



BiomX Reports Second Quarter 2025 Financial Results and Provides Program Updates

August 13, 2025

Positive Phase 2 results for BX211 demonstrated >40% wound size reduction vs. placebo in diabetic foot osteomyelitis patients; Planning underway for potential registrational study

Nature Communications publication of new BX004 Phase 1b/2a data demonstrated further ~500-fold (2.7 log₁₀)² bacterial reduction versus placebo with no detectable emergence of resistance observed, highlighting strength of BiomX platform capabilities

Phase 2b trial of BX004 in Cystic Fibrosis (CF) has successfully commenced patient dosing; FDA feedback on real-world evidence strategy expected in H2 2025; Company expects to report topline results in Q1 2026

BiomX will host a conference call and webcast today at 8:00 AM ET

NESS ZIONA, Israel, Aug. 13, 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 second quarter ended June 30, 2025, and provided recent clinical and corporate updates.

"In the past few months, BiomX achieved several significant milestones that advance our pipeline and further validate our phage therapy platform," said Jonathan Solomon, Chief Executive Officer of BiomX. "Positive Phase 2 results for BX211 in diabetic foot osteomyelitis demonstrated sustained, statistically significant improvements in wound size reduction, with over 40% reduction in ulcer size compared to placebo, and a favorable safety profile. In parallel, new peer-reviewed data for BX004, published in *Nature Communications*, reported approximately 500-fold (2.7 log₁₀)² further bacterial reduction versus placebo and no detectable emergence of resistance, critical evidence supports the strength of our candidate BX004. With BX004's Phase 2b trial now underway, FDA feedback on our real-world evidence plan expected later this year, and planning for a potential registrational BX211 study in progress, BiomX is positioned for multiple value-driving catalysts over the next 12 months."

Clinical Program Updates

BX211 – Phage for the treatment of patients with diabetic foot infections and osteomyelitis (DFI/DFO) associated with *Staphylococcus aureus* (*S. aureus*)

- BiomX reported positive topline results from the Phase 2 trial of BX211 in March 2025 just prior to the start of the second quarter, demonstrating that BX211 was safe and well-tolerated and produced sustained and statistically significant¹ percentage area reduction (PAR) of ulcer size (p = 0.046 at week 12; p=0.052 at week 13) with separation from placebo starting at week 7 and a difference greater than 40% by week 10.
- The Phase 2 trial results also showed that BX211 produced statistically significant improvements in both ulcer depth at week 13 in patients with ulcer depth defined as bone exposure at baseline (p=0.048) and in reducing the expansion of ulcer area (p=0.017) compared to placebo, with all patients receiving standard of care including systemic antibiotic therapy as appropriate over the 12-week treatment period.
- Planning for a potential registrational study of BX211 is underway, pending feedback from the U.S. Food and Drug Administration (FDA).
- Following strong Phase 2 results, the Company hosted a Virtual Key Opinion Leader event during the second quarter featuring leading clinical experts in diabetic foot infections and osteomyelitis. The discussion highlighted the clinical significance of the BX211 data, its potential role alongside standard of care, and perspectives on the path to registrational development. A replay of the webcast is available at the following [Link](#), the content of which does not form a part of this press release.
- The Company is in continued discussions with the U.S. Defense Health Agency regarding next steps for the BX211 program following the positive Phase 2 results.

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

- In July 2025, BiomX successfully initiated dosing of patients in its Phase 2b trial of BX004. The Phase 2b trial is a randomized, double-blind, placebo-controlled, multicenter study in approximately 60 CF patients with chronic *P. aeruginosa* infections. Patients are randomized 2:1 to receive either BX004 or placebo via inhalation twice daily for 8 weeks. The trial is designed to measure multiple efficacy endpoints, including reduction in bacterial burden, improvements in lung function, and enhanced quality of life as measured by validated patient questionnaires.
- The Company expects to report topline results from the Phase 2b study in the first quarter of 2026.
- In the second half of 2025, BiomX expects to receive feedback from the FDA regarding the potential investigation and use of real-world evidence linking bacterial reduction to clinical outcomes. Successful alignment could potentially streamline approval pathway.
- Earlier in July, *Nature Communications* published new findings from the Company's Phase 1b/2a trial, showcasing previously unreported antimicrobial efficacy data showing that BX004 achieved a substantially greater improvement of approximately 500-fold (2.7 log₁₀)² in bacterial reduction compared with placebo in CF patients. The data also highlight that no bacterial resistance to BX004 was detected during the trial, and also detailed in the article are BiomX's innovative approach to large-scale data analysis in order to optimize bacteriophage cocktails.

Second Quarter 2025 Financial Results

Cash balance and restricted cash as of June 30, 2025, were \$15.2 million, compared to \$18 million as of December 31, 2024. The decrease was primarily due to 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 \$5.0 million for the second quarter of 2025, compared to \$6.9 million for the second quarter of 2024. The decrease was primarily driven by: reduced salary expenses from workforce reductions; lower rent expenses following a right-of-use asset impairment in 2024; and increased grant funding from the Medical Technology Enterprise Consortium (under the DHA) and the Israel Innovation Authority. This was partially offset by higher expenses from initiating the Phase 2b clinical trial of the Company's CF product candidate, BX004.

General and administrative expenses were \$2.4 million for the second quarter of 2025, compared to \$2.8 million for the second quarter of 2024. The decrease was primarily attributed to a reduction in legal and other professional service fees, partially offset by increased share-based compensation

expenses.

Net loss was \$6.0 million for the second quarter of 2025, compared to income of \$4.5 million for the second 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 six months ended June 30, 2025, was \$14.8 million, compared to \$22.6 million for the same period in 2024.

Conference Call and Webcast Details

BiomX will host a conference call and webcast on August 13, 2025, at 8 AM ET to discuss its second quarter 2025 financial results and to provide a corporate update.

Conference Call

<https://register-conf.media-server.com/register/BI35d84b315cb147c78290b6b8f1fde487>

Webcast Link

<https://edge.media-server.com/mmc/p/89dfoxpe/>

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 significant¹ 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 significant¹ 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 potential registrational study pending discussions and feedback from the FDA, and availability of cash resources.

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 February 2023, BiomX announced positive results from Part 1 of the Phase 1b/2a study, showing safety, tolerability, and microbiologic activity. In November 2023, BiomX announced positive topline results from Part 2 of the Phase 1b/2a trial, in which 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 is now enrolling 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 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 of clinical trials thereof, future catalysts, potential timing and outcome of expected feedback from the FDA and discussions with the U.S. Defense Health Agency, the potential safety, efficacy and toleration of BX004 and BX211, the potential benefits of BX004 and BX211, future clinical development of BX004 and BX211, including conducting a registrational trial in BX211, the potential of its 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. 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.

Contacts:

BiomX, Inc.

Ben Cohen

Head Corporate Communications

benc@biomx.com

¹ All p-values described in this release are non-adjusted

² A 2.7 log₁₀ reduction represents a 10^{2.7} = ~500-fold reduction in bacterial load, which equates to approximately 99.8% reduction.

BIOMX INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

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

(unaudited)

	As of	
	June 30, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	14,046	16,8€
Restricted cash	979	9€
Other current assets	1,610	2,7€
Total current assets	<u>16,635</u>	<u>20,5€</u>
Non-current assets		
Non-current restricted cash	161	1€
Operating lease right-of-use assets	4,959	5,4€
Property and equipment, net	4,245	5,04
In-process Research and development asset	12,050	12,0€
Total non-current assets	<u>21,415</u>	<u>22,71</u>
	<u>38,050</u>	<u>43,2€</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade accounts payable	2,178	1,8
Current portion of lease liabilities	1,233	1,1
Other accounts payable	2,851	5,2
Total current liabilities	<u>6,262</u>	<u>8,2</u>
Non-current liabilities		
Operating lease liabilities, net of current portion	8,143	8,4
Other liabilities	80	
Warrants	4,405	2,2
Total non-current liabilities	<u>12,628</u>	<u>10,8</u>
Commitments and Contingencies (Note 6)		
Stockholders' equity		
Preferred Stock, \$0.0001 par value; Authorized – 1,000,000 shares as of June 30, 2025 and December 31, 2024. Issued and outstanding- 147,735 as of June 30, 2025 and December 31, 2024.	18,645	18,6
Common Stock, \$0.0001 par value; Authorized – 750,000,000 shares as of June 30, 2025 and December 31, 2024. Issued and outstanding- 26,443,257 shares as of June 30, 2025 and 18,176,661 shares as of December 31, 2024.	7	
Additional paid in capital	194,901	186,1
Accumulated deficit	(194,393)	(180,6)
Total stockholders' equity	<u>19,160</u>	<u>24,1</u>
	<u>38,050</u>	<u>43,2</u>

BIOMX INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(unaudited)

Three Months Ended		S
June 30,		
2025	2024	202

Research and development ("R&D") expenses, net	5,014	6,897
General and administrative expenses	<u>2,419</u>	<u>2,828</u>
Operating loss	7,433	9,725
Other expenses (income)	70	(2,017)
Interest expenses	5	13
Income from change in fair value of warrants	1,498	(11,868)
Finance expense (income), net	<u>25</u>	<u>(329)</u>
Loss (income) before tax	6,035	(4,476)
Tax expenses	2	5
Net loss (income)	6,037	(4,471)
Basic loss (earnings) per share of Common Stock	0.19	(0.14)
Diluted loss per share of Common Stock	0.19	0.69
Weighted average number of shares used in computing basic loss (earnings) per share of Common Stock	31,308,396	6,980,943
Weighted average number of shares used in computing diluted loss per share of Common Stock	<u>31,308,396</u>	<u>10,750,194</u>



Source: BiomX Inc

Released August 13, 2025