

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 31, 2025**

BiomX Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction
of incorporation)

001-38762

(Commission File Number)

82-3364020

(I.R.S. Employer
Identification No.)

**22 Einstein St., Floor 4
Ness Ziona, Israel**

(Address of Principal Executive Offices)

7414003

(Zip Code)

Registrant's telephone number, including area code: **+972 723942377**

n/a

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	PHGE	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On March 31, 2025, BiomX Inc., or the Company, issued a press release announcing positive results from its Phase 2 Trial evaluating BX211 for the treatment of Diabetic Foot Osteomyelitis, or DFO, a copy of which is furnished as Exhibit 99.1. In addition, on March 31, 2025, the Company posted an updated corporate slide presentation in the “Investors” portion of its website at www.biomx.com. A copy of the slide presentation is furnished as Exhibit 99.2 hereto. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

Item 8.01 Other Events.

As disclosed above, on March 31, 2025, the Company announced positive results from Phase 2 Trial Evaluating BX211 for the treatment of DFO, or the Phase 2 Trial.

The Phase 2 Trial is a randomized, double-blind, placebo-controlled, multi-center study investigating the safety, tolerability, and efficacy of BX211 for individuals with DFO associated with *S. aureus*. The Phase 2 Trial enrolled a total of 41 patients randomized for treatment at a 2:1 ratio, 26 of whom received intravenous (IV) and topical administration of BX211 on week 1 followed by a topical weekly dose through week 12, while 15 patients were assigned to the placebo arm. Over the 12-week treatment period, all subjects (treatment and placebo) were also treated in accordance with standard of care, including with systemic antibiotic therapy as appropriate. A readout of study results at Week 13 evaluated healing of the wound associated with osteomyelitis. The primary efficacy endpoint was Percent Area Reduction, or PAR, of study ulcer through week 13. Study design was guided in part by experience with numerous compassionate cases using phage therapy for the treatment of DFO and osteomyelitis.

The topline Phase 2 Trial results included:

- BX211 was found to be safe and well-tolerated.
- BX211 produced sustained and statistically significant¹ PAR of ulcer size, ($p = 0.046$ at week 12; $p=0.052$ at week 13), with a separation from placebo (standard of care) starting at week 7 and a difference greater than 40% by week 10.
- BX211 produced statistically significant¹ improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline) ($p=0.048$), and in reducing the expansion of ulcer area ($p=0.017$), compared to placebo.
- BX211 demonstrated favorable trends compared to placebo across several additional clinical parameters, including: proportion of visits with no clinical evidence of infection; evidence of resolving DFO by MRI/X-ray at week 12; proportion of patients with abnormal C-Reactive Protein at baseline that achieved a reduction of CRP of at least 50% at any point in the study; and greater Wagner scale improvement².
- Through week 13, BX211 demonstrated comparable efficacy against both Methicillin susceptible and resistant strains, as well as against high and low biofilm producers—consistent with the orthogonal mechanism of phage therapy to antibiotics and its inherent anti-biofilm capabilities.

1 All p-values described in this Form 8-K are non-adjusted.

2 The Wagner Scale is a clinical grading system used to classify the severity of diabetic foot ulcers, ranging from 0 (intact skin) to 5 (extensive gangrene).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release dated March 31, 2025, titled “BiomX Announces Positive Results from Phase 2 Trial Evaluating BX211 for the Treatment of Diabetic Foot Osteomyelitis (DFO)” (furnished herewith)
99.2	Investor Presentation Deck dated February 26, 2025 (furnished herewith)
104	Cover Page Interactive Data File (embedded within the Inline XBRL documents)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

March 31, 2025

BIOMX INC.

By: /s/ Jonathan Solomon
Name: Jonathan Solomon
Title: Chief Executive Officer

BiomX Announces Positive Topline Results from Phase 2 Trial Evaluating BX211 for the Treatment of Diabetic Foot Osteomyelitis (DFO)

- *BX211 was safe and well-tolerated*
- *BX211 produced sustained and statistically significant¹ Percent Area Reduction (PAR) of ulcer size ($p = 0.046$ 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*
- *Compared to placebo, BX211 also produced statistically significant¹ improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline) ($p=0.048$), and in reducing the expansion of ulcer area ($p=0.017$).*
- *BiomX is planning for a Phase 2/3 trial of BX211, pending U.S. Food and Drug Administration (FDA) feedback*

The Company will host a conference call and webcast today at 9:00 AM ET, followed by a Key Opinion Leader (KOL) event on April 3, 2025, at 11:00 AM ET to discuss the results

NESS ZIONA, Israel, March 31, 2025 (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 positive, topline safety and efficacy results from the Company’s DFO Adaptive Novel Care Evaluation (DANCE™) Phase 2 trial evaluating its BX211 phage treatment for DFO associated with *Staphylococcus aureus* (*S. aureus*). The findings demonstrated BX211 to be safe and well-tolerated and that 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. Following the successful Phase 2 readout of BX211, the Company is planning for a Phase 2/3 trial, pending discussions and feedback from the U.S Food and Drug Administration.

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

² The Wagner Scale is a clinical grading system used to classify the severity of diabetic foot ulcers, ranging from 0 (intact skin) to 5 (extensive gangrene).

“We believe these data represent one of the strongest demonstrations to date of the therapeutic potential of phage therapy. We are grateful to all the patients who participated, and the treating teams who enrolled patients into the study, as well as the continued and ongoing support from the U.S. Defense Health Agency (DHA) for this program,” said Jonathan Solomon, BiomX’s Chief Executive Officer. “Today, 30-40% of DFO cases lead to lower extremity amputations related to serious bacterial infections, accounting for the majority of the 160,000 lower limb amputations in diabetic patients each year in the United States. Based on the results announced today, we believe BiomX’s novel phage therapy approach has the potential to help address the major unmet need in DFO. Moreover, in an era of modern conflict and rising antibiotic-resistant wounds, the need for innovative wound care solutions underscores the broader relevance of this program beyond DFO. BiomX is dedicated to the advancement of phage therapy, which we believe holds promise in redefining the treatment of chronic infections.”

“Phage therapy has a critical role to play in treating infections where antibiotic resistance has emerged or existing treatments have underperformed,” said Dr. Robert T. “Chip” Schooley, M.D., Distinguished Professor of Medicine, Division of Infectious Diseases and Global Public Health and Co-Director, Center for Innovative Phage Applications and Therapeutics at the University of California, San Diego. “The promising topline data in this trial provide an important inflection point for this approach and its potential to address the most challenging infections.”

“Diabetic foot infections are often a complex and difficult-to-treat consequence of diabetes, leading to serious adverse effects on patient quality of life,” said Dr. Benjamin A. Lipsky, M.D., FACP, FIDSA, FRCP (London), FRCPS (Glasgow), Professor of Medicine Emeritus at University of Washington, Seattle. “The most serious and feared complication of DFO is lower extremity amputation, which is associated with a five-year mortality rate of about 50%. With the progress seen so far and given the improved ulcer healing seen in this study, BX211 may have the potential to reduce amputations. BX211 is a program to watch closely as it progresses into more advanced clinical studies.”

Summary of Phase 2 BX211 Results

BiomX’s Phase 2 trial is a randomized, double-blind, placebo-controlled, multi-center study investigating the safety, tolerability, and efficacy of BX211 for individuals with DFO associated with *S. aureus*. The study enrolled a total of 41 patients randomized for treatment at a 2:1 ratio, 26 of whom received intravenous (IV) and topical administration of BX211 on week 1 followed by a topical weekly dose through week 12, while 15 patients were assigned to the placebo arm. Over the 12-week treatment period, all subjects (treatment and placebo) were also treated in accordance with standard of care, including with systemic antibiotic therapy as appropriate. A readout of study results at week 13 evaluated healing of the wound associated with osteomyelitis. The primary efficacy endpoint was PAR of study ulcer through week 13. Study design was guided in part by experience with numerous compassionate cases using phage therapy for the treatment of DFO and osteomyelitis.

The topline Phase 2 results included:

- *BX211 was found to be safe and well-tolerated.*
- *BX211 produced sustained and statistically significant¹ PAR of ulcer size ($p = 0.046$ at week 12; $p=0.052$ at week 13), with a separation from placebo (standard of care) starting at week 7 and a difference greater than 40% by week 10.*
- *BX211 produced statistically significant¹ improvements in both ulcer depth at week 13 (in patients with ulcer depth defined as bone at baseline) ($p=0.048$), and in reducing the expansion of ulcer area ($p=0.017$), compared to placebo.*
- *BX211 demonstrated favorable trends compared to placebo across several additional clinical parameters, including: proportion of visits with no clinical evidence of infection; evidence of resolving DFO by MRI/X-ray at week 12; proportion of patients with abnormal C-Reactive Protein at baseline that achieved a reduction of CRP of at least 50% at any point in the study; and greater Wagner scale improvement².*
- *Through week 13, BX211 demonstrated comparable efficacy against both Methicillin-susceptible and resistant strains, as well as against high and low biofilm producers—consistent with the orthogonal mechanism of phage therapy to antibiotics and its inherent anti-biofilm capabilities.*

BiomX expects to present additional data from the Phase 2 study at upcoming scientific conferences.

Today's Conference Call and Webcast Information

BiomX management will host a conference call and webcast today at 9:00 AM ET to review the topline Phase 2 trial results, accompanied by a slide deck presentation, which will be available on the Company's website and filed via Form 8-K. To participate in the conference, please dial +877-407-0724 (U.S.), or +1 201-389-0898 (International), or click on the webcast link here.

A live and archived webcast of the call will also be available on the Investors section of the Company's website at www.biomx.com.

BiomX to Host Virtual KOL Event – April 3, 2025

The Company has scheduled a virtual KOL Event to discuss the topline results from the Phase 2 trial. The event will take place on April 3, 2025, at 11:00 am ET, and will include participation from BiomX senior management and two KOLs, Dr. Robert T. “Chip” Schooley, M.D., Distinguished Professor of Medicine, Division of Infectious Diseases and Global Public Health and Co-Director, Center for Innovative Phage Applications and Therapeutics at the University of California, San Diego, and Dr. Benjamin A. Lipsky, M.D., FIDSA, FRCP (London), FRCPS (Glasgow) Professor of Medicine Emeritus at University of Washington, Seattle. To register for the event, please click here.

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. Pending feedback from the FDA, BiomX is planning for a Phase 2/3 clinical trial of BX211.

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 the potential safety and toleration of BX211, the potential benefits of BX211, future clinical development of BX211 and the relevance and potential of phage therapy in the treatment of chronic infections, 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 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



BiomX

**Revolutionizing the Treatment of
Infections Associated with Chronic
Disease Through Phage Therapy**

INVESTOR PRESENTATION

March 2025

NYSE American: PHGE

SAFE HARBOR STATEMENT

About this Presentation

The information contained in this presentation has been prepared by BiomX Inc. and its subsidiaries (collectively, the "Company" or "BiomX") and contains information pertaining to the business and operations of the Company. The information contained in this presentation is current only as of the date on its cover. For any time after the cover date of this presentation, the information, including information concerning our business, financial condition, results of operations and prospects, may have changed. The delivery of this presentation shall not, under any circumstances, create any implication that there have been no changes in our affairs after the date of this presentation. We have not authorized any person to give any information or to make any representations about us in connection with this presentation that is not contained herein. If any information has been or is given or any representations have been or are made to you outside of this presentation, such information or representations should not be relied upon as having been authorized by us.

Forward-Looking Statements

This presentation contains certain "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. 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. For example, when we discuss future potential clinical trials, including their design, objectives, costs, endpoints, potential benefits and timing thereof, the potential outcomes of discussions that we may have with the U.S. Food and Drug Administration and foreign regulatory agencies, potential commercial opportunities, our financial needs to fund future clinical trials, forecasted expenses and our ability to protect our intellectual property assets in the future we are making forward-looking statements. In addition, past and current pre-clinical and clinical results, as well as compassionate use, are not indicative and do not guarantee future success of BiomX clinical trials. 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 our control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. You should review additional disclosures we make in our filings with the Securities and Exchange Commission (the "SEC"), which are available on the SEC's website at www.sec.gov. Except as required by law, we are under no duty to (and expressly disclaim any such obligation to) update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

No Offer or Solicitation

This presentation is for informational purposes only. Nothing in this presentation constitutes an offer to buy or sell or a solicitation of an offer to buy or sell investments, loans, securities, partnership interests, commodities or any other financial instruments. This presentation and any oral statements made in connection with this presentation do not constitute and may not be used for or in connection with, an offer or solicitation by anyone in any state or jurisdiction in which such an offer or solicitation is not authorized or permitted, or to any person to whom it is unlawful to make such offer or solicitation.

Trademarks and Service Marks

The trademarks and service marks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

FDA

This presentation concerns certain products that are under clinical investigation and which have not yet been cleared for marketing by the U.S. Food and Drug Administration. These products are currently limited by federal law to investigational use, and no representation is made as to the safety or effectiveness of these products for the purposes for which they are being investigated.

AT-A-GLANCE

Company

Clinical stage biotech harnessing the therapeutic potential of phage therapy

Unmet need

Treatment of underlying persistent infections in chronic diseases that become harder to treat as antibiotic-resistant pathogens emerge

- Pulmonary infections in Cystic Fibrosis (CF) and Non-Cystic Fibrosis Bronchiectasis (NCFB) patients are the primary causes of death
- 20%-40% of Severe to moderate Diabetic Foot Infections (DFI) & Diabetic Foot Osteomyelitis (DFO) cases result in amputation due to bacterial infection

Pipeline Highlights

- BX004 for CF – Positive results in P1b/2a study. P2b results expected in Q1 2026
- BX211 for moderate-severe DFO & DFI – Positive results in P2 study, Preparing for Phase 2/3

Partners



WRAIR

Key Investors

DEERFIELD
Advancing Healthcare™

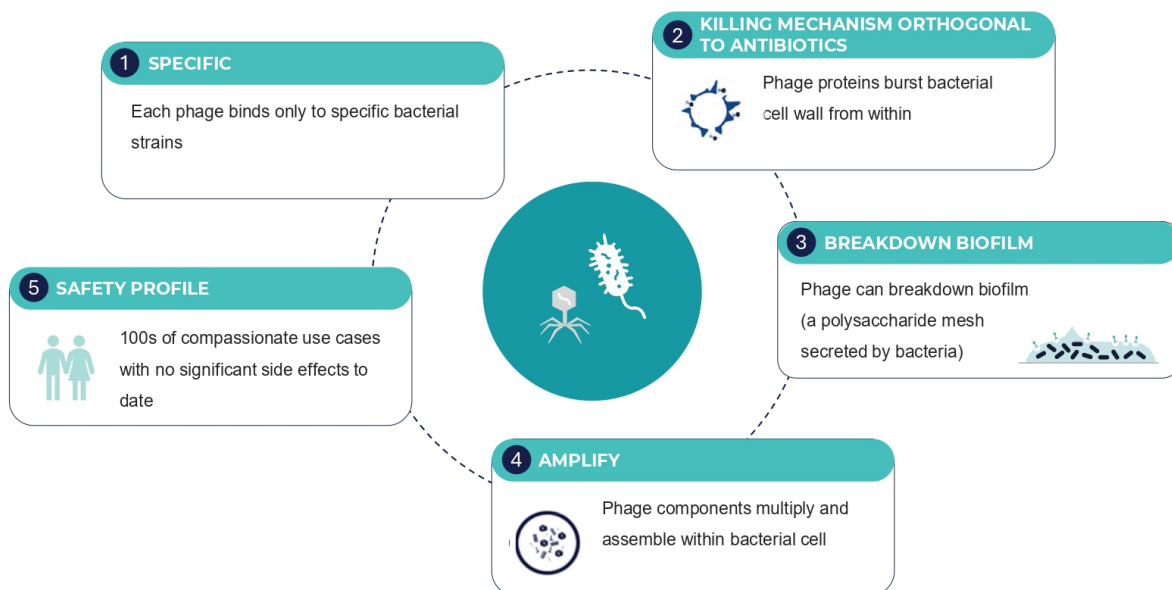


OrbiMed
Healthcare Fund Management

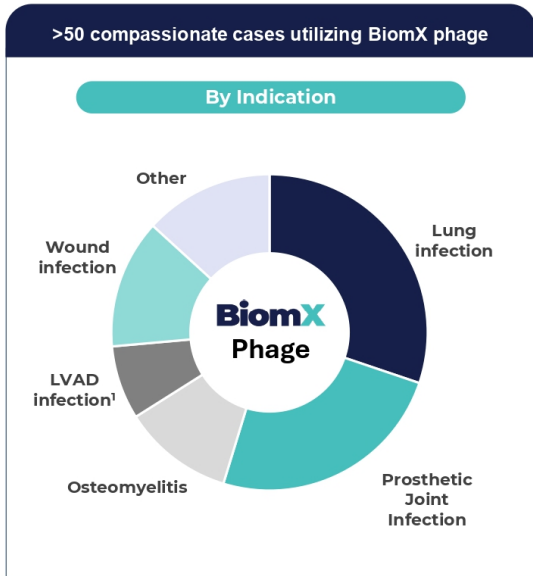
A microscopic view of numerous phages, which are virus-like particles, floating in a blue, fluid-like environment. The phages are elongated, cylindrical structures with a textured, ribbed surface and a distinct head at one end. They are scattered throughout the frame, with some in sharp focus and others blurred in the background, creating a sense of depth and movement. The overall color palette is a range of blues, from deep navy to light cyan.

OUR SCIENCE
PHAGE THERAPIES

Phage: Nature's tool to target bacteria

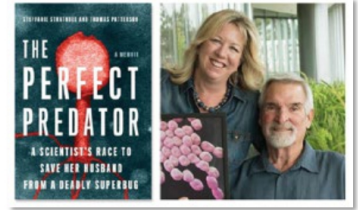


Phage therapy picking up momentum

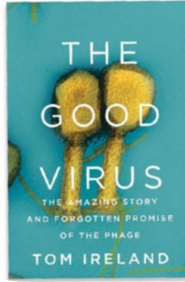


100 cases of compassionate phage treatment (Belgian consortium)²

- 35 hospitals, 29 cities
- Clinical improvement reported in **77% of cases**



Feb. 2019



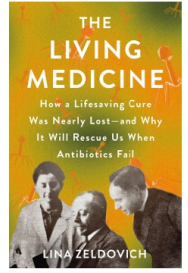
Aug. 2023



Sept. 2023

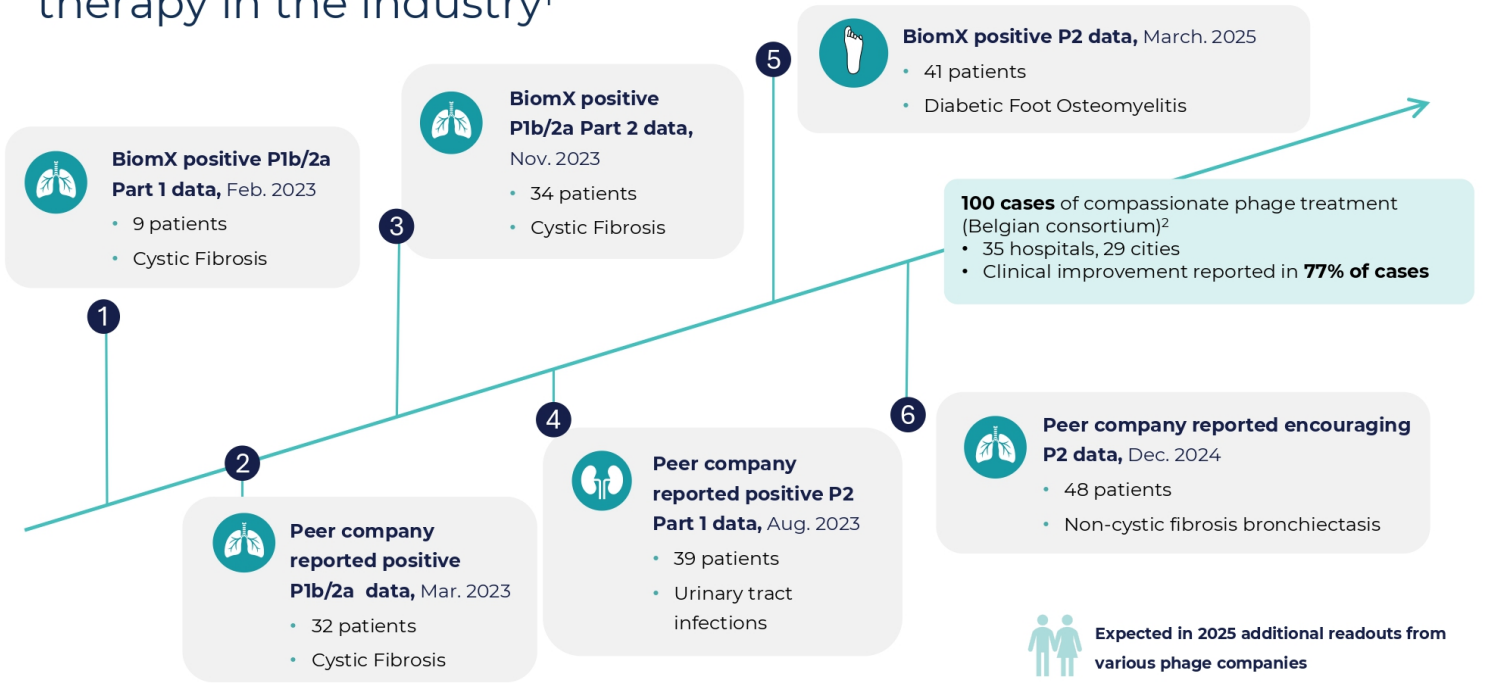


March. 2024






Oct. 2024

Accumulating clinical efficacy and safety data for phage therapy in the industry¹



Pipeline: Addressing Chronic Disease with Hard-to-treat Bacterial infections

BiomX harnesses its proprietary **Bolt** platform to develop novel phage therapies to treat underlying persistent infections in chronic diseases that become harder to treat as antibiotic-resistant pathogens emerge

		Preclinical	Clinical-Ready	Phase 2	Status	Partners	
Program	Indication						
BX004	Cystic Fibrosis ¹⁾	Phase 2a Completed			Ph2b topline expected Q1 2026		
	Non-Cystic Fibrosis Bronchiectasis (NCFB)	Phase 2a Completed			Ph2-Ready		
BX211	Diabetic Foot Osteomyelitis / Diabetic Foot Infections	Phase 2 Completed			Preparing for Phase 2/3, pending FDA feedback	 	

BX004

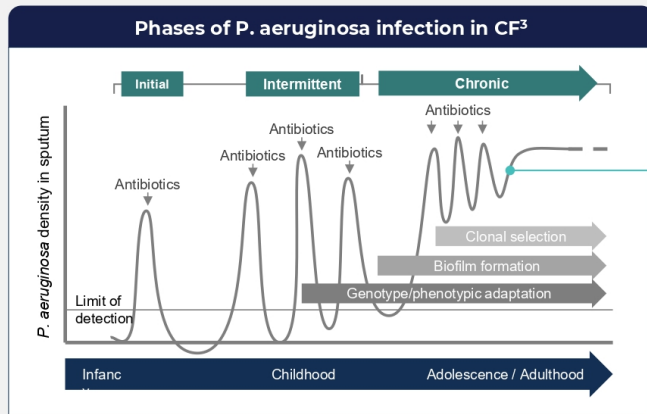
**CYSTIC FIBROSIS
and NCFB**



Chronic pulmonary infections and the inflammatory response are a primary cause of death in CF patients

CF causes severe damage to the lungs, digestive system and other organs with > 80% of deaths from respiratory failure. 105K individuals are estimated to live with CF worldwide, with 33k in the US alone¹

After prolonged and repeated antibiotic courses, increased resistance to antibiotics has lowered efficacy, creating a large unmet need for CF patients suffering from chronic *Pseudomonas aeruginosa* (PsA) infections - Estimated at **17,000 patients in the US and Western Europe**²

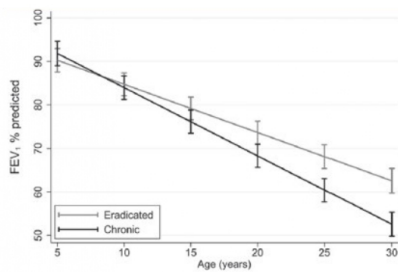


Lack of antibiotic efficacy driven by:

1. *P. aeruginosa* strains with multidrug resistance (MDR)
2. Formation of biofilm => making infection harder to treat

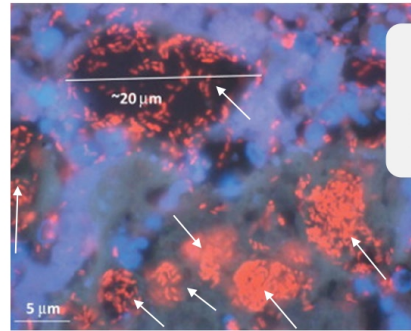
Pseudomonas aeruginosa (PsA) bacteria are associated with decreased lung function (FEV1) in CF patients

PsA colonization associated with lower FEV1¹



Eradicated – Cleared early/first time PsA when treated with the antibiotic eradication treatment
Chronic – Did not clear early/first time PsA infection when treated with the antibiotic eradication treatment

PsA colonization associated with lower FEV1²



Arrows show aggregates of PsA (red) within biofilm patches surrounded by inflammatory cells (Blue)

PsA bacteria and biofilm lead to persistent inflammation causing tissue damage and eventually necrosis of lung tissue

BX004 – BiomX’s proprietary phage cocktail has the potential to treat CF patients with chronic PsA lung infections



Product – Proprietary phage cocktail targeting PsA

Patient population – CF patients with chronic PsA lung infections

Delivery – Nebulized

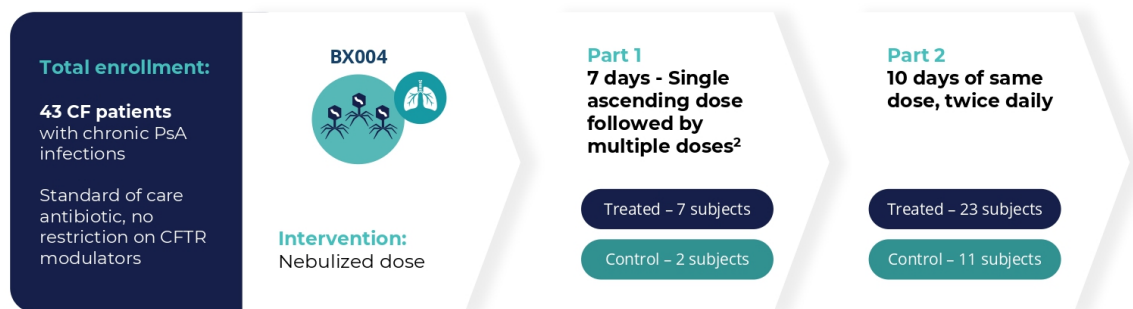
Key features – Potentially effective on antibiotic resistant strains, enables breakdown of biofilm

Potential impact:

- Suppression/eradication of PsA (CFU in sputum)
- Improved lung function (FEV1)
- Fewer exacerbations, hospitalizations
- Increased efficacy of antibiotic treatment
- Reduced oral, inhaled and IV antibiotic treatments

PHASE 1B/2A STUDY – Study design¹

Multicentered, double blind, placebo controlled study to assess safety, reduction of PsA burden and improvement in clinical outcomes

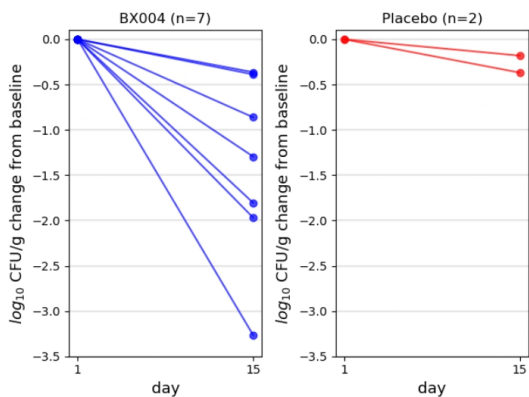


- Key Endpoints:**
- Safety and tolerability
 - Decrease in PsA burden
 - FEV1 (forced expiratory volume)
 - CFQ-R (CF Questionnaire-Revised) and CRISS

Phase 1b/2a – Result highlights (Parts 1 and 2)

- Study drug was well-tolerated
- In Part 1, Mean PsA CFU/g¹ reduction at Day 15: -1.42 log₁₀ CFU/g (BX004) compared to -0.28 log₁₀ CFU/g (placebo)
- Culture conversion: Part 2, in the BX004 arm, 3 of 21 (14.3%) patients converted to sputum culture negative for PsA after 10 days of treatment compared to 0 out of 10 (0%) in the placebo arm². In Part 1, 1 of 7 (14.3%) treated patients also had converted based on physician report
- Part 2: BX004 showed signals of improvement in pulmonary function vs. placebo : Relative FEV₁³ improvement (5.67%) and CF Questionnaire-Revised respiratory³ (8.87 points) at Day 17 (1 week after EOT³) in subgroup of patients with reduced lung function⁴
- Part 2: In full population, BX004 vs. placebo PsA levels were more variable. In a prespecified subgroup of patients on SOC³ inhaled antibiotics on continuous regimen, BX004 vs. placebo showed bacterial reduction of 2.8 log₁₀ CFU/g at EOT³, exceeding Part 1 results

PART 1 BX004 demonstrated greater reduction in PsA levels compared to placebo



	BX004	Placebo
n	7	2
Mean reduction (SD) Log ₁₀ CFU/g	-1.42 (1.03)	-0.28 (0.13)
Max, Min	-3.27, -0.37	-0.37, -0.18

PART 2 BX004 showed greater conversion (bacterial culture turned negative) in treatment over placebo

In the BX004 arm 3 out of 21 (14.3%) patients converted to sputum culture negative for *P. aeruginosa* after 10 days of treatment (2 already after 4 days)². In the placebo arm 0 out of 10 (0%)²

Patients which were converted:

Patient	Duration of PsA infection (years)	Baseline PsA ¹ in sputum (CFU/g)
1	18	2.40x10 ³
2	13	5.60x10 ⁷
3*	35	1.09x10 ⁷

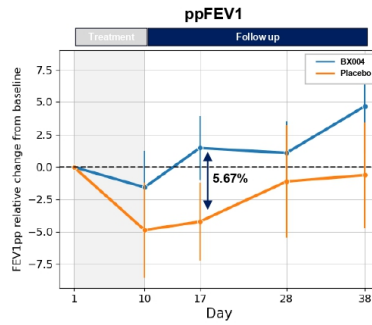
*Subject had negative sputum culture for *P. aeruginosa* at D4, D10, D28, D38, and at follow-up standard of care clinic visits (D63, D150, and D175)

In addition, in Part 1 of the study, one subject in the BX004 arm (1/7: 14.3%) who was persistently positive for PsA for at least 13 years had a 3.3 log reduction at D15 later converted to sputum negative

PART 2 BX004 shows meaningful clinical improvement after 10 days of treatment in multiple clinical readouts

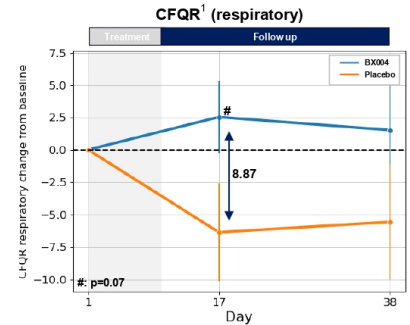
Clinical improvements were observed on both objective & patient reported outcomes

Clinical readouts in patients with reduced baseline lung function (predefined group, ppFEV1 of <70%)



ppFEV1 change from Baseline: Mean(SE)

	BX004 (N=12) ¹	Placebo (N=8) ²	Difference
D10	-1.57 (2.64)	-4.86 (3.39)	3.29
D17	1.46 (2.33)	-4.21 (2.78)	5.67
D28	1.07 (2.32)	-1.12 (3.96)	2.19
D38	4.68 (3.28)	-0.62 (3.65)	5.3



CFQR respiratory change from Baseline: Mean(SE)

	BX004 (N=12) ¹	Placebo (N=8) ²	Difference
D17	2.52 (2.61)	-6.35 (3.45)	8.87
D38	1.51 (5.1)	-5.56 (4.05)	7.07

PHASE 2B STUDY – Study design

International, multicenter, double blind, placebo-controlled study to assess reduction of PsA burden and improvement in clinical outcome



- Key Endpoints:**
- Decrease in PsA burden (incl. Culture conversion/eradication)
 - FEV1 (forced expiratory volume)
 - CFQ-R (CF Questionnaire-Revised) and CRIS
 - Safety and tolerability

Topline results expected in Q1 2026

Bacterial Reduction Potential Regulatory Endpoint

Evaluating Real-World Evidence

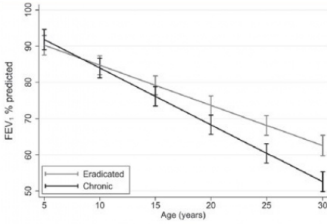
Peer-reviewed publications demonstrated that *P. aeruginosa* reduction improves patient outcomes, and ongoing real-world evidence (RWE) analysis may support regulatory filings

Journal of Cystic Fibrosis 22 (2023) 98–102

Impact of antibiotic eradication therapy of *Pseudomonas aeruginosa* on long term lung function in cystic fibrosis

Isabel Gascon Casaredi^{a,b}, Michelle Shaw^c, Valerie Waters^{c,d}, Ryan Seeto^c, Ana C. Blanchard^d, Felix Ratjen^{a,b,c,e}

^aDivision of Respiratory Medicine, Department of Pediatrics, Hospital Sant Joan de Déu de Barcelona, Universidad de Barcelona, Barcelona, Spain
^bDivision of Respiratory Medicine, Department of Pediatrics, University of Toronto, Toronto, Canada
^cTranslational Medicine, Research Institute, The Hospital for Sick Children, Toronto, Canada
^dDivision of Infectious Diseases, Department of Pediatrics, The Hospital for Sick Children, University of Toronto, Toronto, Canada

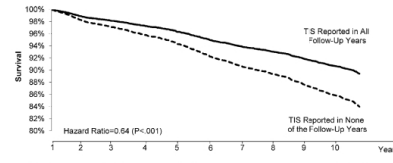


Eradicated – Cleared early/first time PsA when treated with the antibiotic eradication treatment
Chronic – Did not clear early/first time PsA infection when treated with the antibiotic eradication treatment

Pediatric Pulmonology 47:44–52 (2012)

Reduced Mortality in Cystic Fibrosis Patients Treated With Tobramycin Inhalation Solution

Gregory S. Sawicki, MD, MPH,¹ James E. Signorovitch, PhD,² Jie Zhang, PhD,³ Dominick Latremouille-Viau, MS,² Markus von Wartburg, PhD,² Eric Q. Wu, PhD,² and Lizheng Shi, PhD⁴



Tobramycin Inhalation Solution – Antibiotic treatment to target PsA
Chronic – Patients on TIS throughout follow-up years had reduced mortality and improved survival

Fig. 2. Survival curves for patients reporting TIS use in all versus none of the follow-up years. TIS, tobramycin inhalation solution.

BX004 is a promising candidate for treating NCFB

Non-Cystic Fibrosis

Bronchiectasis (NCFB) is a chronic progressive inflammatory lung disease with >1 million diagnosed patients (US, 5EU and Japan)¹

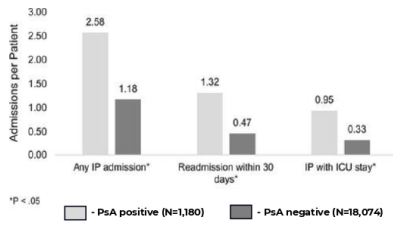
Characterized by permanent dilatation of the bronchi caused by multiple etiologies but with similar symptoms

No FDA approved treatments. Insmed recently announced positive results with brensocatib (reversible inhibitor of dipeptidyl peptidase 1) for treatment of NCFB³

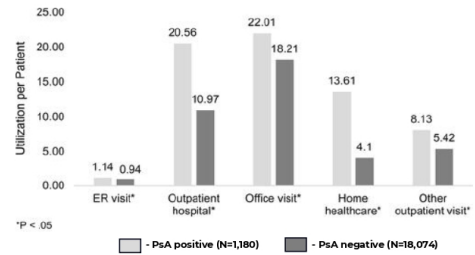
NCFB patients infected with *PsA* present worse clinical symptoms compared to non-infected patients

More frequent inpatient and outpatient encounters in NCFB patients positive for *PsA*²

Inpatient encounters within 1 year



Outpatient encounters within 1 year



• PsA – *Pseudomonas Aeruginosa*, IP: In Patient
 • Based on 19,254 NCFB patient registries in the US between 2006-2020, IQVIA's PharMetrics Plus database

BX211

**Diabetic Foot Infections &
Diabetic Foot Osteomyelitis
(DFI & DFO)**



High unmet need in DFI & DFO

- DFI is a bacterial infection of the soft tissue of the foot in patients with diabetes
- In DFO the infection spreads from the adjacent infected soft tissue to the bone



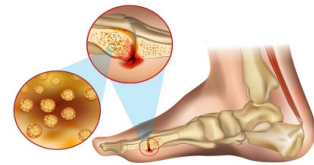
1. Superficial ulcer



2. **DFI** - Ulcer deepens extending through subcutis, and becomes infected



3. **DFO** - Ulcer and infection further penetrate and reach bone, displaying destruction of periosteum



Staphylococcus aureus is the most common bacteria present in DFI and DFO

Standard of care Moderate-Severe DFI & DFO

- Hospitalization and off-loading (removing all pressure from foot, reducing patient mobility)
 - Debridement and/or antibiotic therapy, typically 4-6 weeks of IV/oral antibiotics
- ▶ **20-40% of cases result in amputation**

Amputations in diabetic patients are an enormous burden to the health system



Individuals diagnosed with diabetes, US 2024



Amputation costs (direct), per patient, US



ER hospital visits due to DFI, annually, US



Staggering economic burden
Diabetic amputations cost the US healthcare system **~8 Billion USD per year**



Lower limb amputations, diabetic patients annually, US



Undergoing an amputation increases five-year mortality rate from 30% to ~50%



Amputations in diabetic patients are due to DFO/DFI



An episode of lower limb amputation is a major risk factor for subsequent amputations

No new anti-infectives approved in the US for DFI and DFO in the last 20 years

Most recent anti-infectives approved for the treatment of DFI:

	Drug	Study type	Endpoint	Year of approval (for DFI)
1	Zosyn (Pfizer), Piperacillin/tazobactam	non-inferiority	Primary: Clinical success : cure or improvement Secondary: Bacteriologic success: eradication or presumed eradication	2003
2	Zyvox (Pfizer), linezolid	non-inferiority	Clinical cure: resolution of all clinical signs and symptoms of infection and a healing wound	2004
3	INVANZ (Merck) ertapenem	non-inferiority	Proportion of patients with a favorable clinical response (cure or improvement)	2005

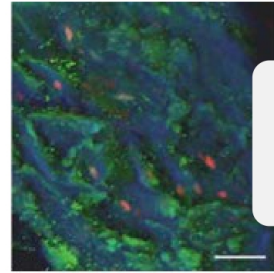
- All drugs approved for DFI in 2003 – 2005 are based on “non-inferiority” to older antibiotics
- No Approved drugs for DFO in the US

Biofilm and antibiotic resistance among key drivers of treatment failure

Key drivers of treatment failure:

- Biofilm – lead to greater remittance to antibiotics
 - Poor blood supply limits effectiveness of IV/oral antibiotics
 - Antibiotic resistance
-
- *S. aureus* present in ~50% of chronic DFI/DFO cases
 - While other organisms are often present, *S. aureus* is considered the main pathogenic species

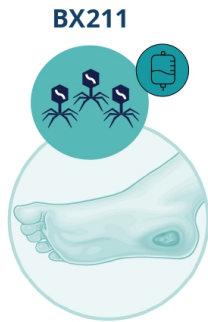
S. aureus forms biofilm patches in diabetic foot ulcers



S. aureus bacteria (green)
Bacterial biofilms, EPS (blue)
Host cell nuclei (red)

Confocal laser scanning microscopy of soft tissue from patient with diabetic foot ulcer infected by *S. aureus*

BX211 phage treatment for moderate to severe DFI & DFO patients with *S. aureus*



Product – Proprietary phage treatment targeting *S. aureus*

Patient population – Moderate to severe DFI & DFO patients with *S. aureus* infection (note: moderate-severe DFI and DFO patient populations overlap)

Delivery – IV + Topical

Treatment – On top of standard of care

Potential Key features – Effective on antibiotic resistant strains, enables breakdown of biofilm

Potential impact:

- Infection resolution
- Prevention of clinical deteriorations
- Wound healing
- DFO clinical resolution
- Reduced surgery

PHASE 2 – Study design

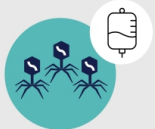
Multicenter, double blind, placebo controlled study to assess improvement of clinical outcomes

Enrollment:

41 patients with Diabetic Foot Osteomyelitis positive for *S. aureus*

Background standard of care antibiotic

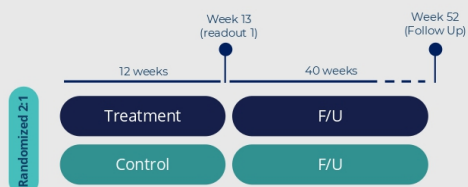
BX211



Intervention:
IV & topical

Duration: 12 weeks of once weekly treatment

IV in week 1, topical for 12 weeks



Primary Endpoint: • Percent area reduction of study ulcer through Week 13

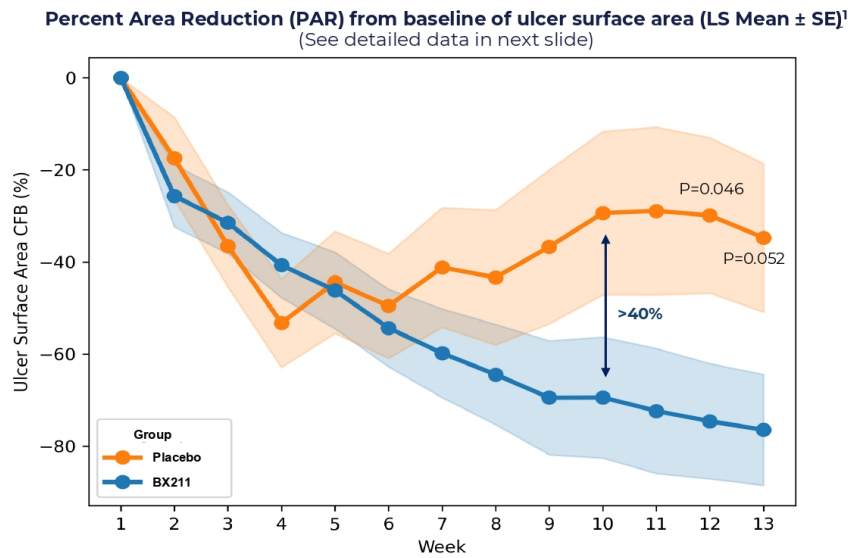
BX211 – Phage originating from a 'phage-bank', personally matched for each patient's *S. aureus*

Topline results from week 13 available

Results highlight – Phase 2 Diabetic Foot Osteomyelitis

- BX211 was **safe and well-tolerated**
- BX211 **demonstrated sustained and statistically significant¹ PAR ulcer size²** ($p = 0.046$ at week 12; $p = 0.052$ at week 13), with a separation from placebo starting at week 7 with a difference greater than 40% by week 10
- BX211 also **produced statistically significant¹ improvements in both ulcer depth at week 13** (in patients with ulcer depth defined as bone at baseline ($p=0.048$), and in **reducing the expansion of ulcer area** ($p=0.017$), compared to placebo
- BX211 **demonstrated favorable trends** compared to placebo across several additional clinical parameters
- Through week 13, BX211 demonstrated comparable **efficacy against both Methicillin-susceptible and resistant strains**, as well as against **high and low biofilm producers** — consistent with the orthogonal mechanism of phage therapy to antibiotics and its inherent anti-biofilm capabilities

BX211 showed clinically relevant, statistically significant², reduction in ulcer surface area



From week 10 and on, BX211 showed an ulcer surface area reduction of >40% compared to placebo

BX211 showed clinically relevant, statistically significant², reduction in ulcer surface area

Percent Area Reduction (PAR) from baseline of ulcer surface area (LS Mean ± SE)¹ (Detailed data from previous slide)

PAR at week:	BX211		Placebo		Difference (95% CI)	P-value ²
	N (%)	Mean (95% CI)	N (%)	Mean (95% CI)		
Week 12	22 (84.6%)	-74.57% (-100.78, -48.35)	12 (80.0%)	-29.85% (-65.08, 5.38)	-44.72% (-88.65, -0.78)	0.046
Week 13	20 (76.9%)	-76.43% (-101.56, -51.30)	12 (80.0%)	-34.70% (-68.42, -0.99)	-41.73% (-83.60, 0.34)	0.052

	BX211		Placebo		Difference (95% CI)	P-value
	N, e (%)	Mean (95% CI)	N, e (%)	Mean (95% CI)		
Through weeks 1 to 13³:	N=26, e=264 (90.5%)	-57.05% (-39.07, -75.04)	N=15, e=164 (84.1%)	-37.09% (-12.91, -61.27)	-19.96% (10.20, -50.12)	0.186

N = Number of patients, e = Number of events

Day	1	2	3	4	5	6	7	8	9	10	11	12	13
BX211 (N)	26	23	23	25	24	23	22	19	23	23	22	22	20
Placebo (N)	14	14	13	12	14	12	12	12	12	12	12	12	12

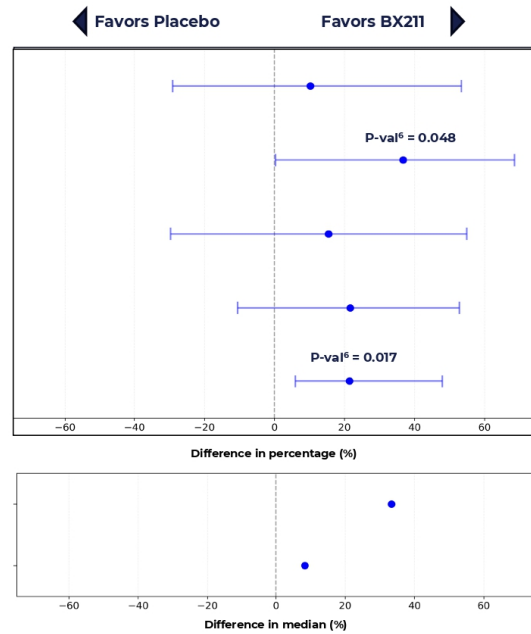


1. Full Analysis Set (FAS) population, all data are MMRM (Mixed Model Repeated Measure) LS mean and SEs (Standard Error)
 2. PAR – Percent Area Reduction, CI - Confidence Interval, CFB – Change From Baseline
 3. Primary endpoint

BX211 performs better than placebo across a range of clinical outcomes

Outcomes

- **Evidence of DFO resolution by MRI/X-ray** at week 12^{1,4} (BX211 N=13, Placebo N=6)
- **Improvement in tissue involvement** at week 13^{1,2,5} (BX211 N=13, Placebo N=9)
- **50% Reduction From Baseline in CRP** through week 13^{1,3,5} (BX211 N=12, Placebo N=7)
- **Decrease in Wagner scale** at week 13^{1,4} (BX211 N=20, Placebo N=12)
- **No worsening in ulcer area** through week 13^{1,5} (BX211 N=25, Placebo N=14)
- **Proportion of visits with no clinical evidence of infection (<2 symptoms)** through week 13⁵ (BX211 N=12, Placebo N=11)
- **Proportion of visits with no deterioration of clinical symptoms** through week 13⁵ (BX211 N=25, Placebo N=14)



BX211: Potential Breakthrough in DFO/DFI

- Results of the Phase 2 study mark, to the Company's knowledge, the first well-controlled, double-blind, placebo-controlled clinical study to demonstrate statistically significant efficacy of a phage therapy in a clinical endpoint for a chronic bacterial infection
- Treating patients with DFO and demonstrated clinical effect on top of standard of care including antibiotics, highlights the clinical strength of BX211 and the unique properties of phage therapy
- In the last 20 years, no new drugs were approved for DFI or DFO, providing a unique opportunity for BX211 to address this dire unmet need

Executive Summary



UNMET NEED

- In several chronic diseases, such as CF, NCFB, and diabetes, underlying related infections become harder to treat as resistant pathogens emerge
- Accordingly, the need for new antimicrobial therapies becomes more urgent every year



PHAGE THERAPY - PICKING UP MOMENTUM

- BiomX and peer companies have shown evidence of clinical effects with phage therapy
- Hundreds of cases of compassionate usage of phage



BX004

- *Pseudomonas aeruginosa* ("PsA") lung infections are a leading cause of morbidity and mortality in CF. Potential commercial opportunity of > \$1.5 billion worldwide¹
- Positive results in a Phase 1b/2a study - 14.3% of patients in the BX004 arm converted to sputum culture negative for PsA after 10 days of treatment compared to none in the placebo arm²
- Phase 2b readout expected Q1 26



BX211

- Incidence of moderate-severe DFI + DFO annually in US approximately 400,000. Potential commercial opportunity of > \$2.5 billion worldwide³
- Positive results in P2 study, preparing Phase 2/3 pending FDA feedback



FINANCING AND INVESTORS

- Publicly traded (NYSE American: PHGE)
- \$18.0 million cash and cash equivalents as of Dec 31, 2024 (Excluding 12M in gross proceeds raised in February 2025 financing)

• Key investors:
DEERFIELD
Advancing Healthcare™



Thank you

BiomX

BX004 CF addressable market of > \$1.5 billion worldwide

	BX004	References/Comments
Patient population (US)	~8,000	Number of CF patients with chronic PsA infections ¹
Potential effect on PsA CFU in lungs	Suppression/eradication of PsA (CFU in sputum)	Magnitude observed under tobramycin Phase 3 study was ~1.5-2 log ²
Potential impact on lungs	Improved lung function (FEV1)	Magnitude observed under tobramycin Phase 3 study was 8-12% ²
Potential pricing (US)	\$100K - \$120K annually per patient	Benchmarks (cost annually per patient): Trikafta: \$300K, alternating antibiotics treatment, Tobi Podhaler and Cayston solution: \$80K, Arikayce for MAC: \$100-120K ³
Relevant market potential	~\$1 Billion in the US alone (worldwide \$1.6 billion) ⁴	US patient population times potential pricing

BX211 moderate-severe DFI & DFO addressable market of >\$2.5B worldwide

	BX211	References/Comments
Incidence of moderate-severe DFI + DFO (annually, US)	400,000	Moderate-Severe DFI overlaps with DFO population Incidence assumed based on 400K ER hospital visits due to DFI ¹
Relevant incidence for BX211 treatment (annually, US)	200,000	Deduction for cases positive for S. aureus – 50%
Pricing (US)	\$7,500	Antibiotic pricing per course of treatment for ABSSSI ² ranges 2,500-7,500\$ (Dalvance, Orbactiv, Sivextro, Teflaro) ³ High range of pricing selected as addressing hard to treat moderate-severe DFI & DFO cases saving potential amputation costs (direct \$50K/patient)
Relevant market for BX211, US	\$1.5 Billion	200K times \$7.5K
Relevant market for BX211, Worldwide	>\$2.5 Billion	OECD (without US) estimated at >\$1 billion. Assumes: OECD diabetic population outside US >1.5 times US diabetic population, OECD pricing to be 50% of US pricing ⁴

Management Team



JONATHAN SOLOMON | CEO & BOARD MEMBER

Prior to his role in BiomX, Mr. Solomon was a co-founder, president, and CEO of ProClara (formerly NeuroPhage), which is pioneering an approach to treating neurodegenerative diseases. Under his leadership, the company raised more than \$100 million and launched an ongoing clinical trial related to Alzheimer's disease. Mr. Solomon holds a B.Sc. magna cum laude in Physics and Mathematics from the Hebrew University, an M.Sc. summa cum laude in Electrical Engineering from Tel Aviv University, and an M.B.A. with honors from the Harvard Business School.



MERAV BASSAN, PH.D. | CDO

Dr. Bassan was most recently Vice President Head of Translational Sciences at Teva Pharmaceutical Industries, Inc., where she was responsible for early stages of clinical development via translation from animal data to human. Prior to this role, Dr. Bassan served as Vice President of Project Leadership at Teva Pharmaceutical, where she managed project leaders overseeing end-to-end drug development at pre-clinical, PI-III and post marketing stages in multiple therapeutic areas, such as pain, oncology, women's health, endocrinology, GI, biosimilars and other areas. Overall, Dr. Bassan has over 20 years of leadership experience with clinical and drug development teams in her various roles at Teva Pharmaceutical and other smaller biotech companies.

Management Team (cont'd)



MARINA WOLFSON | CFO

Marina Wolfson, Chief Financial Officer, joined BiomX in December 2019, bringing extensive experience from large pharmaceutical and high-tech companies, as well as venture capital funds. Prior to joining the company, Ms. Wolfson served as Vice President of Finance at BioView Ltd. (TASE) from 2010 to 2019 and as a senior auditor at Ernst & Young, an international auditing and business advisory firm, from 2007 to 2010. Ms. Wolfson is a certified public accountant in Israel and holds a B.A. in Economics and Accounting (with honors) and an MBA (with honors, specializing in finance) from Ben-Gurion University.



INBAL BENJAMINI-ELRAN | CHRO

Ms. Benjamini-Elran has over 15 years of experience in executive HR roles in global and diverse environments. At Teva Pharmaceuticals Industries Inc (NYSE:TEVA) she served in various senior roles including Director of HR of the European HQ (Netherlands) and HR manager of R&D API division. Her most recent experience was as Head of HR at Herzog, one of the largest law firms in Israel and as an independent HR consultant, advising a variety of companies in the Israeli hi-tech and biotech sectors. Ms. Benjamini-Elran holds an M.B.A. from Bar-Ilan University and a B.A. in behavioural science from Ben-Gurion University.

Board of Directors



RUSSELL GREIG, PH.D.
CHAIRMAN OF THE BOARD OF DIRECTORS

Russell G. Greig, Ph.D. worked at GlaxoSmithKline for three decades, most recently as President of SR One, GlaxoSmithKline's corporate venture group. Prior to joining SR One, he served as President of GlaxoSmithKline's Pharmaceuticals International from 2003 to 2008 as well as on the GlaxoSmithKline corporate executive team. Currently, Dr. Greig serves as Chairman of MedEye Solutions in the Netherlands, eTheRNA in Belgium and Sanifit in Spain.



ALAN MOSES, MD
DIRECTOR

Alan Moses, M.D., was co-founder and co-director of the Clinical Investigator Training Program at Beth Israel Deaconess-Harvard Medical School-MIT. Dr. Moses served as Senior Vice President and Chief Medical Officer of the Joslin Diabetes Center in Boston. He was appointed Professor of Medicine at Harvard Medical School. Over the course of 14 years at Novo Nordisk, Dr. Moses served in multiple roles, rising to the position of Senior Vice President and Global Chief Medical Officer.



EDDIE WILLIAMS
DIRECTOR

Mr. Eddie Williams is a well-recognized, senior global life sciences executive with extensive boardroom and commercial operations experience. He most recently served as a Special Advisor to the Chief Executive Officer of Ascendis Pharma, Inc., and previously as their interim U.S. Chief Commercial Officer.



JONATHAN SOLOMON
DIRECTOR

Prior to his role in BiomX, Mr. Solomon was a co-founder, president, and CEO of ProClara (formerly NeuroPhage), which is pioneering an approach to treating neurodegenerative diseases. Under his leadership, the company raised more than \$100 million and launched an ongoing clinical trial related to Alzheimer's disease.



JONATHAN LEFF
DIRECTOR

Jonathan Leff is a Partner on the Therapeutics team at Deerfield and Chairman of the Deerfield Institute, and joined the Firm in 2013. He focuses on venture capital and structured investments in biotechnology and pharmaceuticals. He is a member of the Boards of several public and private healthcare companies as well as several not-for-profit organizations, including the Spinal Muscular Atrophy Foundation and the Columbia University Medical Center.



GREG MERRIL
DIRECTOR

Mr. Greg Merrill is a serial life-science entrepreneur, recognized by Ernst & Young as a regional Entrepreneur of the Year winner. He has served as Chair of several international phage therapy conferences. As prior founding CEO of Immersion Medical (NASDAQ: IMMR) he led the creation of the world's first commercially successful virtual reality surgical training simulators.



JESSE GOODMAN, MD, MPH
DIRECTOR

Jesse Goodman, M.D., M.P.H. is Professor of Medicine at Georgetown University and Director of the Center on Medical Product Access, Safety and Stewardship which focuses on science and policy to address public health needs including antimicrobial resistance. He is Attending Physician in Infectious Diseases at Georgetown University, Washington DC Veterans Administration and Walter Reed Medical Centers.



SUSAN BLUM
DIRECTOR

Ms. Blum is the Chief Financial Officer of Melinta Therapeutics, LLC. ("Melinta"), a company focused on the development and commercialization of innovative therapies for acute and life-threatening illnesses. She joined Melinta in 2016 as the company's Controller, and then served as Vice President of Finance & Chief Accounting Officer prior to being appointed to the CFO position in 2021.