May 12, 2022

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

Completed sale of sofpironium bromide to Botanix Pharmaceuticals for up to $9 million in upfront and potential near-term regulatory milestone payments, $168 million in potential future regulatory and sales milestone payments, plus tiered earnout payments on net sales

Sale reflects Brickell's new business strategy and commitment to developing its pipeline of novel, potential first-in-class treatments in immunology and inflammation

On track to initiate a Phase 1 study of BBI-02, an oral DYRK1A inhibitor for the treatment of autoimmune and inflammatory diseases, in the second quarter of 2022, with SAD and MAD topline results expected by early 2023

BOULDER, Colo., May 12, 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 first quarter ended March 31, 2022 and provided a corporate update.

"Last week, we announced the sale of our rights to sofpironium bromide to Botanix Pharmaceuticals, which we believe will provide an optimal pathway for sofpironium bromide gel, 15% to become a potential best-in-class treatment for millions of patients suffering from primary axillary hyperhidrosis," commented Robert Brown, Chief Executive Officer of Brickell. "Through this transaction, we have immediately started to unlock the value of sofpironium bromide while eliminating the significant investment required by Brickell through the NDA review process and commercialization. Importantly, this sale aligns with our new business strategy to develop innovative therapeutics in the immunology and inflammatory fields. The proceeds and potential future economics from this transaction allow us to directly invest additional resources to advance our pipeline of novel, potential first-in-class therapies."

Mr. Brown continued, "As we look ahead, there are several exciting company milestones planned for 2022 and beyond, which we believe will help us address the needs of several high-impact patient populations afflicted by autoimmune and inflammatory diseases, while creating shareholder value. Our plans include conducting a first-in-human Phase 1 clinical study starting in the second quarter of 2022 for our lead DYRK1A inhibitor, BBI-02, and progressing the development of our lead STING inhibitor, BBI-10, and other next-generation kinase inhibitors through early preclinical stage studies this year."

Research and Development Highlights

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

inflammatory diseases

- On track to initiate the Phase 1 clinical trial of BBI-02 (BBI-02-101) in Canada in the second quarter of 2022, which is 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).

    - Successfully submitted the Clinical Trial Application for BBI-02 to Health Canada and subsequently received a No Objection Letter in the first quarter of 2022, allowing the BBI-02-101 study to proceed as planned.

    - Part 1A of the study will be 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.

    - Topline results from the SAD and MAD parts of the Phase 1 trial are expected to be announced by early 2023.

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

- In February 2022, Brickell acquired exclusive global rights to develop and commercialize a portfolio of novel, potent, and orally available Stimulator of Interferon Genes (STING) inhibitors from Carna Biosciences, Inc., an established Japanese drug discovery company.

- Preclinical development activities for BBI-10 are underway, and the Company expects to conduct experimental characterization of the STING inhibitor library throughout 2022.

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

- Currently 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, as potential treatments for autoimmune, inflammatory, and other debilitating diseases.

Recent Events

On May 3, 2022, Brickell signed and closed a definitive asset purchase agreement with Botanix SB Inc., a subsidiary of Botanix Pharmaceuticals Limited ("Botanix"). Under the terms of the agreement, Botanix acquired all of Brickell's rights and assets primarily related to sofpironium bromide. In exchange, Brickell received $3 million at closing and is eligible to receive up to $6 million in potential near-term regulatory milestone payments over the next 18 months from Botanix. 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”). Botanix will be 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 whereby Brickell will provide consulting services to Botanix as an independent contractor through submission and potential approval of the U.S. NDA for sofpironium bromide gel, 15%.

On May 3, 2022, Brickell adjourned its 2022 annual meeting of stockholders to May 17, 2022 at 10 a.m. MDT. At the time the annual meeting was adjourned, proxies had been submitted by stockholders constituting a quorum, but there were not sufficient votes to approve two of the proposals, one related to an increase in the number of authorized shares of common stock and the other to approve a reverse stock split, each of which requires approval by the holders of a majority of the outstanding shares of common stock of Brickell. Brickell continues to solicit votes from its stockholders with respect to all of the proposals for the annual meeting.

First Quarter 2022 Financial Results

The Company reported cash and cash equivalents of $17.3 million as of March 31, 2022, compared to $26.9 million as of December 31, 2021. The Company expects its cash and cash equivalents as of March 31, 2022, combined with $3.0 million in upfront fees it received from Botanix on May 3, 2022, and other expected near-term milestone payments under the agreement with Botanix, will support its operations for at least the next 12 months.

Revenue was $92.0 thousand for the first quarter of 2022, compared to $17.0 thousand for the first quarter of 2021. Revenue in both periods resulted from royalty revenue related to sales of ECCLOCK® (sofpironium bromide gel, 5%) in Japan by Kaken.

Research and development expenses were $6.0 million for the first quarter of 2022, compared to $6.1 million for the first quarter of 2021. During the first quarter of 2022, Brickell incurred $3.3 million in lower clinical costs related to its U.S. Phase 3 pivotal clinical program for sofpironium bromide gel, 15%, which was completed in the fourth quarter of 2021. This decrease was almost fully offset by increases of $2.0 million in upfront costs related to Brickell’s acquisition of the STING inhibitor platform, $0.7 million in development costs related to its DYRK1A inhibitor program, and $0.4 million related to personnel and other expenses.

General and administrative expenses were $3.5 million for the first quarter of 2022, compared to $3.0 million for the first quarter of 2021. The increase was primarily due to higher compensation-related expenses, professional fees, insurance, and other miscellaneous expenses.

Brickell’s net loss was $9.4 million for the first quarter of 2022 compared to $9.0 million for the first 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 1-877-705-6003 for domestic participants and 1-201-493-6725 for international participants, with Conference ID #: 13728736. 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 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, 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 non-clinical 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 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," 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; 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 therefore Brickell not receiving any additional payments, under its agreement with them; 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, 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 March 31,	
	2022	**2021**
Revenue	$ 92	$ 17
Operating expenses:		
Research and development	6,013	6,052
General and administrative	3,486	2,967
Total operating expenses	9,499	9,019
Loss from operations	(9,407)	(9,002)
Other income	1	31
Interest expense	(4)	(34)
Net loss	$ (9,410)	$ (9,005)
Net loss per share, basic and diluted	$ (0.08)	$ (0.15)

Weighted-average shares used to compute net loss per share, basic and diluted	119,377,286	61,163,581

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

	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 17,289	$ 26,884
Prepaid expenses and other current assets	3,404	2,716
Total assets	20,789	29,717
Total liabilities	4,741	4,810
Total stockholders' equity	16,048	24,907

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Source: Brickell Biotech, Inc.