



BiomX Reports Second Quarter 2022 Financial Results and Provides Business Update

August 10, 2022

Enrollment Continues in Phase 1/2 Trial of BX004 for Treatment of Lung Infections in Cystic Fibrosis (“CF”); results from Part 1 expected by the end of Q3 2022

Entered into Second Collaboration with Boehringer Ingelheim to Discover Microbiome Markers for Inflammatory Bowel Disease

Announced Publications in the Journals Cell and Bioinformatics

Cash Runway Through Multiple Data Readouts and Extended to at Least Mid-2024

Company Will Host a Conference Call and Webcast Today at 8:00 am ET

BRANFORD, Conn. & NESS ZIONA, Israel--(BUSINESS WIRE)-- BiomX Inc. (NYSE American: PHGE) (“BiomX” or the “Company”), a clinical-stage microbiome company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results, and provided a business update for the second quarter ended June 30, 2022.

“It has been an eventful quarter for the Company. We enrolled our first patients in our BX004 cystic fibrosis program, expanded our partnering activities, published important research, and successfully restructured our operations to further extend our cash runway,” said **Jonathan Solomon**, Chief Executive Officer of BiomX. “With the ongoing enrollment of patients in our CF study, we are one step closer towards reaching an important milestone in the BX004 program. Sites have been opening according to plan and, provided that the pace of enrollment for the study will continue as expected, we continue to anticipate a data readout from the first part of the study by the end of the third quarter of 2022. Our recent KOL event also highlighted the unmet medical need that exists today for so many CF patients who require innovative new therapeutic approaches to help combat these persistent and difficult-to-treat lung infections.

“As we enter the second half of 2022, BiomX also remains well positioned financially, with our cash runway now expected to take us through at least mid-2024. Over this period, we expect to reach potential milestones intended to help drive significant shareholder value, and I look forward to sharing additional updates later this year.”

RECENT CORPORATE HIGHLIGHTS

- In June, BiomX announced the dosing of the first two patients in the Company’s Phase 1b/2a study evaluating BX004 for the treatment of chronic respiratory infections in patients with cystic fibrosis.
- Also in June, BiomX announced a second partnership with Boehringer Ingelheim to discover inflammatory bowel disease (“IBD”) microbiome markers. BiomX will utilize its XMarker microbiome-based biomarker discovery platform with the goal of identifying biomarkers for a pathogenic bacterium thought to be associated with IBD. Such biomarkers could help identify IBD patients that would benefit from potential therapies targeted at the microbiome. In September 2020, Boehringer Ingelheim and BiomX entered into their first collaboration, which focused on identifying biomarkers associated with patient phenotypes in IBD.
- In August, the Company announced the publication of a scientific paper titled “Targeted suppression of human IBD-associated gut microbiota commensals by phage consortia for treatment of intestinal inflammation” in the journal, *Cell*. The research was conducted across several organizations, including BiomX and the Weizmann Institute of Science (Rehovot, Israel), and presents positive results from a proof-of-concept assessment in a preclinical model of inflammatory bowel disease. The paper is available online at [https://www.cell.com/cell/fulltext/S0092-8674\(22\)00850-9](https://www.cell.com/cell/fulltext/S0092-8674(22)00850-9).
- On May 12th, the Company hosted a Key Opinion Leader Event on BX004 for Treatment of Pseudomonas Aeruginosa (“PsA”) Infections in CF patients. The live webinar featured presentations from Key Opinion Leaders, Dave Nichols, M.D. and Saima Aslam, M.D., who discussed phage therapy, the current treatment landscape, and the unmet medical need in CF patients with chronic PsA pulmonary infections. The webinar is now available on the Company’s website at <https://ir.biomx.com/news-events/ir-calendar/detail/7514/kol-webinar-on-bx004-for-treatment-of-pseudomonas>.
- Also in May, BiomX announced a corporate restructuring plan intended to extend the Company’s capital resources at least until the middle of 2024. With this plan, the Company reduced its operating costs, which included a reduction in personnel, while prioritizing the ongoing CF program.
- Also in May, BiomX announced the publication of a scientific paper titled “Exodus: Sequencing-based Pipeline for Quantification of Pooled Variants” in the journal, *Bioinformatics*. The research was conducted by scientists at BiomX and is available online at <https://doi.org/10.1093/bioinformatics/btac319>.

Clinical Program Updates

Cystic Fibrosis (BX004)

- In June, BiomX announced the dosing of the first two patients in the Company's Phase 1b/2a study evaluating BX004 for the treatment of chronic respiratory infections in patients with CF.
- BX004 is being developed for the treatment of chronic respiratory infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with CF.
- The Phase 1b/2a trial is composed of two parts. Part 1 of the study will evaluate the safety, pharmacokinetics, and microbiologic/clinical activity of BX004 in eight CF patients in a single ascending dose and multiple dose design, with results expected by the end of the third quarter of 2022. Part 2 of the study will evaluate the safety and efficacy of BX004 in 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 are expected in the first quarter of 2023.
- BiomX has received a Therapeutics Development Award of up to \$5 million from the Cystic Fibrosis Foundation ("CF Foundation"). The award is structured as an equity investment in which the CF Foundation has agreed to purchase up to \$5M million of BiomX common stock across two separate tranches. The first tranche was received on December 21, 2021, with the CF Foundation making an initial equity investment of \$3 million. Upon completion of all patient dosing in Part 1 of the Company's Phase 1b/2a study of BX004, BiomX would have the right to receive the second tranche of \$2 million, also as an equity investment.

Atopic Dermatitis (BX005)

- In April, the United States Food and Drug Administration ("FDA") approved the Company's IND application for BX005, which is being developed for the treatment of moderate to severe atopic dermatitis ("AD").
- While the recently announced restructuring is expected to result in a delay to the AD program, the Company plans to support a range of activities that will continue to move this program forward and will provide a more detailed update later in the year.
- The Company and Maruho Co. Ltd., a leading dermatology-focused pharmaceutical company in Japan, entered into an agreement in the second half of 2021 granting Maruho a right of first offer to license BX005 in Japan.
- The Company is collaborating with Maruho and working on evaluating timelines for a clinical trial.

Second Quarter 2022 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of June 30, 2022, were \$46.7 million, compared to \$63.1 million as of December 31, 2021. The decrease was primarily due to net cash used in operating activities. Based upon the Company's strategic focus on the CF program, the existing cash and cash equivalents are expected to be sufficient to fund the current operating plan through middle of 2024.
- **Research and development ("R&D") expenses, net** were \$4.6 million for the three months ended June 30, 2022, compared to \$3.8 million for the same period in 2021. R&D expenses, net were \$9.5 million for six months ended June 30, 2022, as well as for the six months ended June 30, 2021. A decrease in Israel Innovation Authority grants resulted in higher R&D expenses, net, offset by a decrease in salaries and related expenses and stock-based compensation expenses due to a reduction in workforce. An additional offset is due to pauses in the development of BX003, the product candidate for the treatment of IBD and primary sclerosing cholangitis, and the colorectal cancer product candidate, as well as due to the discontinuation of the product candidate, BX001, for the treatment of acne.
- **General and administrative expenses** were \$2.4 million for the three months ended June 30, 2022, compared to \$3.1 million for the same period in 2021. General and administrative expenses were \$4.8 million for the six months ended June 30, 2022, compared to \$5.6 million for the prior year. The decrease for the six months ended June 30, 2022 was primarily due to a decrease in salaries and related expenses and stock-based compensation expenses due to a reduction in workforce. In addition, the decrease is due to additional expenses incurred in 2021 that resulted from moving into new premises.
- **Net loss** for the second quarter of 2022 was \$7.5 million, compared to \$7.3 million for the same period in 2021.
- **Net cash used in operating activities** for the six months ended June 30, 2022 was \$16.4 million, compared to \$12.8 million for the same period in 2021.

Conference Call and Webcast Information

BiomX management will host a conference call and webcast today at 8:00 am ET to report financial results and business updates for the second quarter 2022. To participate in the conference, please dial 1-877-407-0724 (U.S.), 1-809-406-247 (Israel), or 1-201-389-0898 (International). A live and archived webcast of the call will be available on the Investors section of the Company's website at www.biomx.com.

About BiomX

BiomX is a clinical-stage microbiome company developing both natural and engineered phage cocktails designed to target and destroy bacteria in the treatment of chronic diseases. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at www.biomx.com, the content of which does not form a part of this press release.

Safe Harbor

This press release contains express or implied "forward-looking statements" within the meaning of the "safe harbor" provisions of

the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: “target,” “believe,” “expect,” “will,” “may,” “anticipate,” “estimate,” “would,” “positioned,” “future,” and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. For example, when BiomX discusses future updates on its CF, AD and other programs, its expectations regarding the opening of sites, pace of enrollment and timing of the results of the CF trial, the potential safety, tolerability and potential treatment effect of its product candidates, the potential to achieve the applicable clinical milestones required to receive an additional \$2 million investment from CFF, and its cash runway, capitalization and financial condition, BiomX is making forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on BiomX management’s current beliefs, expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of BiomX’s control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, investors should not rely on any of these forward-looking statements and should review the risks and uncertainties described under the caption “Risk Factors” in BiomX’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (the “SEC”) on March 30, 2022 and additional disclosures BiomX makes in its other filings with the SEC, which are available on the SEC’s website at www.sec.gov. Forward-looking statements are made as of the date of this press release, and except as provided by law BiomX expressly disclaims any obligation or undertaking to update forward-looking statements.

BIOMX INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(USD in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development (“R&D”) expenses, net	4,584	3,824	9,513	9,494
Amortization of intangible assets	379	380	759	759
General and administrative expenses	2,361	3,098	4,838	5,591
Operating loss	7,324	7,302	15,110	15,844
Interest expenses	488	-	949	-
Financial expenses (income), net	(339)	31	(426)	(112)
Loss before tax	7,473	7,333	15,633	15,732
Tax expenses	9	3	18	6
Net loss	7,482	7,336	15,651	15,738
Basic and diluted loss per share of Common Stock	0.25	0.30	0.53	0.65
Weighted average number of shares of Common Stock outstanding, basic and diluted	29,774,709	24,320,259	29,764,588	24,134,065

BIOMX INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)
(unaudited)

	As of	
	June 30, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	37,745	62,099
Restricted cash	963	996

Short-term deposits	8,000	-
Other current assets	1,605	3,543
Total current assets	<u>48,313</u>	<u>66,638</u>
Property and equipment, net	5,252	5,694
Intangible assets, net	760	1,519
Operating lease right-of-use assets	4,057	4,139
Total non-current assets	<u>10,069</u>	<u>11,352</u>
	<u>58,382</u>	<u>77,990</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Trade accounts payable	1,656	2,795
Other accounts payable	2,394	5,453
Contract liability	-	1,976
Current portion of operating lease liabilities	708	819
Current portion of long-term debt	1,732	-
Total current liabilities	<u>6,490</u>	<u>11,043</u>

Non-current liabilities

Contract liability	1,976	-
Long-term debt, net of current portion	12,929	14,410
Operating lease liabilities, net of current portion	4,039	4,787
Other liabilities	209	215
Total non-current liabilities	<u>19,153</u>	<u>19,412</u>

Stockholders' equity

Preferred Stock, \$0.0001 par value; Authorized - 1,000,000 shares as of June 30, 2022 and December 31, 2021. No shares issued and outstanding as of June 30, 2022 and December 31, 2021.

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Common Stock, \$0.0001 par value; Authorized - 60,000,000 shares as of June 30, 2022 and December 31, 2021. Issued – 29,780,409 shares as of June 30, 2022 and 29,753,238 shares as of December 31, 2021. Outstanding – 29,774,709 shares as of June 30, 2022 and 29,747,538 shares as of December 31, 2021.

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Additional paid in capital	156,872	156,017
Accumulated deficit	(124,135)	(108,484)
Total stockholders' equity	<u>32,739</u>	<u>47,535</u>
	<u>58,382</u>	<u>77,990</u>

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