

March 25, 2025



BiomX Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business and Program Updates

- *In February 2025, BiomX announced a series of financings with total gross proceeds of approximately \$12 million to support completion of Phase 2b study of BX004; topline results anticipated in Q1 2026*
- *Topline Phase 2 results for BX211 in diabetic foot osteomyelitis (DFO) expected by end of March 2025*
- *Initiated exploration and analysis of real-world evidence in people with Cystic Fibrosis (CF) on the relationship between Pseudomonas aeruginosa reduction and clinical outcomes, ahead of expected regulatory discussions in second half of 2025*

NESS ZIONA, Israel, March 25, 2025 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE, the "Company" or "BiomX"), a clinical-stage company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today announced financial results for the fourth quarter and full year ended December 31, 2024, and provided program and business updates.

"BiomX is in the process of finalizing the analysis of topline results from the Phase 2 trial of BX211 in DFO, with readout expected by the end of the quarter," said Jonathan Solomon, Chief Executive Officer of BiomX. "In the first quarter of 2025, we also completed a financing round that generated \$12 million in gross proceeds. We believe that these resources will enable readout of BX004 Phase 2b topline results, which are anticipated in the first quarter of 2026. In addition, the funds will support the analysis of real-world evidence to assess the relationship between *Pseudomonas aeruginosa* reduction and clinical outcomes in individuals with cystic fibrosis ahead of regulatory discussions expected in the second half of this year."

Clinical Program Updates

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

- BiomX expects to report initial topline results from the Phase 2 trial evaluating BX211 for the treatment of DFO by the end of March 2025. The safety, tolerability, and efficacy of BX211 are being evaluated in a randomized, double-blind, placebo-controlled, multi-center Phase 2 study for individuals with DFO associated with *S. aureus*. The topline results will evaluate healing of the wound associated with osteomyelitis at Week 13. The Phase 2 study design was guided in part by experience with numerous compassionate cases using phage therapy for the treatment of DFO and osteomyelitis.

- In October 2024, BiomX received a milestone payment from the U.S. Defense Health Agency (DHA), approved to support the BX211 Phase 2 trial in DFO. To date, total non-dilutive funding received for this study has reached \$36.8 million.

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

- Trial remains on track to report topline results in the first quarter of 2026. During the fourth quarter of 2024, BiomX encountered manufacturing delays relating to scaling up of materials for the larger phase 2 trial. These challenges have since been resolved, supporting continued progress in the program.
- Discussions with the U.S. Food and Drug Administration (FDA) and other regulatory authorities are expected during the second half of 2025, during which the Company intends to present its analyses of real-world evidence and will seek to obtain endorsement that supports potential future regulatory filings.

Business Update

BiomX entered into a securities purchase agreement with investors in February 2025 in connection with a registered direct offering, concurrent private placement of the Company's securities, and simultaneous exercise of certain existing common stock purchase warrants. Aggregate gross proceeds were approximately \$12 million, before deducting placement agent fees and other offering expenses. Following these offerings, the Company expects to have sufficient funding to reach substantial inflection points, including topline results of its Phase 2b study of BX004 in the first quarter of 2026.

Full Year 2024 Financial Results

Cash balance and restricted cash as of December 31, 2024 were \$18.0 million, compared to \$15.9 million as of December 31, 2023. The increase was primarily due to funds raised in the Company's March 2024 financing, partly offset by net cash used in operating activities. The December 31, 2024 cash balance does not reflect the additional \$12 million in gross proceeds raised in the Company's February 2025 financing round. BiomX estimates its cash, cash equivalents and short-term deposits are sufficient to fund its operations into the first quarter of 2026.

Research and development expenses, net were \$24.7 million for the year ended December 31, 2024, compared to \$16.7 million for the prior year. 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 acquisition of Adaptive Phage Therapeutics (APT). This increase was partly offset by higher governmental grants BiomX received.

General and administrative expenses were \$11.8 million for the year ended December 31, 2024, compared to \$8.7 million for the prior year. The increase is primarily attributed to a consolidation of expenses following APT's acquisition, incorporating the combined workforce, increased professional services, and additional subcontractor expenses.

Goodwill impairment was \$0.8 million for the year ended December 31, 2024, following an

impairment of the Company's goodwill resulting from the APT acquisition. The Company had no goodwill impairment in the year ended December 31, 2023.

IPR&D impairment was \$3.2 million for the year ended December 31, 2024, following the Company's quantitative assessment for in process research and development (IPR&D) impairment. The Company had no IPR&D impairment in the year ended December 31, 2023.

Long-lived assets impairment was \$4.0 million for the year ended December 31, 2024, after evaluating the right-of-use asset and related leasehold improvements following the Company's decision to cease the use of the property in Gaithersburg, Maryland and make it available for sublease. The Company had no long-lived assets impairment in the year ended December 31, 2023.

Net loss for 2024 was \$17.7 million, compared to \$26.2 million for the prior year. The decrease is mainly due to the change in the fair value of the warrants issued as part of the Company's March 2024 financing.

Net cash used in operating activities for the year ended December 31, 2024 was \$37 million, compared to \$21.3 million for the same period in 2023.

Conference Call and Webcast

BiomX intends to host a conference call and a live audio webcast at a later date to discuss its fourth quarter and full year 2024 financial results, in conjunction with its expected announcement of initial topline results from its Phase 2 trial for subjects with DFO.

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 U.S. Food and Drug Administration ("FDA") has granted BX004 Fast Track designation and Orphan Drug Designation.

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. The ongoing randomized, double-blind, placebo-controlled, multi-center Phase 2 trial investigating the safety, tolerability, and efficacy of BX211 for subjects with DFO associated with *S. aureus* has finished enrollment of

patients, randomized at a 2:1 ratio of BX211 to placebo. BX211 or placebo is designed to be administered weekly, by topical and IV route at Week 1 and by the topical route only at each of Weeks 2-12. Over the 12-week treatment period, all subjects are expected to continue to be treated in accordance with standard of care which will include antibiotic treatment as appropriate. A first readout of study topline results is expected at Week 13 evaluating healing of the wound associated with osteomyelitis. This readout is expected in the first quarter of 2025.

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 to its anticipated timing for reporting results for its clinical assets as well as the design thereof, expected discussions with the FDA 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 short-term deposits, 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 and other regulatory authorities; 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

Current portion of lease liabilities	1,130	666
Other account payables	5,255	3,344
Current portion of long-term debt	-	5,785
Total current liabilities	<u>8,267</u>	<u>11,176</u>

Non-current liabilities

Contract liability	-	1,976
Long-term debt, net of current portion	-	5,402
Operating lease liabilities, net of current portion	8,454	3,239
Other liabilities	77	155
Private Placement Warrants	2,287	-
Total non-current liabilities	<u>10,818</u>	<u>10,772</u>

Commitments and Contingencies

Stockholders' equity

Preferred Stock, \$0.0001 par value; Authorized - 1,000,000 shares as of December 31, 2024 and December 31, 2023. Issued and outstanding – 147,735 as of December 31, 2024. No shares issued and outstanding as of December 31, 2023.

18,645 -

Common stock, \$0.0001 par value ("Common Stock"); Authorized - 750,000,000 shares as of December 31, 2024 and 120,000,000 shares as of December 31, 2023. Issued and outstanding – 18,176,661 and 4,723,380 as of December 31, 2024 and December 31, 2024, respectively. (*)

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Additional paid in capital	186,194	166,048
Accumulated deficit	<u>(180,697)</u>	<u>(162,970)</u>
Total Stockholders' equity	<u>24,148</u>	<u>3,081</u>
	<u>43,233</u>	<u>25,029</u>

(*) All share amounts have been retroactively adjusted to reflect a 1-for-10 reverse share split effective August 26, 2024.

BIOMX INC.

CONSOLIDATED STATEMENTS OF OPERATIONS (USD in thousands, except share and per share data)

Year ended December
31,

	<u>2024</u>	<u>2023</u>
Research and development (“R&D”) expenses, net	24,663	16,698
General and administrative expenses	11,776	8,650
Goodwill impairment	801	-
IPR&D impairment	3,237	-
Long-lived assets impairment	4,046	-
Operating loss	44,523	25,348
Other income	(2,143)	(357)
Interest expenses	873	2,404
Finance expense (income), net	919	(1,249)
Income from change in fair value of Private Placement Warrants	(26,458)	-
Loss before tax	17,714	26,146
Tax expenses	13	23
Net Loss	17,727	26,169
Basic loss per share of Common Stock	1.47	5.1
Diluted loss per share of Common Stock	3.36	5.1
Weighted average number of shares used in computing basic loss per share of Common Stock (*)	12,019,401	5,133,093
Weighted average number of shares used in computing diluted loss per share of Common Stock (*)	13,138,106	5,133,093

(*) All share amounts have been retroactively adjusted to reflect a 1-for-10 reverse share split effective August 26, 2024.



Source: BiomX