November 14, 2024

BiomX Announces Third Quarter 2024 Financial Results and Provides Business and Program Updates

BX211 Phase 2 for treatment of Diabetic Foot Osteomyelitis (DFO) patient enrollment completed and on track to report topline results in Q1 2025

BX004 Phase 2b study in Cystic Fibrosis (CF) is now expected to report topline results in H1 2026 following resolved manufacturing delays

Company to host conference call and webcast today at 8:00AM ET

NESS ZIONA, Israel, Nov. 14, 2024 (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 announces financial results for its third quarter ended September 30, 2024, and provides program and business updates.

"We continue to be encouraged by the progress in diabetic foot osteomyelitis (DFO), having achieved an important milestone by completing patient enrollment for the BX211 program. We remain on track to share topline (through Week 13) Phase 2 results of BX211 in the first quarter of 2025," said Jonathan Solomon, BiomX's Chief Executive Officer. "BX211 is a novel phage treatment for DFO and holds the potential to prevent amputations associated with intractable infections that have penetrated the bone in patients with diabetic foot ulcers. In October 2024, we received additional non-dilutive funding from the US Defense Health Agency ("DHA") to continue advancing the DFO program and are grateful for the continued support provided by the DHA. During the last quarter, our CF program experienced manufacturing delays, which have been resolved, and we now expect to report topline results for BX004 in our Phase 2b study in the first half of 2026. Results from our Phase 1b/2a study for the BX004 program in CF continue to receive positive feedback at major scientific conferences, including those attended during the past quarter, and we remain confident about the future of this program and its potential to address the significant unmet medical need of CF patients."

Clinical Program Updates

BX211 – personalized phage for the treatment of DFO associated with *Staphylococcus aureus*

- Patient enrollment for BX211 Phase 2 trial in DFO was completed. The safety, tolerability, and efficacy of BX211 is currently being evaluated in a randomized, double-blind, placebo-controlled, multi-center Phase 2 trial for subjects with DFO. Initial topline results of the Phase 2 trial (Week 13) are expected in the first quarter of 2025. 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, the Company received additional funding from the DHA to advance the BX211 trial in DFO. To date, total non-dilutive funding received towards this trial has totaled $36.8 million.

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

- In the third quarter, BiomX presented positive safety and efficacy data from the Phase 1b/2a trial of BX004 at the North American Cystic Fibrosis conference and European Respiratory Society's annual meeting.
- Key highlights from Part 2 of the Phase 1b/2a study included:

    - Study drug was safe and well-tolerated, with no related SAEs (serious adverse events) or related APEs (acute pulmonary exacerbations) to study drug.
    - In the BX004 arm, 3 out of 21 (14.3%) patients converted to sputum culture negative for *P. aeruginosa* (PsA) after 10 days of treatment (including 2 patients after 4 days) compared to 0 out of 10 (0%) in the placebo arm, in subjects with quantitative sputum PsA CFU at baseline. Lung function, as measured by forced expiratory volume in 1 second (FEV1), increased in subjects receiving the cocktail (+5.66%) compared to placebo (-3.23%), in the subgroup on continuous inhaled antibiotics (same antibiotic with no cycling or alternating regimen), on elexacaftor / tezacaftor / ivacaftor (ETI) and with lower lung function (FEV1 <70%).

Business Updates

- In August 2024, the Company effected a 1-for-10 reverse stock split of its issued share capital combining and converting every ten issued and outstanding shares of Common Stock into one issued and outstanding new share of Common Stock. The Reverse Stock Split has not changed the par value of the Common Stock or the authorized number of shares of Common Stock or preferred stock.
- In October 2024, the Company also announced a mandatory separation of its units that traded under the ticker symbol "PHGE.U", each of which consisted of one share of Common Stock and one warrant to purchase one-half of a share of Common Stock (the "Units"). Each warrant (a "Warrant") entitled the holder to purchase one-half of a share of Common stock at a price of $115 per share. The Units were mandatorily separated and no longer trade on the NYSE American. In the separation, Unit holders received the number of shares of Common Stock and Warrants underlying such Units. The Warrants expired on October 28, 2024.

Third Quarter 2024 Financial Results

Cash balance, short-term deposits and restricted cash as of September 30, 2024, were $24.7 million, compared to $30.7 million as of December 31, 2023. The decrease was primarily due to net cash used in operating activities and the repayment in April 2024, of the Company's prior debt facility, which was partially offset by the Company's private placement financing of $50 million in March 2024. BiomX estimates its cash, cash equivalents and short-term deposits are sufficient to fund its operations into the fourth quarter of 2025.

Research and development expenses, net were $7.3 million for the third quarter of 2024, compared to $5.6 million for the third quarter of 2023. 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 grants BiomX received.

General and administrative expenses were $3.2 million for the third quarter of 2024, compared to $2.2 million for the third quarter of 2023. The increase is primarily attributed to a full quarter consolidation of expenses following APT's acquisition, incorporating the combined workforce, increased professional services, and additional subcontractor expenses.

The Company recognized **goodwill** impairment expenses of $801 thousand in the third quarter of 2024, resulting from the fair value assessment of goodwill related to the 2024 APT acquisition. No comparable goodwill impairment expenses were recorded in the same period of 2023.

Net income was $9.6 million for the third quarter of 2024, compared to a net loss of $7.9 million for the third quarter of 2023. The increase is mainly due to the change in the fair value of the warrants issued as part of the March 2024 financing.

Net cash used in operating activities for the nine months ended September 30, 2024, was $30.7 million, compared to $15.0 million for the same period in 2023.

Conference Call and Webcast Details

BiomX will host a conference call and webcast on November 14, 2024, at 8:00 a.m. ET to discuss its third quarter 2024 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 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 half 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 personalized phage treatment for the treatment of DFO associated with *S. aureus*. The personalized phage treatment tailors a specific phage selected from a proprietary phage-bank according to the specific strain of *S. aureus* biopsied and isolated from each patient. 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 for a randomized at a 2:1 ratio to BX211 or 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, followed by a second readout at Week 52 evaluating amputation rates and resolution of osteomyelitis based on X-ray, clinical assessments, and established biomarkers (ESR and CRP). These readouts are expected in the first quarter of 2025 and the first quarter of 2026, respectively.

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, 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, BiomX's ability to regain compliance with the listing standards set forth in the NYSE American Company Guide by November 23, 2025; 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 and Exchange Commission (the "SEC") on April 4, 2024, 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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BIOMX INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)
(unaudited)

	As of

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	23,537	14,907
Restricted cash	1,114	957
Other current assets	3,665	1,768
Total current assets	28,316	17,632
Non-current assets		
Other assets	96	-
Operating lease right-of-use assets	9,700	3,495
Property and equipment, net	6,581	3,902
In-process Research and development (“IPR&D”) assets	15,287	-
Total non-current assets	31,664	7,397
	59,980	25,029

	As of	
	September 30, 2024	December 31, 2023
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities		
Trade accounts payable	2,779	1,381
Current portion of lease liabilities	1,096	666
Other accounts payable	5,069	3,344
Current portion of long-term debt	-	5,785
Total current liabilities	8,944	11,176
Non-current liabilities		
Contract liability	-	1,976
Long-term debt, net of current portion	-	5,402
Operating lease liabilities, net of current portion	8,651	3,239
Other liabilities	161	155
Private Placement Warrants	4,328	-
Total non-current liabilities	13,140	10,772

Commitments and Contingencies (Note 7)

Stockholders' equity

Preferred Stock, $0.0001 par value; Authorized – 1,000,000 shares as of September 30, 2024 and December 31, 2023. Issued and outstanding- 14,774 as of September 30, 2024. No shares issued and outstanding as of December 31, 2023.	18,645	-
Common Stock, $0.0001 par value; Authorized – 750,000,000 shares as of September 30, 2024 and 120,000,000 shares as of December 31, 2023. Issued and outstanding -18,176,602 shares as of September 30, 2024 and 4,723,320 shares as of December 31, 2023. (*)	6	3
Additional paid in capital	185,429	166,048
Accumulated deficit	(166,184)	(162,970)
Total stockholders' equity	37,896	3,081
	59,980	25,029

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,	
	2024	**2023**	**2024**	**2023**
Research and development ("R&D") expenses, net	7,279	5,641	18,281	14,023
General and administrative expenses	3,248	2,154	8,756	6,053
Goodwill impairment	801	-	801	-
Operating loss	11,328	7,795	27,838	20,076
Other income	(84)	(89)	(2,189)	(270)
Interest expenses	5	574	868	1,884
Income from change in fair value of Private Placement Warrants	(20,559)	-	(24,417)	-
Finance expense (income), net	(332)	(382)	1,104	(1,034)

Loss (income) before tax	(9,642)	7,898	3,204	20,656
Tax expenses	-	8	10	22
Net loss (income)	(9,642)	7,906	3,214	20,678
Basic loss (earnings) per share of Common Stock (*)	(0.31)	1.30	0.32	4.29
Diluted loss per share of Common Stock (*)	(0.31)	1.30	2.45	4.29
Weighted average number of shares used in computing basic loss (earnings) per share of Common Stock	16,366,122	6,058,774	9,944,267	4,819,658
Weighted average number of shares used in computing diluted loss per share of Common Stock	16,387,633	6,058,774	11,294,879	4,819,658

Source: BiomX