

# BiomX Reports First Quarter 2023 Financial Results and Provides Business Update

Announced Positive Results from Part 1 of Ongoing Phase 1b/2a Trial of BX004 for Treatment of Lung Infections in Cystic Fibrosis ("CF"); Results from Part 2 Expected in Third Quarter of 2023

Second and Final Closing of PIPE Investment Completed, Raising Total Gross Proceeds of \$7.5 million; Cash Runway into the Third Quarter of 2024

Jason M. Marks and Michael E. Dambach Appointed to Board of Directors

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

CAMBRIDGE, Mass. and NESS ZIONA, Israel, May 15, 2023 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the first quarter ended March 31, 2023.

"Based on the better-than-expected results from Part 1 of our cystic fibrosis ("CF") trial, I am pleased to note that the BX004 program continues to gain increased visibility among patients and physicians," said Jonathan Solomon, Chief Executive Officer of BiomX. "Part 1 results demonstrated that treatment with BX004 was safe, well-tolerated, and resulted in notable reductions in *P. aeruginosa* bacterial counts. Part 2 of the study is underway with enrollment rate as planned. In Part 2 CF patients will be dosed with BX004 twice a day and over a longer, 10-day treatment period compared to Part 1. Part 2 of the study will provide additional data on safety and reduction in *P. aeruginosa* bacterial burden, along with other exploratory clinical endpoints. We expect to report results from Part 2 in the third quarter of 2023.

"The growing interest in our BX004 program has also allowed us to strengthen our balance sheet during the quarter, and I am pleased to announce that we closed the second part of our private placement earlier this month. We would like to thank our existing shareholders, including OrbiMed and the Cystic Fibrosis Foundation, for this continued financial support, which will provide us with additional funding through the expected Part 2 data readout. I am also pleased to note the addition of Jason Marks and Michael Dambach to our Board of Directors, who both bring a wealth of talent and experience spanning across multiple areas of finance, regulatory, governance and legal expertise."

#### Clinical Program Updates

#### Cystic Fibrosis (BX004)

- In February 2023, BiomX announced positive results from Part 1 of the Phase 1b/2a trial evaluating the Company's novel phage cocktail, BX004, for the treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa* (or *P. aeruginosa*) in patients with cystic fibrosis. Highlights from the data included:
  - No safety events related to treatment with BX004
  - Mean P. aeruginosa colony forming units (CFU) at Day 15 (compared to baseline) were reduced by more than 90%: -1.42 log10 CFU/g (BX004) vs. -0.28 log10 CFU/g (placebo). This reduction occurred in the presence of standard of care inhaled antibiotics
  - Phages were detected in all patients treated with BX004 during the dosing period, including in several patients up to Day 15 (one week after end of therapy); no phages were detected in patients receiving placebo
  - There was no emerging bacterial resistance to BX004 during or after treatment with BX004
  - As expected, likely due to the short course of therapy, there was no detectable effect on % predicted FEV1 (First-second Forced Expiratory Volume)
- BX004 is being developed for the treatment of chronic respiratory infections caused by *P. 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 evaluated the safety, pharmacokinetics, and microbiologic/clinical activity of BX004 in nine CF patients in a single ascending dose and multiple dose design. 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 of the trial are expected in the third quarter of 2023.
- As previously announced, BiomX has received a Therapeutics Development Award of up to \$5 million from the Cystic Fibrosis Foundation ("CF Foundation"). The award was structured as an equity investment in which the CF Foundation agreed to purchase up to \$5 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. Following the results from Part 1 of the ongoing Phase 1b/2a trial, the CF Foundation completed its second tranche investment of \$2 million through its participation in the Company's recently announced \$7.5 million private placement.

#### Atopic Dermatitis ("AD") (BX005)

• The Company is collaborating with Maruho Co. Ltd., a leading dermatology-focused pharmaceutical company in Japan, supporting a range of pre-clinical activities to move this program forward and working on evaluating timelines for a clinical trial.

#### RECENT CORPORATE HIGHLIGHTS

 On May 12, 2023, the Company announced the appointments of Jason M. Marks and Michael E. Dambach, CFA to its Board of Directors. Mr. Marks most recently served as Executive Vice President, Chief Legal and Compliance Officer & Corporate Secretary/Senior Advisor with Amarin Corporation plc, and Mr. Dambach serves as

- Vice President and Treasurer of Biogen Inc.
- In February 2023, the Company announced a \$7.5 million private placement with a select group of institutional and individual investors, including existing investors. OrbiMed and the CF Foundation. The financing closed in two parts. The first closing for gross proceeds of \$1.5 million occurred in February 2023. The second closing, which was contingent upon approval by the Company's stockholders in accordance with NYSE American rules, closed in May 2023. BiomX expects to use the net proceeds from the PIPE, together with existing cash and cash equivalents, to fund clinical development of BX004 for the treatment of lung infections in patients with CF, the development of other programs, and research activities as well as working capital and other general corporate purposes.

#### First Quarter 2023 Financial Results

- Cash balance, short-term deposits and restricted cash as of March 31, 2023, were \$30.3 million, compared to \$34.3 million as of December 31, 2022. The decrease was primarily due to net cash used in operating activities. During the quarter, the Company raised \$1.5 million in gross proceeds through a private placement. Inclusive of net proceeds from the private placement, the Company estimates its cash runway is sufficient to fund operations into the third quarter of 2024.
- Research and development ("R&D") expenses, netwere \$4.6 million for the three months ended March 31, 2023, compared to \$4.9 million for the same period in 2022. The decrease was primarily due to reduced salaries and related expenses and stock-based compensation expenses that resulted from a reduction in workforce, as part of a corporate restructuring the Company announced in May 2022 (the "Corporate Restructuring"); as well as deprioritizing pre-clinical and clinical activities related to our AD product candidate, BX005, partially offset by expenses related to conducting the Phase 1b/2a clinical trial of our CF product candidate, BX004.
- General and administrative expenses were \$1.6 million for the three months ended March 31, 2023, compared to \$2.5 million for the same period in 2022. The decrease was primarily due to reduced salaries and related expenses and stock-based compensation expenses due to a reduction in the workforce, as part of the corporate restructuring, as well as a decrease in the premium of the Company's directors and officers' insurance policy.
- **Net loss** for the first quarter of 2023 was \$6.4 million, compared to \$8.2 million for the same period in 2022.
- **Net cash used in operating activities** for the three months ended March 31, 2023 was \$5.0 million, compared to \$7.4 million for the same period in 2022.

#### **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 first quarter of 2023. 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, the content of which does not form a

part of this press release.

#### About BiomX

BiomX is a clinical-stage 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. For more information, please visit 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 the potential safety or efficacy of BX004, the expected timing, design and patient enrollment of Part 2 of the Phase 1b/2a study and the potential of targeted phage therapy to treat infections in CF patients, when it refers to other programs, such as the program to treat Atopic Dermatitis, and when it discusses the estimate of the sufficiency of its cash runway, BiomX is making forwardlooking 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 29, 2023 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 BALANCE SHEETS (USD in thousands, except share and per share data) (unaudited)

As of		
March 31,	December 31,	
2023	2022	

**ASSETS** 

**Current assets** 

Cash and cash equivalents	29,346	31,332
Restricted cash	956	962
Short-term deposits	-	2,000
Other current assets	2,632	2,587
Total current assets	32,934	36,881
Non-current assets		
Other assets	129	-
Operating lease right-of-use assets	3,767	3,860
Property and equipment, net	4,577	4,790
Total non-current assets	8,473	8,650
	41,407	45,531

### BIOMX INC.

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

	As of		
	March 31, 2023	December 31, 2022	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Trade accounts payable	1,359	820	
Current portion of lease liabilities	669	687	
Other accounts payable	2,956	2,150	
Current portion of long-term debt	5,216	4,282	
Total current liabilities	10,200	7,939	
Non-current liabilities			
Contract liability	1,976	1,976	
Long-term debt, net of current portion	9,306	10,591	
Operating lease liabilities, net of current portion	3,587	3,798	
Other liabilities	192	188	
Total non-current liabilities	15,061	16,553	

# **Commitments and Contingencies**

## Stockholders' equity

2022. No shares issued and outstanding as of March 31, 2023 and December 31, 2022.		
Common Stock, \$0.0001 par value; Authorized - 120,000,000 shares as of March 31, 2023 and December	-	-
31, 2022. Issued –33,181,772 shares as of March 31, 2023 and 29,982,282 shares as of December 31, 2022.		
Outstanding –33,176,072 shares as of March 31, 2023 and 29,976,582 shares as of December 31, 2022.	2	2
Additional paid in capital	159,306	157,838
Accumulated deficit (**	143,162)	(136,801)
Total stockholders' equity	16,146	21,039
	41,407	45,531

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

	Three Months Ended March 31,	
	2023	2022
Research and development ("R&D") expenses, net Amortization of intangible assets General and administrative expenses	4,564 - 1,644	4,929 380 2,477
Operating loss	6,208	7,786
Other income Interest expenses Finance income, net	(91) 565 (327)	- 461 (87)
Loss before tax	6,355	8,160
Tax expenses	6	9
Net loss	6,361	8,169
Basic and diluted loss per share of Common Stock	0.20	0.27

#### **BiomX Contacts**

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Source: BiomX Inc.



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