



## BiomX Reports Third Quarter 2025 Financial Results and Provides Program Updates

November 12, 2025

*Positive FDA feedback confirms clear clinical pathway for BX011 targeting *S. aureus* in Diabetic Foot Infections, building on Company's prior Phase 2 success*

*BiomX expects FDA feedback on BX004 clinical hold imminently; Enrollment and dosing of patients outside the U.S. are continuing in accordance with protocol*

*Positive FDA feedback received in October provided guidance for potential Phase 3 development pathways of BX004*

*BiomX will host a conference call and webcast today at 8:30 AM ET*

NESS ZIONA, Israel, Nov. 12, 2025 (GLOBE NEWSWIRE) -- BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage company advancing novel natural and engineered phage therapies targeting specific pathogenic bacteria, today announced financial results for the third quarter ended September 30, 2025, and provided recent clinical and corporate updates.

"This past quarter was defined by significant advancements in our regulatory discussions with the Food and Drug Administration (FDA) across our pipeline," said Jonathan Solomon, Chief Executive Officer of BiomX. "For BX004, we anticipate imminent FDA feedback regarding the clinical hold, and we have already received supportive guidance outlining potential Phase 3 development pathways that reflect recognition of the significant unmet need among cystic fibrosis patients treated with CFTR (Cystic Fibrosis Transmembrane Conductance Regulator) modulators. In parallel, we received additional positive FDA feedback confirming a clear clinical development path for BX011, our new fixed multi-phage cocktail targeting *Staphylococcus aureus* (*S. aureus*) in diabetic foot infections, building on the success of our prior Phase 2 trial in diabetic foot osteomyelitis."

### Clinical Program Updates

#### **BX004 – Fixed phage cocktail for chronic *Pseudomonas aeruginosa* (*P. aeruginosa*) in patients with cystic fibrosis (CF)**

- In July 2025, BiomX successfully initiated patient dosing in its Phase 2b trial of BX004, a randomized, double-blind, placebo-controlled, multicenter study in approximately 60 CF patients with chronic *P. aeruginosa* infections. The trial is designed to measure multiple efficacy endpoints, including reduction in bacterial burden, improvements in lung function, and enhanced quality of life.
- In October 2025, BiomX received written FDA feedback recognizing the significant unmet need among cystic fibrosis patients treated with CFTR modulators. The FDA outlined potential Phase 3 development pathways, including opportunities for population enrichment and optimized trial design.
- The FDA has placed a clinical hold on the Phase 2b study as it reviews data submitted by BiomX on third-party nebulizer used to deliver BX004; no concerns were raised in the clinical hold notification regarding the BX004 drug candidate. Enrollment and dosing of patients outside the U.S. is continuing in accordance with protocol. Feedback on the U.S. clinical hold of BX004 is expected imminently.
- The Company expects to report topline results from the Phase 2b study in the first quarter of 2026.

#### **BX011 – Fixed phage cocktail for patients with diabetic foot infections (DFI) associated with *S. aureus***

- Earlier this month, BiomX announced that it has received positive feedback from the FDA on the proposed clinical development pathway for BX011, a next-generation fixed multi-phage cocktail targeting *S. aureus* in DFI. BiomX plans to prioritize DFI as the lead indication for regulatory development, ahead of the Company's potential future development of BX211 in diabetic foot osteomyelitis (DFO).
- This plan builds on the significant positive Phase 2 results from BX211 in diabetic foot osteomyelitis (DFO), while enabling the Company to target the large DFI patient population.
- BiomX is currently planning a Phase 2a trial for BX011 following recent discussions and feedback from the FDA, with no additional non-clinical studies required, pending sufficiency of financial resources.
- The Company is in continued discussions with the U.S. Defense Health Agency (DHA) regarding next steps to support the utilization of phage therapy to target *S. aureus*-driven infections.
- In the third quarter, BiomX attended Infectious Disease Week 2025 in which the Company presented previously reported results targeting *S. aureus* during oral and poster presentations. Separately, during attendance at DFCon 2025 – Diabetic Foot Conference, the abstract accepted for poster presentation was awarded Best Clinical Abstract Award.

### Third Quarter 2025 Financial Results

**Cash balance and restricted cash** as of September 30, 2025, were \$8.1 million, compared to \$18 million as of December 31, 2024. The decrease was primarily due to net cash used in operating activities, partially offset by funds raised in the Company's February 2025 financing. 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 \$6.1 million for the third quarter of 2025, compared to \$7.3 million for the third quarter of 2024. The decrease was primarily driven by reduced salary expenses due to workforce reductions, lower rent expenses following a right-of-use asset impairment in 2024, and decreased expenses related to the CF product candidate, primarily due to the significantly higher manufacturing costs that were incurred in 2024. Such decrease was partially offset by an increase in depreciation expenses attributable to the accelerated depreciation of leasehold improvements resulting from the modification of our office lease agreement in Ness Ziona, Israel, as well as by decreased grant funding from the Medical Technology Enterprise Consortium (under the DHA) and the Israel Innovation Authority.

**General and administrative expenses** were \$2.4 million for the third quarter of 2025, compared to \$3.2 million for the third quarter of 2024. The decrease was primarily driven by reduced salary and share-based compensation expenses and lower legal and other professional service fees. This decrease was partially offset by an increase in depreciation expenses attributable to the accelerated depreciation of leasehold improvements resulting from the modification of our office lease agreement in Ness Ziona, Israel.

**Net loss** was \$9.2 million for the third quarter of 2025, compared to net income of \$9.6 million for the third quarter of 2024. The decrease was mainly due to the change in the fair value of warrants issued as part of the Company's March 2024 financing.

**Net cash used in operating activities** for the nine months ended September 30, 2025, was \$22.0 million, compared to \$30.7 million for the same period in 2024.

#### **Conference Call and Webcast Details**

BiomX will host a conference call and webcast on November 12, 2025, at 8:30 AM ET to discuss its third quarter 2025 financial results and to provide a corporate update.

#### **Conference Call**

<https://register-conf.media-server.com/register/Blf7434533b852452a822a8e5f48b669e2>

#### **Webcast Link**

<https://edge.media-server.com/mmc/p/s6tntmgo>

#### **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%). Pending resolution of the clinical hold imposed by the FDA, BiomX expects to enroll up to approximately 60 patients in a randomized, double blind, placebo-controlled, multi-center Phase 2b trial of BX004 in CF patients with chronic *P. aeruginosa* lung infections. The 8-week study will assess lung function, bacterial load, and quality of life metrics. BX004 has received FDA Fast Track and Orphan Drug Designations.

#### **About BX011**

BX011 is a fixed multi-phage cocktail designed to treat *S. aureus*-associated DFI. DFI is a serious bacterial infection which frequently develops from ulcers on the foot and is a leading cause of amputation in patients with diabetes. BX011 incorporates multiple proprietary phages, including phage previously evaluated in the Company's former DFO trial, to provide broad and potent coverage against this *S. aureus* in DFI patients. Following the FDA's supportive feedback, BiomX plans to initiate a Phase 2a trial of BX011 in DFI, subject to available resources.

BiomX's development of phage therapies for *S. aureus* has been supported by approximately US \$40 million in non-dilutive funding from the 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).

#### **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](http://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 of clinical trials thereof, timing of lifting FDA clinical hold, if at all, future catalysts, potential timing, outcome and consequences of expected feedback from the FDA and discussions with the U.S. DHA, the potential safety, efficacy and toleration of BX004, BX011 and BX211, the potential benefits of BX004 and BX211, future clinical development of BX004, BX011 and BX211, the potential of its drug candidates to address the substantial unmet needs of patients, 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; 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](http://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)

	<b>As of</b>	
	<b>September 30, 2025</b>	<b>December 31, 2024</b>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	6,923	16,856
Restricted cash	985	958
Other current assets	954	2,706
Total current assets	<u>8,862</u>	<u>20,520</u>
<b>Non-current assets</b>		
Non-current restricted cash	161	161
Operating lease right-of-use assets	2,091	5,457
Property and equipment, net	3,004	5,045
In-process Research and development asset ("IPR&D")	12,050	12,050
Total non-current assets	<u>17,306</u>	<u>22,713</u>
	<u>26,168</u>	<u>43,233</u>

**LIABILITIES AND STOCKHOLDERS' EQUITY**

**Current liabilities**

Trade accounts payable	1,508	1,882
Current portion of lease liabilities	1,296	1,130
Other accounts payable	2,422	5,255
Total current liabilities	5,226	8,267

**Non-current liabilities**

Operating lease liabilities, net of current portion	5,287	8,454
Other liabilities	34	77
Warrants	5,135	2,287
Total non-current liabilities	10,456	10,818

**Commitments and Contingencies (Note 6)****Stockholders' equity**

Preferred Stock, \$0.0001 par value; Authorized – 1,000,000 shares as of September 30, 2025 and December 31, 2024. Issued and outstanding - 147,512 shares as of September 30, 2025 and 147,735 shares as of December 31, 2024.	18,617	18,645
Common Stock, \$0.0001 par value; Authorized – 750,000,000 shares as of September 30, 2025 and December 31, 2024. Issued and outstanding- 26,800,980 shares as of September 30, 2025 and 18,176,661 shares as of December 31, 2024.	7	6
Additional paid in capital	195,421	186,194
Accumulated deficit	(203,559)	(180,697)
Total stockholders' equity	10,486	24,148
	26,168	43,233

**BIOMX INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(USD in thousands, except share and per share data)

(unaudited)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2025</b>	<b>2024</b>	<b>2025</b>	<b>2024</b>
Research and development ("R&D") expenses, net	6,122	7,279	16,386	18,281
General and administrative expenses	2,414	3,248	7,339	8,756
Goodwill impairment	-	801	-	801
<b>Operating loss</b>	8,536	11,328	23,725	27,838
Other expenses (income)	(24)	(84)	52	(2,189)
Interest expenses	5	5	15	868
Loss (income) from change in fair value of warrants	730	(20,559)	(1,682)	(24,417)
Finance expense (income), net	(84)	(332)	746	1,104
<b>Loss (income) before tax</b>	9,163	(9,642)	22,856	3,204
Tax expenses	3	-	6	10
<b>Net loss (income)</b>	9,166	(9,642)	22,862	3,214
Basic loss (earnings) per share of Common Stock	0.29	(0.31)	0.80	0.32
Diluted loss (earnings) per share of Common Stock	0.29	(0.31)	0.80	2.45
Weighted average number of shares used in computing basic loss (earnings) per share of Common Stock	31,399,552	16,366,122	28,653,244	9,944,266

Weighted average number of shares used in computing diluted loss (earnings) per share of Common Stock

<u>31,399,552</u>	<u>16,387,633</u>	<u>28,653,244</u>	<u>11,294,880</u>
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Source: BiomX Inc