BiomX Reports Third Quarter 2023 Financial Results and Provides Business Update

November 14, 2023

Analysis of Part 2 data from Phase 1b/2a trial of BX004 ongoing; Company expects to announce Part 2 data later this month

BX004 received FDA Fast Track designation in August

Part 1 data recently presented at the North American Cystic Fibrosis Conference (NACFC)

CAMBRIDGE, Mass. and NESS ZIONA, Israel, Nov. 14, 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 third quarter ended September 30, 2023.

"Thanks to the continued execution of our clinical team, we are now analyzing data from Part 2 of the Phase 1b/2a trial of BX004 and expect to announce the results later this month," said Jonathan Solomon, Chief Executive Officer of BiomX. "I am also pleased to note that the positive data from Part 1 of our trial has been well received by physicians and patient advocacy groups at several prominent medical meetings, reflecting the need to develop innovative new therapies for combating these persistent and deadly lung infections. In addition, the U.S. Food and Drug Administration recently granted Fast Track designation for BX004, further underscoring the potential of this promising program.

"As a reminder, Part 2 of the trial is evaluating BX004 in a larger number of cystic fibrosis patients who are dosed twice a day and over a longer, 10-day treatment period compared to Part 1 of the trial. Part 2 of the trial will provide additional clinical data on safety and reduction in bacterial burden, along with other exploratory clinical endpoints, all of which will help us guide our clinical development strategy for the program. In light of the expected readout of the Part 2 data, we are forgoing our usual earnings call and will instead host a conference call and webcast following the release of the Part 2 data."

Business Update

- In October 2023, the Company announced the appointment of Edward L. Williams to its Board of Directors. Mr. Williams is a well-recognized, senior global life sciences executive with extensive boardroom and commercial operations experience. He most recently served as a Special Advisor to the Chief Executive Officer of Ascendis Pharma, Inc. ("Ascendis"), and previously as their interim U.S. Chief Commercial Officer overseeing the preparation for Ascendis' first product launch. Mr. Williams has held key leadership positions as a Senior Vice President of biopharmaceuticals at Novo Nordisk Inc. and Vice President of Sales in the Respiratory and Dermatology Business Unit at Novartis Pharmaceuticals Corp.

Clinical Program Updates

Cystic Fibrosis (BX004)

- In October 2023, BiomX announced the completion of patient dosing in Part 2 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 ("CF"). The Company expects data from Part 2 will be announced later this month.
- In October 2023, BiomX presented data from Part 1 of its Phase 1b/2a trial evaluating BX004 for the treatment of chronic pulmonary infections caused by *P. aeruginosa* (*PsA*) bacteria in patients with CF at the North American Cystic Fibrosis Conference (NACFC). Highlights from the Part 1 data, which were initially reported in February 2023 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 the sputum of 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)
- In August 2023, the U.S. Food and Drug Administration ("FDA") granted BX004 Fast Track designation for the treatment of chronic respiratory infections caused by Pseudomonas aeruginosa (PsA) bacterial strains in patients with CF. The FDA's Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat

serious conditions and address significant unmet medical needs. The FDA defines addressing a significant unmet medical need as providing a therapy where none exists or providing a therapy which may be potentially better than available therapies. The benefits of Fast Track designation include but are not limited to early and frequent communication with the FDA throughout the entire drug development and review process. In addition, a drug with Fast Track designation is eligible for rolling submission and priority review of its Biologics License Application and/or New Drug Application. These assure that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.[1]

- 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 trial 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 trial evaluates the safety and efficacy of BX004 in at least 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio.

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.

Third Quarter 2023 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of September 30, 2023, were $23.4 million, compared to $34.3 million as of December 31, 2022. The decrease was primarily due to net cash used in operating activities. The Company estimates its cash runway is sufficient to fund operations into the third quarter of 2024.

- **Research and development ("R&D") expenses, net** were $5.6 million for the three months ended September 30, 2023, compared to $3.5 million for the same period in 2022. The increase was primarily attributed to an increase in expenses related to conducting the clinical trial of the Company's CF product candidate, BX004. Such increase was partially offset by reduced salaries and related expenses and stock-based compensation expenses that resulted from a workforce reduction, as well as the appreciation of the U.S. dollar against the NIS, which led to reduced salaries and related expenses in the Company's Israeli subsidiary.

- **General and administrative expenses** were $2.2 million for the three months ended September 30, 2023, compared to $2.6 million for the same period in 2022. The decrease primarily resulted from a reduction in the premium for the Company's directors' and officers' insurance policy, as well as a decrease in professional services expenses.

- **Net loss** for the third quarter of 2023 was $7.9 million, compared to $6.8 million for the same period in 2022.

- **Net cash used in operating activities** for the nine months ended September 30, 2023, was $15.0 million, compared to $21.9 million for the same period in 2022.

Given the close proximity between the Company's third quarter earnings report and the expected announcement of the Part 2 data from the Phase 1b/2a trial, BiomX management will forgo holding a call to review its third quarter 2023 earnings and will instead host a conference call and webcast following the release of the Part 2 data.

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 of announcement of results from Part 2 of the Phase 1b/2a trial, the potential benefits from Fast Track designation for BX004, and the potential of targeted phage therapy to treat infections in CF patients, the potential timeline for the program to treat Atopic Dermatitis, and when it discusses the estimate of the sufficiency of its cash runway, 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 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.

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Source: BiomX Inc.

[1] Source: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

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

	As of	
	September 30, 2023	**December 31, 2022**
ASSETS		
Current assets		
Cash and cash equivalents	22,450	31,332
Restricted cash	943	962
Short-term deposits	-	2,000
Other current assets	1,908	2,587
Total current assets	25,301	36,881
Non-current assets		
Operating lease right-of-use assets	3,576	3,860
Property and equipment, net	4,179	4,790
Total non-current assets	7,755	8,650
	33,056	45,531

	As of	
	September 30, 2023	**December 31, 2022**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade accounts payable	1,066	820
Current portion of lease liabilities	632	687
Other accounts payable	5,504	2,150
Current portion of long-term debt	5,582	4,282

Total current liabilities	12,784	7,939
Non-current liabilities		
Contract liability	1,976	1,976
Long-term debt, net of current portion	6,815	10,591
Operating lease liabilities, net of current portion	3,179	3,798
Other liabilities	148	188
Total non-current liabilities	12,118	16,553
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock, $0.0001 par value; Authorized - 1,000,000 shares as of September 30, 2023 and December 31, 2022. No shares issued and outstanding as of September 30, 2023 and December 31, 2022.	-	-
Common Stock, $0.0001 par value; Authorized - 120,000,000 shares as of September 30, 2023 and December 31, 2022. Issued –45,979,730 shares as of September 30, 2023 and 29,982,282 shares as of December 31, 2022. Outstanding 45,974,030 shares as of September 30, 2023 and 29,976,582 shares as of December 31, 2022.	3	2
Additional paid in capital	165,630	157,838
Accumulated deficit	(157,479)	(136,801)
Total stockholders' equity	8,154	21,039
	33,056	45,531

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Research and development ("R&D") expenses, net	5,641	3,536	14,023	13,049
Amortization of intangible assets	-	380	-	1,139
General and administrative expenses	2,154	2,633	6,053	7,471
Operating loss	7,795	6,549	20,076	21,659
Other income	(89)	(52)	(270)	(52)
Interest expenses	574	555	1,884	1,504
Finance income, net	(382)	(280)	(1,034)	(706)
Loss before tax	7,898	6,772	20,656	22,405
Tax expenses	8	8	22	26
Net loss	7,906	6,780	20,678	22,431
Basic and diluted loss per share of Common Stock	0.13	0.23	0.43	0.75
Weighted average number of shares of Common Stock outstanding, basic and diluted	60,587,718	29,907,812	48,196,566	29,812,542

Source: BiomX

Released November 14, 2023