

August 15, 2024



BiomX Reports Second Quarter 2024 Financial Results and Provides Business and Program Updates

BiomX anticipates reporting important results in 2025 for two clinical assets from the Company's leading phage therapy pipeline

Recent stockholder vote approves conversion of Series X Non-Voting Convertible Preferred Stock (issued upon merger with Adaptive Phage Therapeutics and concurrent financing) to BiomX's common stock

Company will host a conference call and webcast today at 8:00 am ET

GAITHERSBURG, Md., Aug. 15, 2024 (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 second quarter ended June 30, 2024, and provided program and business updates.

"We are excited by the progress of our programs and the continued integration of our leading phage therapy pipeline following the merger with Adaptive Phage Therapeutics ("APT") and the concurrent financing earlier this year," said Jonathan Solomon, Chief Executive Officer of BiomX. "As part of this progress, we recently announced the stockholder vote approving conversion of the preferred stock the Company issued to common stock. Our focus continues to be on advancing our clinical-stage candidates — BX004 and BX211 — toward reporting of key Phase 2 findings in 2025. This includes our anticipated readout in the first quarter of 2025 of topline results for BX211, currently in an ongoing Phase 2 study for the treatment of diabetic foot osteomyelitis associated with *Staphylococcus aureus*."

Clinical Program Updates

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

- During the second quarter, the Company presented positive safety and efficacy results from the Phase 1b/2a trial evaluating the Company's novel phage cocktail, BX004, including at the 47th European Cystic Fibrosis Conference and ASM Microbe 2024.
- Presented highlights from the Part 2 data of the Phase 1b/2a study have 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* after 10 days of treatment (including 2 patients after 4

days) compared to 0 out of 10 (0%) in the placebo arm¹. BX004 vs. placebo showed a clinical effect in a predefined subgroup of patients with reduced baseline lung function (FEV1<70%). Differences between groups at Day 17: relative FEV1 improvement of 5.67% (change from baseline +1.46 vs. -4.21) and +8.87 points in CFQR respiratory symptom scale (change from baseline +2.52 vs. -6.35).

- BiomX anticipates initiating a Phase 2b trial of BX004 in CF patients with chronic *P. aeruginosa* pulmonary infections, with results expected in the third quarter of 2025.

BX211 - personalized phage treatment for patients with diabetic foot osteomyelitis ("DFO") associated with *Staphylococcus aureus* (*S. aureus*)

- 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. The study is anticipated to enroll up to 45 patients. Initial topline results (through Week 13) for the Phase 2 trial 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.

Business Update

- In July 2024, BiomX announced that the Company's stockholders voted to approve, among other things, a proposal to convert BiomX's outstanding Series X Non-Voting Convertible Preferred Stock ("Series X Preferred Stock") into shares of BiomX's common stock. The Series X Preferred Stock was issued upon BiomX's acquisition of APT ("the Merger") and a concurrent \$50 million financing (the "Financing"), which were consummated in March 2024. As a result of the stockholder vote, each share of Series X Preferred Stock issued in the Merger and the private placement was converted into 1,000 shares of BiomX common stock, subject to certain beneficial ownership limitations set by certain investors in the Financing. Subject to such beneficial ownership limitations to date, 109,152 shares of Series X Preferred Stock were converted to 109,152,000 shares of the Company's common stock that were added to the Company's outstanding share count.
- Also in July 2024, BiomX received a notification ("Acceptance Letter") from the NYSE American LLC ("NYSE American") stating that the NYSE American accepted the Company's previously submitted plan to regain compliance with the NYSE American's listing standards. In the Acceptance Letter, the NYSE American confirmed that it has granted the Company until November 23, 2025 (the "Plan Period") to regain compliance with the continued listing standards. As previously disclosed, on May 23, 2024, BiomX received a deficiency letter from the NYSE American indicating that the Company was not in compliance with the NYSE American continued listing standards set forth in Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide. The Acceptance Letter has no immediate impact on the listing of the Company's shares of common stock, which will continue to be listed and traded on the NYSE American during the Plan Period, subject to the Company's compliance with the other listing requirements of the NYSE American.

Second Quarter 2024 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of June 30, 2024, were \$32.7 million, compared to \$30.7 million as of June 30, 2023. The increase was primarily due to the Company's private placement financing of \$50 million in March 2024, which was partially offset by net cash used in operating activities and the repayment of a debt facility. BiomX estimates its cash, cash equivalents and short-term deposits are sufficient to fund its operations through the fourth quarter of 2025.
- **Research and development expenses, net** were \$6.9 million for the second quarter of 2024, compared to \$3.8 million for the second quarter of 2023. The increase was primarily due to preparations for Phase 2b in the clinical trial of our CF product candidate, BX004, as well as expenses related to our clinical trial of the DFO product candidate, BX211. In addition, the second quarter of 2024 represents the first full quarter post-merger, incorporating the combined workforce. This was partly offset by higher grants received.

General and administrative expenses were \$2.8 million for the second quarter of 2024, compared to \$2.3 million for the second quarter of 2023. This increase primarily reflects the full consolidation of expenses following the Merger. The second quarter of 2024 represents the first full quarter post-merger, incorporating the combined workforce, increased professional services, and additional subcontractor costs.

- **Net income** was \$4.5 million for the second quarter of 2024, compared to a net loss of \$6.4 million for the second quarter of 2023. The increase is mainly due to the change in the fair value of the warrants issued as part of the Financing.
- **Net cash used in operating activities** for the six months ended June 30, 2024, was \$22.6 million, compared to \$9.1 million for the same period in 2023.

Conference Call and Webcast Details

BiomX will host a conference call and webcast on August 15, 2024, at 8:00 a.m. ET to discuss its second quarter 2024 financial results and to provide a corporate update.

Conference Call Dial-In Information

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

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

Webcast: [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, results are expected in the third quarter 2025. 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* is expected to enroll up to 45 subjects 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 to compliance with NYSE American Continued Listing Standards, 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 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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¹ In patients that had quantitative CFU levels at study baseline

	As of	
	June 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	31,611	14,907
Restricted cash	1,103	957
Other current assets	2,367	1,768
Total current assets	35,081	17,632
Non-current assets		
Other assets	378	-
Operating lease right-of-use assets	10,423	3,495
Property and equipment, net	6,949	3,902
In-process Research and development ("IPR&D") assets and Goodwill	15,788	-
Total non-current assets	33,538	7,397
	68,619	25,029

	As of	
	June 30, 2024	December 31, 2023
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade accounts payable	3,240	1,381
Current portion of lease liabilities	1,047	666
Other accounts payable	3,018	3,344
Current portion of long-term debt	-	5,785
Total current liabilities	7,305	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	8,849	3,239
Other liabilities	153	155
Private Placement Warrants	24,887	-

Total non-current liabilities	33,889	10,772
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Commitments and Contingencies (Note 7)

Stockholders' equity

Preferred Stock, \$0.0001 par value; Authorized – 1,000,000 shares as of June 30, 2024 and December 31, 2023. Issued and outstanding- 256,887 as of June 30, 2024. No shares issued and outstanding as of December 31, 2023.	32,420	-
Common Stock, \$0.0001 par value; Authorized – 120,000,000 shares as of June 30, 2024 and December 31, 2023. Issued and outstanding -69,806,447 shares as of June 30, 2024 and 45,979,930 shares as of December 31, 2023.	5	3
Additional paid in capital	170,826	166,048
Accumulated deficit	(175,826)	(162,970)
Total stockholders' equity	27,425	3,081
	68,619	25,029

BIOMX INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development ("R&D") expenses, net	6,897	3,818	11,002	8,382
General and administrative expenses	2,828	2,255	5,508	3,899
Operating loss	9,725	6,073	16,510	12,281
Other income	(2,017)	(90)	(2,105)	(181)
Interest expenses	13	745	863	1,310
Income from change in fair value of Private Placement Warrants	(11,868)	-	(3,858)	-
Finance expense (income), net	(329)	(325)	1,436	(652)

Loss (income) before tax	(4,476)	6,403	12,846	12,758
Tax expenses	5	8	10	14
Net loss (income)	(4,471)	6,411	12,856	12,772
Basic loss (earnings) per share of Common Stock	(0.01)	0.12	0.19	0.31
Diluted loss per share of Common Stock	0.07	0.12	0.19	0.31
Weighted average number of shares used in computing basic loss (earnings) per share of Common Stock	69,809,421	51,552,923	66,059,510	41,860,338
Weighted average number of shares used in computing diluted loss per share of Common Stock	107,501,932	51,552,923	66,059,510	41,860,338



Source: BiomX