August 11, 2022

Brickell Biotech Reports Second Quarter 2022 Financial Results and Provides Corporate Update

Phase 1 study of BBI-02 progressing well and expect to initiate MAD part of the study next month

On track to report SAD and MAD topline results from BBI-02 Phase 1 study by early 2023

Development of BBI-10 and next-generation kinase inhibitors advancing through early preclinical stage studies

BOULDER, Colo., Aug. 11, 2022 (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 autoimmune, inflammatory, and other debilitating diseases, today announced financial results for the second quarter ended June 30, 2022 and provided a corporate update.

"Advancement of BBI-02 into the clinic is a significant milestone for our company as it marks the first time a DYRK1A inhibitor intended for patients with autoimmune diseases has been orally administered in humans," commented Robert Brown, Chief Executive Officer of Brickell. "We are pleased with the progress in the Phase 1 study and remain on track to initiate the MAD part of the study next month and report SAD and MAD topline results by early 2023."

Research and Development Highlights

BBI-02*: a potential first-in-class DYRK1A inhibitor for the treatment of autoimmune and inflammatory diseases*

- Continue to enroll and dose patients in the Phase 1 clinical trial of BBI-02 (BBI-02-101) in Canada, a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of BBI-02 capsules in both healthy subjects and patients with atopic dermatitis (AD).
    - Part 1A of the study is a single ascending dose (SAD) assessment of BBI-02 capsules or placebo in healthy subjects. Part 1B of the study will be a multiple ascending dose (MAD) assessment of BBI-02 capsules or placebo administered once daily for 14 days in healthy subjects. Part 2 of the study will compare BBI-02 to placebo in patients with moderate-to-severe AD over 28 days of dosing and will include a preliminary assessment of efficacy. Additional information on this clinical trial can be found on www.clinicaltrials.gov under identifier NCT05382819.

    - The Company expects to initiate the MAD assessment next month and remains

on track to report topline results from the SAD and MAD parts of the Phase 1 trial by early 2023.

BBI-10*: a covalent Stimulator of Interferon Genes (STING) inhibitor for the potential treatment of autoimmune, inflammatory, and rare genetic diseases*

- Preclinical development activities for BBI-10, the Company's lead STING inhibitor candidate, are underway.

Next-Generation Kinase Inhibitors*: a cutting-edge platform with the potential to produce treatments for autoimmune, inflammatory, and other debilitating diseases*

- The Company is engaged in research to identify both brain penetrant and non-brain penetrant kinase inhibitors from the Company's library of novel compounds, including next-generation DYRK1A inhibitors and other new chemical entities that specifically inhibit LRRK2, TTK, and CLK kinases.

- A number of these drug candidates have the potential to penetrate the blood brain barrier, presenting an opportunity to address neuroinflammatory conditions of high unmet need such as Down Syndrome, Alzheimer's Disease, and Parkinson's Disease, while other peripherally acting novel LRRK2, TTK, and CLK kinase inhibitors could be developed in additional therapeutic areas within autoimmunity, inflammation, and oncology.

Recent Corporate Highlights

On July 5, 2022, Brickell effected a 1-for-45 reverse stock split of the Company's common stock. Proportional adjustments were also made to the number of shares of Brickell's common stock subject to outstanding equity awards and warrants, as well as the applicable exercise price(s). The purpose of the 1-for-45 reverse stock split was to raise the per-share trading price of the Company's common stock to regain compliance with the $1.00 per share minimum bid price requirement for continuous listing on The Nasdaq Capital Market ("Nasdaq"). On July 19, 2022, the Company received formal notice from Nasdaq stating that the Company had regained compliance with the minimum bid price requirement for continued listing on Nasdaq, and, accordingly, the previously-scheduled hearing regarding the delisting action had been canceled and the Company's common stock will continue to be listed and traded on Nasdaq.

On May 3, 2022, Brickell signed and closed a definitive asset purchase agreement ("APA") with Botanix SB Inc., a subsidiary of Botanix Pharmaceuticals Limited (ASX: BOT) ("Botanix"). Under the terms of the APA, Botanix acquired all of Brickell's rights and assets primarily related to sofpironium bromide. In exchange, Brickell received $3.0 million at closing and is eligible to receive from Botanix potential near-term regulatory milestone payments of (a) $2.0 million upon the acceptance by the U.S. Food and Drug Administration of a new drug application ("NDA") submission for sofpironium bromide gel, 15%, and (b) $4.0 million if marketing approval in the U.S. for sofpironium bromide gel, 15%, is received on or before September 30, 2023, or $2.5 million if such marketing approach is received after September 30, 2023 but on or before February 17, 2024. Brickell also is eligible to receive additional success-based regulatory and sales milestone payments of up to $168 million and tiered earnout payments ranging from high-single digits to mid-teen digits on net sales of

sofpironium bromide gel. Certain of these amounts are subject to payments by Brickell to its former licensor. Brickell additionally will receive certain payments from sales by its former sublicensee, Kaken Pharmaceutical Co. ("Kaken"). Under the APA, Botanix is responsible for all further research, development, and commercialization of sofpironium bromide globally. In connection with the sale of sofpironium bromide, Brickell and Botanix entered into a transition services agreement ("TSA") whereby Brickell is providing consulting services to Botanix as an independent contractor through filing and potential approval of the U.S. NDA for sofpironium bromide gel, 15%. Botanix has reported that it plans to submit the NDA for sofpironium bromide gel, 15% in the third quarter of 2022.

Second Quarter 2022 Financial Results

The Company reported cash and cash equivalents of $14.5 million as of June 30, 2022, compared to $26.9 million as of December 31, 2021. The Company expects its cash and cash equivalents as of June 30, 2022, combined with $2.0 million from expected near-term payments under the APA with Botanix, will support its operations for at least the next 12 months.

Revenue was $4.3 million for the second quarter of 2022, compared to $0.2 million for the second quarter of 2021. Revenue for the three months ended June 30, 2022 consisted of contract revenue recognized under the APA and TSA with Botanix, while revenue for the three months ended June 30, 2021 was driven by royalty revenue earned on a percentage of net sales of ECCLOCK in Japan under the Kaken agreement. Contract revenue for the three months ended June 30, 2022 consisted of an upfront payment from Botanix of $3.0 million, reimbursed development expenditures from Botanix under the APA of $0.6 million, fees for consulting services the Company provided under the TSA of $0.4 million, and sublicense income under the APA of $0.3 million.

Research and development expenses were $1.9 million for the second quarter of 2022, compared to $8.8 million for the second quarter of 2021, which decrease was driven primarily by lower clinical expenses related to sofpironium bromide, partially offset by increased clinical costs for BBI-02. Throughout 2021, the Company was executing its U.S. Phase 3 pivotal clinical program for sofpironium bromide gel, 15%, which concluded in the fourth quarter of 2021. During the second quarter of 2022, the Company initiated its Phase 1 clinical trial for BBI-02 and began incurring research and development expenses related to the clinical trial.

General and administrative expenses were $3.9 million for the second quarter of 2022, compared to $2.9 million for the second quarter of 2021. The increase was primarily related to expenses incurred in the second quarter of 2022 associated with entering into the APA and higher legal, compensation, and other administrative fees.

Brickell's net loss was $1.1 million for the second quarter of 2022 compared to $11.1 million for the second quarter of 2021.

Conference Call and Webcast Information

Brickell's management will host a conference call today at 4:30 p.m. EDT to discuss the financial results and recent corporate developments. The dial-in number for the conference call is 1-844-826-3035 for domestic participants and 1-412-317-5195 for international

participants, with Conference ID #: 10168280. A live webcast of the conference call can be accessed at (click here) or through the Investors section of the Brickell 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 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 autoimmune, inflammatory, and other debilitating diseases. Brickell's pipeline consists of several development-stage candidates and a cutting-edge platform with broad potential in autoimmune and inflammatory disorders. Brickell's executive management team and board of directors bring extensive experience in product development and global commercialization, having served in senior 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®, Juvederm®, Pluvicto®, and Sofpironium Bromide. 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, Brickell's strategy; future operations; future financial position; future liquidity; future revenue; territorial focus; projected expenses; results of operations; the anticipated timing, scope, design, progress, results, and/or reporting of data of ongoing and future nonclinical and clinical trials; intellectual property rights, including the acquisition, validity, term, and enforceability of such; the expected timing and/or results of regulatory submissions and approvals; and prospects for commercializing any product candidates of Brickell or third parties, or research and/or licensing collaborations with, or actions of, its partners, including in the United States, Japan, South Korea, or any other country, or business development activities with other potential partners, 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," "reflects," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," evaluate," "advance," "excited," "aim," "strive," "help," "progress," "select," "initiate," "look forward," "promise," "provide," "commit," "best-in-class," "first-in-class," "on track," "eligible to receive," "opportunity," and similar expressions and their variants, as they relate to Brickell or any of Brickell's partners or third parties, 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 acquire, 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; litigation, regulatory agency feedback or requests; supply chain disruptions; unanticipated demands on cash resources; disruptions and negative effects related to the COVID-19 pandemic and the conflict in Ukraine; interruptions, disruption, or inability by Brickell, its partners or third parties to obtain or supply research material, raw materials, and/or product anywhere, or secure essential services, in the world; ability to continue to comply with Nasdaq minimum bid price requirements; efforts to obtain and retain adequate pricing and adequate reimbursement and other insurance coverage for Brickell's products; the outcome of Brickell's current and planned preclinical and clinical trials across its portfolio of assets; the inability of Botanix to achieve the regulatory and sales-based events and/or to make payments to Brickell under its agreement with them; and other risks associated with (i) developing and obtaining regulatory approval for, and commercializing, product candidates, (ii) raising additional capital, and (iii) maintaining compliance with Nasdaq listing requirements.

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, 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue				
Contract revenue	$ 4,315	$ —	$ 4,315	$ —
Royalty revenue	—	151	92	168
Total revenue	4,315	151	4,407	168
Operating expenses:				
Research and development	1,865	8,838	7,878	14,890
General and administrative	3,908	2,891	7,394	5,858
Total operating expenses	5,773	11,729	15,272	20,748
Loss from operations	(1,458)	(11,578)	(10,865)	(20,580)
Other income	313	459	314	490

Interest expense	(2)	(30)	(6)	(64)
Net loss attributable to common stockholders	$ (1,147)	$ (11,149)	$ (10,557)	$ (20,154)
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.01)	$ (0.16)	$ (0.09)	$ (0.31)
Weighted-average shares used to compute net loss per common share attributable to common stockholders, basic and diluted	119,486,317	68,856,370	119,432,103	64,646,565

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

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 14,480	$ 26,884
Prepaid expenses and other current assets	3,771	2,716
Total assets	18,507	29,717
Total liabilities	2,870	4,810
Total stockholders' equity	15,637	24,907

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Source: Brickell Biotech, Inc.