 10,888
Operating expenses:				
Research and development	6,629	4,389	20,214	12,960
General and administrative	4,881	1,685	12,171	6,379
Total operating expenses	11,510	6,074	32,385	19,339
Loss from operations	(10,841)	(3,601)	(24,468)	(8,451)
Investment and other income, net	93	16	157	61
Gain on extinguishment	—	—	2,318	—
Interest expense	(114)	(321)	(2,096)	(1,090)
Change in fair value of derivative liability	—	—	(11)	—
Change in fair value of warrant liability	—	236	223	244
Net loss	(10,862)	(3,670)	(23,877)	(9,236)
Reduction (accretion) of redeemable convertible preferred stock to redemption value	—	(865)	10,274	(5,936)
Net loss attributable to common stockholders	$ (10,862)	$ (4,535)	$ (13,603)	$ (15,172)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.38)	$ (7.72)	$ (4.50)	$ (25.85)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	7,890,823	587,763	3,023,023	586,969

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

	December 31,	
	2019	2018
Cash and cash equivalents	$ 7,232	$ 8,067
Marketable securities, available-for-sale	4,497	—
Prepaid expenses and other current assets	6,240	204
Total assets	18,144	8,749
Note payable	—	4,639
Total liabilities	10,570	22,077
Total stockholders' equity (deficit)	7,574	(71,618)

Brickell Investor Contact:

Patti Bank
Managing Director, Westwicke
IR@brickellbio.com

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Source: Brickell Biotech, Inc.