UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported) March 15, 2022

BRICKELL BIOTECH, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**000-21088**	**93-0948554**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5777 Central Avenue
Suite 102
Boulder, CO 80301
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (720) 505-4755

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.01 per share	**BBI**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 15, 2022, Brickell Biotech, Inc. issued a press release reporting, among other things, its financial results for the three months and year ended December 31, 2021. A copy of the press release is attached as Exhibit 99.1 to this Current Report.

The information in this Item 2.02, and Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press release issued by Brickell Biotech, Inc. on March 15, 2022

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 15, 2022

Brickell Biotech, Inc.

By: /s/ Robert B. Brown
Name: Robert B. Brown
Title: Chief Executive Officer

Brickell Biotech Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

Broadened strategic focus and expanded pipeline in immunology and inflammation following acquisition of rights to BBI-02, a potential first-in-class oral DYRK1A inhibitor, a portfolio of novel STING inhibitors, and a next-generation kinase inhibitor platform

On track to initiate Phase 1 study for BBI-02 for the treatment of autoimmune and inflammatory diseases in Q2 2022, with SAD and MAD topline results anticipated year-end 2022

New Drug Application (NDA) submission to the U.S. FDA for sofpironium bromide gel, 15% expected in mid-2022

BOULDER, CO — **March 15, 2022** — 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 fourth quarter and full year ended December 31, 2021 and provided a corporate update.

"Over the course of the last year, the entire Brickell team successfully executed on our strategic plan," commented Robert Brown, Chief Executive Officer of Brickell. "Our robust pipeline of recently-acquired proprietary drug candidates firmly establishes our presence in the immunology and inflammation fields with multiple promising and novel targets. We are on track to advance our lead DYRK1A inhibitor, BBI-02, into a Phase 1 clinical study in the coming months, and the team is progressing the development of our lead STING inhibitor, BBI-10, and other next-generation kinase inhibitors through early preclinical stage studies. In addition, we continue to execute towards a mid-2022 NDA submission for sofpironium bromide gel, 15% for the treatment of primary axillary hyperhidrosis and evaluate all available options designed to maximize commercial product success. We believe 2022 is shaping up to be a pivotal year for Brickell, and we look forward to providing updates on our progress across these exciting programs in the coming months."

Research and Development Highlights

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

- Brickell is on track to progress BBI-02, its lead development-stage program, into a Phase 1 clinical trial (BBI-02-101) in Canada in the second quarter of 2022.
- **BBI-02-101**: This Phase 1 study is expected to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of BBI-02 in both healthy volunteers and subjects with atopic dermatitis (AD) and will also include a preliminary assessment of efficacy as to AD.
    - Part 1A of the study will be a single ascending dose (SAD) assessment in healthy volunteers, Part 1B of the study will be a multiple ascending dose (MAD) assessment in healthy volunteers, and Part 2 of the study will compare BBI-02 to placebo in moderate-to-severe AD patients.
    - Topline results from the SAD and MAD parts of the Phase 1 study anticipated year-end 2022.

BBI-10*: a covalent STING inhibitor for the potential treatment of autoinflammatory 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., which have potential to treat autoinflammatory disorders, such as systemic lupus erythematosus and rheumatoid arthritis, rare genetic interferonopathies, and potentially other diseases.
- 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 licensed library of 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.

Sofpironium Bromide*: a potential best-in-class investigational product for the treatment of primary axillary hyperhidrosis*

- Following a pre-NDA meeting held with the U.S. FDA earlier this quarter, the Company remains on track to file an NDA for sofpironium gel, 15% in mid-2022.
- Results from Brickell's U.S. Phase 3 pivotal Cardigan I and Cardigan II studies of sofpironium bromide gel, 15% were selected for an oral presentation at the Late-Breaking Research session during the American Academy of Dermatology's 2022 Annual Meeting, which is being held from March 25-29 in Boston, MA.
- Brickell's development partner, Kaken Pharmaceutical Co., Ltd. (Kaken), continues to commercialize sofpironium bromide gel, 5% (ECCLOCK®) for the treatment of primary axillary hyperhidrosis in Japan.

Financial Results

Fourth Quarter 2021 Financial Results

The Company reported cash and cash equivalents of $26.9 million as of December 31, 2021, compared to $30.1 million as of December 31, 2020. The Company expects its cash and cash equivalents will support operations beyond the receipt of Phase 1 SAD and MAD topline results for BBI-02, which are anticipated year-end 2022.

Revenue was $104.0 thousand for the fourth quarter of 2021, compared to $27.0 thousand for the fourth quarter of 2020. Revenue in both periods related to royalty revenue recognized from sales of ECCLOCK in Japan by Kaken.

Research and development expenses were $3.1 million for the fourth quarter of 2021, compared to $4.6 million for the fourth quarter of 2020. This decrease was primarily due to a $2.9 million reduction in clinical costs related to sofpironium bromide, which was partially offset by a $0.9 million increase in regulatory, personnel, and other expenses, and a $0.5 million increase related to development of the Company's DYRK1A inhibitor programs.

General and administrative expenses were $3.3 million for the fourth quarter of 2021, compared to $2.9 million for the fourth quarter of 2020. The increase of $0.4 million was primarily due to compensation and administrative expenses.

Brickell's net loss was $6.1 million for the fourth quarter of 2021 compared to $7.4 million for the fourth quarter of 2020.

2021 Annual Financial Results

Revenue was $0.4 million for the year ended December 31, 2021, compared to $1.8 million for the year ended December 31, 2020. Revenue in 2021 consisted of royalty revenue recognized related to sales of ECCLOCK in Japan by Kaken, while revenue in 2020 was driven primarily by collaboration revenue recognized for research and development activities under an agreement pursuant to which Kaken provided research and development funding to the Company.

Research and development expenses were $28.2 million for the year ended December 31, 2021, compared to $11.2 million for the year ended December 31, 2020, which was primarily due to an increase of $10.7 million in clinical costs related to the Company's U.S. Phase 3 pivotal clinical program for sofpironium bromide gel, 15%, an increase of $5.4 million in upfront costs and development expenses related to the Company's DYRK1A inhibitor programs and next-generation kinase inhibitor platform, and an increase of $0.9 million in personnel and other expenses.

General and administrative expenses were $12.4 million for the year ended December 31, 2021, compared to $11.6 million for the year ended December 31, 2020. The increase of $0.8 million was primarily due to compensation and administrative expenses.

Total other income, net was $0.8 million for the year ended December 31, 2021, compared to $0.1 million for the year ended December 31, 2020. The increase of $0.7 million was primarily due to a gain on extinguishment of debt of approximately $0.4 million that resulted from the forgiveness of a loan in June 2021 and other miscellaneous income of $0.3 million.

Brickell's net loss was $39.5 million for the year ended December 31, 2021, compared to $20.9 million for the year ended December 31, 2020.

Conference Call and Webcast Information

Brickell's management will host a conference call today at 8:30 a.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 #13726693. A live webcast of the conference call can be accessed at (click here) (https://viavid.webcasts.com/starthere.jsp?ei=1526473&tp_key=b8f4008a0e) 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 combines several development-stage candidates and a cutting-edge platform with broad potential in autoimmune and inflammatory disorders with a potential best-in-class, late-stage program for the treatment of primary axillary hyperhidrosis. 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," "strive," "help," "progress," "select," "initiate," "look forward," "promise," 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; disruptions and negative effects related to the COVID-19 pandemic and the conflict in Ukraine; 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, 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Revenue				
Collaboration revenue	$ —	$ —	$ —	$ 1,795
Royalty revenue	104	27	404	27
Total revenue	104	27	404	1,822
Operating expenses:				
Research and development	3,119	4,559	28,231	11,216
General and administrative	3,290	2,869	12,417	11,582
Total operating expenses	6,409	7,428	40,648	22,798
Loss from operations	(6,305)	(7,401)	(40,244)	(20,976)
Investment and other income, net	242	36	839	63
Interest expense	(4)	—	(69)	—
Net loss	$ (6,067)	$ (7,365)	$ (39,474)	$ (20,913)
Net loss per share, basic and diluted	$ (0.06)	$ (0.15)	$ (0.49)	$ (0.85)
Weighted-average shares used to compute net loss per share, basic and diluted	108,079,984	48,454,350	80,315,595	24,514,157

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

	December 31,	
	2021	2020
Cash and cash equivalents	$ 26,884	$ 30,115
Prepaid expenses and other current assets	2,716	3,415
Total assets	29,717	33,634
Total liabilities	4,810	6,499
Total stockholders' equity	24,907	27,135