May 15, 2025

BiomX Reports First Quarter 2025 Financial Results and Provides Business and Program Updates

In March 2025, BiomX announced positive topline results of the phase 2 trial evaluating BX211 for the treatment of diabetic foot osteomyelitis (DFO)

BX004 Phase 2b study in Cystic Fibrosis (CF) on track to report topline results in Q1 2026

In April 2025, shareholders approved exercise of warrants issued in $12 million in financings announced in February 2025; funds expected to provide runway through topline Phase 2b results for BX004 trial

The Company will host a conference call and webcast today at 2:00 PM ET

NESS ZIONA, Israel, May 15, 2025 (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 announced financial results for the first quarter ended March 31, 2025, and provided program and business updates.

"The first quarter of 2025 was a period of exceptional progress for BiomX, both on the corporate front and across our clinical pipeline," said Jonathan Solomon, Chief Executive Officer of BiomX. "The strength of the positive Phase 2 results from our BX211 program in diabetic foot osteomyelitis exceeded our expectations and received resounding endorsement from key opinion leaders and industry experts. These positive results represent a significant milestone for the field of bacteriophage therapy and further reinforce our platform's potential to address serious, resistant infections. Notably, the BX211 program has been supported to date by approximately $40 million in non-dilutive funding from the U.S. Defense Health Agency (DHA), which has identified an urgent need for new treatments to combat antibiotic-resistant infections in current and future conflict environments. The work received DHA and Department of Navy funding under an Other Transaction Authority (OTA) award through the Medical Technology Enterprise Consortium (MTEC) and managed by the Naval Medical Research Command (NMRC) – Naval Advanced Medical Development (NAMD). We are currently in discussions regarding potential next steps in partnership with the DHA to further advance this program. Looking ahead, we remain focused on our next major catalyst, which is the anticipated Phase 2b readout of BX004 in cystic fibrosis in the first quarter of next year, supported by the recent financings we secured to advance this program and extend our operational runway."

Clinical Program Updates

BX211 – phage for the treatment of DFO associated with *Staphylococcus aureus (S.*

aureus)

- In March 2025, BiomX announced positive results from the Company's DFO Adaptive Novel Care Evaluation (DANCE™) Phase 2 trial evaluating its BX211 phage treatment for DFO associated with *Staphylococcus aureus* (*S. aureus*).
- Key highlights from the Phase 2 trial results included:
  - *BX211 was found to be safe and well-tolerated.*
  - *BX211 produced sustained and statistically significant[1] Percentage Area Reduction (PAR) of ulcer size (p = 0.046 at week 12; p=0.052 at week 13), with a separation from placebo (standard of care) starting at week 7 and a difference greater than 40% by week 10.*
  - *Compared to placebo, BX211 also produced statistically significant[1] improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline) (p=0.048), and in reducing the expansion of ulcer area (p=0.017), compared to placebo.*
  - *BX211 demonstrated favorable trends compared to placebo across several additional clinical parameters, including: proportion of visits with no clinical evidence of infection; evidence of resolving DFO by MRI/X-ray at week 12; proportion of patients with abnormal C-Reactive Protein at baseline that achieved a reduction of CRP of at least 50% at any point in the study; and greater Wagner scale improvement[2].*
  - *Through week 13, BX211 demonstrated comparable efficacy against both Methicillin-susceptible and resistant strains, as well as against high and low biofilm producers—consistent with the orthogonal mechanism of phage therapy to antibiotics and its inherent anti-biofilm capabilities.*
  - *A key opinion leader (KOL) event discussing the Phase 2 results took place on April 3, 2025. A replay of the webcast is available here, the content of which does not form a part of this press release.*
- Pending feedback from the FDA, BiomX is planning for a Phase 2/3 clinical trial of BX211.

BX004 – fixed phage cocktail for the treatment of CF in patients with chronic pulmonary infections caused by *Pseudomonas aeruginosa* (*P. aeruginosa*)

- During the first quarter, BiomX initiated the exploration and analysis of real-world evidence in people with CF on the relationship between *P. aeruginosa* reduction and clinical outcomes. Regulatory discussions with the U.S. Food and Drug Administration ("FDA") and other regulatory authorities are expected in the second half of 2025, during which we intend to present our plans to analyze real-world evidence and seek endorsement that supports potential future regulatory filings.

Business Update

On April 21, 2025, a BiomX Special Meeting of stockholders took place during which shareholders approved the exercise of certain warrants issued as part of the Company's $12

million financings announced in February 2025. The completed financings will provide runway expected to support the Company's activities into the first quarter of 2026, when the Company anticipates the readout of topline Phase 2b results for BX004 for the treatment of CF patients with chronic pulmonary infections caused by *P. aeruginosa.*

First Quarter 2025 Financial Results

Cash balance and restricted cash as of March 31, 2025, were $21.2 million, compared to $18.0 million as of December 31, 2024. The increase was primarily due to funds raised in the February 2025 financings, partly offset by net cash used in operating activities. BiomX estimates its cash, cash equivalents and restricted cash are sufficient to fund its operations into the first quarter of 2026.

Research and development expenses, net were $5.3 million for the first quarter of 2025, compared to $4.1 million for the first quarter of 2024. The increase was primarily due to the following factors: preparations for the Phase 2b clinical trial of the Company's CF product candidate, BX004; an increase in expenses relating to the Phase 2 clinical trial of the Company's DFO product candidate, BX211; and an increase in rent and related expenses following the March 2024 acquisition of Adaptive Phage Therapeutics (APT). This increase was partly offset by higher grants BiomX received.

General and administrative expenses were $2.5 million for the first quarter of 2025, compared to $2.7 million for the first quarter of 2024. The decrease is primarily attributed to expenses incurred during 2024 in connection with the acquisition of APT completed in March 2024, partially offset by increased salaries and share-based compensation expenses.

Net loss was $7.7 million for the first quarter of 2025, compared to $17.3 million for the first quarter of 2024. The decrease is mainly due to the change in the fair value of the warrants issued as part of the Company's financing completed in March 2024.

Net cash used in operating activities for the three months ended March 31, 2025, was $8.7 million, compared to $11.4 million for the same period in 2024.

Conference Call and Webcast Details
BiomX will host a conference call and webcast on May 15, 2025, at 2:00 PM ET to discuss its first quarter 2025 financial results and to provide a corporate update.

Participant Dial-In Number:
+1 877-407-0724

Participant International Dial-In:
+1 201-389-0898

Webcast Link
Link

About BX211
BX211 is a phage treatment for the treatment of DFO associated with *S. aureus*. DFO is a bacterial infection of the bone that usually develops from an infected foot ulcer and is a leading cause of amputation in patients with diabetes. In March 2025, BiomX announced positive topline results from the Phase 2 trial in which BX211 was demonstrated to be safe

and well-tolerated and patients receiving BX211 exhibited statistically significant[1] and sustained reduction of ulcer size (PAR)(p = 0.046 at week 12; p=0.052 at week 13), with a separation from placebo starting at week 7 and a difference greater than 40% by week 10. In addition, BX211 also produced statistically significant[1] improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline, ulcer depth was classified according to deepest tissue involved as measured by swab) (p=0.048), and in reducing the expansion of ulcer area (p=0.017). Over the 12-week treatment period, all patients (treatment and placebo) were treated in accordance with standard of care, including with systemic antibiotic therapy as appropriate. BiomX is currently planning a Phase 2/3 trial, pending discussions and feedback from the FDA.

About BX004
BiomX is developing BX004, a fixed multi-phage cocktail, for the treatment of CF patients with chronic pulmonary infections caused by *P. aeruginosa*, a main contributor to morbidity and mortality in patients with CF. In November 2023, BiomX announced positive topline results from Part 2 of the Phase 1b/2a trial where BX004 demonstrated improvement in pulmonary function associated with a reduction in *P. aeruginosa* burden compared to placebo in a predefined subgroup of patients with reduced lung function (baseline FEV1<70%). BiomX expects to initiate a randomized, double blind, placebo-controlled, multi-center Phase 2b trial in CF patients with chronic *P. aeruginosa* pulmonary infections. The trial is designed to enroll approximately 60 patients randomized at a 2:1 ratio to BX004 or placebo. Treatment is expected to be administered via inhalation twice daily for a duration of 8 weeks. The trial is designed to monitor the safety and tolerability of BX004 and is designed to demonstrate improvement in microbiological reduction of *P. aeruginosa* burden and evaluation of effects on clinical parameters such as lung function measured by FEV1 and patient reported outcomes. Pending progress of the trial, topline results are expected in the first quarter of 2026. The FDA has granted BX004 Fast Track designation and Orphan Drug Designation.

About BiomX
BiomX is a clinical-stage company leading the development of natural and engineered phage cocktails and personalized phage treatments designed to target and destroy harmful bacteria for the treatment of chronic diseases with substantial unmet needs. BiomX discovers and validates proprietary bacterial targets and applies its BOLT (“BacteriOphage Lead to Treatment”) platform to customize 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 refers its anticipated timing for reporting results for its clinical assets as well as the design thereof, expected discussions with the FDA and other regulatory authorities and the DHA and results thereof, the potential of its candidates to address the substantial unmet needs of patients with intractable infections, and the estimates of the sufficiency of its cash, cash equivalents and restricted cash, it is

using 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. These risks and uncertainties include, but are not limited to, changes in applicable laws or regulations; the possibility that BiomX may be adversely affected by other economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in BiomX's drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies and early clinical trials may not be replicated in later clinical trials, BiomX's ability to enroll patients in its clinical trials, and the risk that any of its clinical trials may not commence, continue or be completed on time, or at all; decisions made by the FDA, DHA and other regulatory authorities; decisions made by investigational review boards at clinical trial sites and publication review bodies with respect to our development candidates; BiomX's ability to obtain, maintain and enforce intellectual property rights for its platform and development candidates; its potential dependence on collaboration partners; competition; uncertainties as to the sufficiency of BiomX's cash resources to fund its planned activities for the periods anticipated and BiomX's ability to manage unplanned cash requirements; and general economic and market conditions. 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 25, 2025, 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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[1] All p-values described in this release are non-adjusted

[2] The Wagner Scale is a clinical grading system used to classify the severity of diabetic foot ulcers, ranging from 0 (intact skin) to 5 (extensive gangrene).

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

	As of	
	March 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	20,116	16,856
Restricted cash	953	958
Other current assets	2,464	2,706
Total current assets	23,533	20,520
Non-current assets		
Non-current restricted cash	161	161
Operating lease right-of-use assets	5,209	5,457
Property and equipment, net	4,701	5,045
In-process Research and development asset	12,050	12,050
Total non-current assets	22,121	22,713
	45,654	43,233

	As of	
	March 31, 2025	December 31, 2024
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade accounts payable	1,670	1,882
Current portion of lease liabilities	1,141	1,130
Other accounts payable	4,210	5,255
Total current liabilities	7,021	8,267
Non-current liabilities		
Operating lease liabilities, net of current portion	8,151	8,454
Other liabilities	79	77
Warrants	5,904	2,287
Total non-current liabilities	14,134	10,818
Commitments and Contingencies (Note 6)		
Stockholders' equity		

Preferred Stock, $0.0001 par value; Authorized – 1,000,000 shares as of March 31, 2025 and December 31, 2024. Issued and outstanding- 147,735 as of March 31, 2025 and December 31, 2024.	18,645	18,645
Common Stock, $0.0001 par value; Authorized – 750,000,000 shares as of March 31, 2025 and December 31, 2024. Issued and outstanding- 24,966,053 shares as of March 31, 2025 and 18,176,661 shares as of December 31, 2024.	7	6
Additional paid in capital	194,203	186,194
Accumulated deficit	(188,356)	(180,697)
Total stockholders' equity	24,499	24,148
	45,654	43,233

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

	Three Months Ended March 31,	
	2025	**2024**
Research and development ("R&D") expenses, net	5,250	4,105
General and administrative expenses	2,506	2,680
Operating loss	7,756	6,785
Other expenses (income)	6	(88)
Interest expenses	5	850
Loss (income) from change in fair value of warrants	(914)	8,010
Finance expense, net	805	1,765
Loss before tax	7,658	17,322
Tax expenses	1	5
Net loss	7,659	17,327
Basic and diluted loss per share of Common Stock (*)	0.33	2.78
Weighted average number of shares used in computing basic and diluted loss per share of Common Stock	23,103,105	6,229,228

Source: BiomX