November 9, 2021

Brickell Biotech Reports Third Quarter 2021 Financial Results and Provides Corporate Update

Announced positive topline results from the Phase 3 pivotal clinical studies of sofpironium bromide gel, 15% in primary axillary hyperhidrosis patients; plan to submit a New Drug Application (NDA) to the FDA in mid-2022

Development of DYRK1A inhibitors is ongoing, including a planned Phase 1 study for BBI-02, a potential first-in-class oral treatment for autoimmune and inflammatory diseases, expected to be initiated and topline results reported in 2022

Strengthened balance sheet with net proceeds of $8.9 million from an equity offering in October 2021

BOULDER, Colo., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Brickell Biotech, Inc. (“Brickell” or the “Company”) (Nasdaq: BBI), a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of dermatologic, autoimmune, and other debilitating diseases, today announced financial results for the third quarter ended September 30, 2021 and provided a corporate update.

“This has been an exciting period for Brickell, as we announced positive data from our Phase 3 pivotal clinical studies of sofpironium bromide gel, 15% and expanded our pipeline with the acquisition of a Phase 1-ready DYRK1A inhibitor and cutting-edge platform with broad potential in autoimmune and inflammatory disorders. We look to build on this momentum by focusing on several near-term clinical, regulatory, and operational milestones that we believe can drive our growth,” commented Robert Brown, Chief Executive Officer of Brickell. “We were pleased to announce last month that the Phase 3 Cardigan I and Cardigan II studies of sofpironium bromide gel, 15% in patients with primary axillary hyperhidrosis, or excessive underarm sweating, achieved statistical significance on all primary and secondary efficacy endpoints. Based on the positive results from these studies, we expect to submit an NDA for sofpironium bromide gel, 15% to the FDA in mid-2022. As we plan the commercial strategy for sofpironium bromide gel, 15%, if approved, we are evaluating all available options to maximize commercial product success and long-term value for the company.”

“We look forward to advancing the development of our DYRK1A inhibitor programs that aim to restore immune balance with a novel and differentiated small molecule approach, which we believe will help improve the lives of patients with autoimmune diseases. To this end, we expect to advance our lead DYRK1A inhibitor program, BBI-02, into a Phase 1 clinical study in the first half of 2022, with topline results anticipated by the end of 2022. We look forward to providing updates on this planned study in the coming months,” continued Mr. Brown.

Business and Recent Developments

- Reported positive topline results from two U.S. Phase 3 pivotal clinical studies of sofpironium bromide gel, 15%, each of which enrolled approximately 350 patients who were nine years of age and older with primary axillary hyperhidrosis. Both studies achieved statistical significance on all primary and secondary efficacy endpoints, and data demonstrated that sofpironium bromide gel, 15% was generally well-tolerated.

- Acquired exclusive, worldwide rights to research, develop, and commercialize novel therapeutics generated from a proprietary DYRK1A inhibitor platform with broad potential in autoimmune and inflammatory diseases. The acquisition includes BBI-02, a Phase 1-ready, highly selective, and orally bioavailable DYRK1A inhibitor; BBI-03, a topically applied preclinical DYRK1A inhibitor; and a platform of DYRK1A inhibitors with potential to create next-generation kinase inhibitors targeting neuroinflammatory and autoimmune disorders.

- Hosted a Key Opinion Leader ("KOL") webinar featuring a presentation by KOL Bernard Khor, M.D., Ph.D., Benaroya Research Institute at Virginia Mason, who discussed the latest findings on the novel target DYRK1A, its role in autoimmune and inflammatory diseases, and the broad therapeutic potential of restoring immune homeostasis by inhibiting DYRK1A. A replay of the event can be found on the Events and Presentations section of the Company's website at https://ir.brickellbio.com/events-presentations.

- Expanded leadership team by appointing Dr. Monica Luchi as Chief Medical Officer to oversee the Company's clinical development strategy, including for the DYRK1A inhibitor pipeline, and medical affairs functions.

- Brickell's development partner, Kaken Pharmaceutical Co., Ltd. ("Kaken"), continued conduct of a Phase 1 clinical study in Japan assessing the pharmacokinetics (PK), safety, and efficacy of sofpironium bromide gel in patients with primary palmoplantar hyperhidrosis.

- Strengthened cash balance with net proceeds of $8.9 million received from a public offering of the Company's common stock in October 2021.

Upcoming Milestones

- Prospective NDA submission to the U.S. FDA for sofpironium gel, 15% in mid-2022.

- Intend to progress BBI-02 into a Phase 1 clinical study in Canada in the first half of 2022, with topline results expected by the end of 2022.

- Expect to conduct formulation development activities for BBI-03 throughout 2022, and to select and initiate development of a lead next-generation candidate from the DYRK1A inhibitor platform with potential for the treatment of neuroinflammatory and/or autoimmune diseases.

Third Quarter 2021 Financial Results

The Company reported cash and cash equivalents of $21.4 million as of September 30,

2021, compared to $30.1 million as of December 31, 2020.

Revenue was $0.1 million for the third quarter of 2021, which consisted of royalty revenue recognized related to sales of ECCLOCK® in Japan by Kaken. Revenue was $0.1 million for the third 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 $10.2 million for the third quarter of 2021, compared to $1.3 million for the third quarter of 2020. This increase was primarily due to a $4.8 million expense recorded related to the upfront payment in cash and shares of our common stock to Voronoi Inc. in exchange for exclusive, worldwide rights to the proprietary DYRK1A inhibitor platform and an increase of $3.8 million in clinical costs related to sofpironium bromide.

General and administrative expenses were $3.3 million for the third quarter of 2021, compared to $3.2 million for the third quarter of 2020, remaining generally consistent with the comparable period.

Brickell's net loss was $13.3 million for the third quarter of 2021 compared to $4.3 million for the third 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 #13723603. A live webcast of the conference call can be accessed at http://public.viavid.com/index.php?id=146695 or through the Brickell Biotech website at https://ir.brickellbio.com. A replay will be available on this website shortly after conclusion of the event for approximately 90 days.

About Sofpironium Bromide

Sofpironium bromide 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 designed to exert their action locally and are potentially rapidly metabolized into a less active form once absorbed into the blood. Brickell has developed sofpironium bromide gel, 15% as a potential best-in-class, self-administered, once daily, topical therapy for the treatment of primary axillary hyperhidrosis, also known as excessive underarm sweating. Sofpironium bromide gel, 15% has completed a U.S. Phase 3 pivotal clinical program for the treatment of primary axillary hyperhidrosis, which achieved statistical significance on all primary and secondary efficacy endpoints, and sofpironium bromide gel, 15% was generally well-tolerated. Sofpironium 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 the DYRK1A Inhibitor Platform

In August 2021, Brickell acquired exclusive, worldwide rights to research, develop, and commercialize novel therapeutics generated from a proprietary DYRK1A inhibitor platform. These novel DYRK1A inhibitors aim to restore immune balance in patients whose immune system has become dysregulated. Based on the promising preclinical efficacy data generated to date on these novel DYRK1A inhibitor programs, Brickell believes this platform has the potential to offer first-in-class, new and potent therapies across a wide array of autoimmune and inflammatory diseases. The initial lead program that the Company expects to advance is BBI-02, a Phase 1-ready, highly selective, and orally bioavailable DYRK1A inhibitor that has demonstrated promising results in various preclinical models, including atopic dermatitis and rheumatoid arthritis. Preclinical data have shown BBI-02 to drive regulatory T-cell differentiation while dampening pro-inflammatory T_H17 cells and MyD88/IRAK4-related signaling pathways. Unlike many existing therapies, as well as those currently being investigated, BBI-02 may have the ability to target both the adaptive and innate immune imbalance simultaneously, potentially resulting in, or substantially achieving, restoration of immune homeostasis that, if proven, would represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases. The platform also includes BBI-03, a topically applied preclinical DYRK1A inhibitor, and has the potential to create next generation kinase inhibitors (NCEs) targeting neuroinflammatory and autoimmune disorders.

About Brickell

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of dermatologic, autoimmune, and other debilitating diseases. Brickell's pipeline combines a potential best-in-class, late-stage program for the treatment of hyperhidrosis with a novel, cutting-edge platform and development-stage candidates with broad potential in autoimmune and neuroinflammatory disorders. 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 pharmaceutical products that Brickell believes can meaningfully benefit patients who are suffering from chronic, debilitating diseases that are underserved by available therapies. 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, our strategy; future operations; future financial position; future liquidity; future revenue; projected expenses; results of operations; the anticipated timing, scope, design, progress, results, and/or reporting of data of ongoing and future non-clinical and clinical trials; intellectual property rights, including the validity, term, and enforceability of such; the expected timing and/or results of regulatory submissions and approvals; and prospects for commercializing any of Brickell's product candidates, or research collaborations with, or actions of, its partners, including in Japan, South 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 press release, the words “may,” “could,” “should,” “might,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict,” “potential,” “will,” evaluate,” “advance,” “excited,” “aim,” “help,” “progress,” “select,” “initiate,” “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 to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation, research results and data that do not meet targets, expectations or regulatory approval requirements; 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 in product development, trials of any type, 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 our business caused by the current COVID-19 pandemic; interruptions, disruption, or inability by Brickell or its partners to obtain or supply research material, raw materials, and/or product anywhere in the world; efforts to obtain and retain adequate pricing and adequate reimbursement and other insurance coverage for our products; the outcome of Brickell’s current and planned preclinical and clinical trials across our portfolio; 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. Brickell specifically disclaims any duty or obligation to update forward-looking statements.

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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,	
	2021	**2020**	**2021**	**2020**
Revenue				
Collaboration revenue	$ —	$ 142	$ —	$ 1,795

Royalty revenue	132	—	300	—
Total revenue	132	142	300	1,795
Operating expenses:				
Research and development	10,222	1,281	25,112	6,657
General and administrative	3,269	3,211	9,127	8,713
Total operating expenses	13,491	4,492	34,239	15,370
Loss from operations	(13,359)	(4,350)	(33,939)	(13,575)
Investment and other income, net	107	24	597	27
Interest expense	(1)	—	(65)	—
Net loss	$ (13,253)	$ (4,326)	$ (33,407)	$ (13,548)
Net loss per share, basic and diluted	$ (0.16)	$ (0.15)	$ (0.47)	$ (0.82)
Weighted-average shares used to compute net loss per share, basic and diluted	83,378,318	28,107,785	70,959,097	16,475,843

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

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 21,383	$ 30,115
Prepaid expenses and other current assets	2,668	3,415
Total assets	24,188	33,634
Total liabilities	4,220	6,499
Total stockholders' equity	19,968	27,135

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Source: Brickell Biotech, Inc.