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): **July 8, 2025**

BiomX Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38762**	**82-3364020**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

22 Einstein St., Floor 4 Ness Ziona, Israel	**7414003**
(Address of Principal Executive Offices)	(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 July 8, 2025, BiomX Inc., or the Company, issued a press release announcing the publication of a peer-reviewed article in Nature Communications presenting new efficacy data from the Phase 1b/2a trial of BX004 in cystic fibrosis patients with chronic Pseudomonas aeruginosa infections. A copy of the press release is furnished as Exhibit 99.1. The Company also posted an updated corporate slide presentation on its website, furnished as Exhibit 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	**Description**
99.1	Press Release dated July 8, 2025, titled "BiomX Announces Publication in*Nature Communications* of Phage Cocktail BX004 Phase 1b/2a Part 1 Data Demonstrating Strong Activity in Cystic Fibrosis" (furnished herewith)
99.2	Corporate Presentation Deck dated July 8, 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.

BIOMX INC.

July 8, 2025

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

Exhibit 99.1

BiomX Announces Publication in *Nature Communications* of Phage Cocktail BX004 Phase 1b/2a Part 1 Data Demonstrating Strong Activity in Cystic Fibrosis

Premier research journal article provides validation for BiomX's phage therapy platform, showcasing first-in-human Phase 1b/2a trial results for antibiotic-resistant P. aeruginosa infections

New, updated data demonstrates a further bacteria reduction of 2.7 log_{10} (approximately 500-fold) compared to placebo, with no emergent resistance and preservation of a healthy microbiome

BiomX is advancing its Phase 2b trial of BX004 with topline results expected Q1 2026

NESS ZIONA, Israel, July 8, 2025 -- 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 the publication of a peer-reviewed article in *Nature Communications* titled, "Phage therapy with nebulized cocktail BX004-A for chronic *Pseudomonas aeruginosa* infections in cystic fibrosis: a randomized first-in-human trial". The article notably features previously unreported antimicrobial efficacy data from the Phase 1b/2a clinical trial and reinforces the strength of BiomX's innovative approach to developing bacteriophage therapies for chronic disease with substantial unmet needs. The publication is available at: Link.

"The publication of our peer-reviewed results in a preeminent research journal, including new data showing antimicrobial activity of BX004, provides significant third-party validation of our phage therapy platform to treat patients with chronic *P. aeruginosa* cystic fibrosis (CF) infections," said Jonathan Solomon, BiomX's Chief Executive Officer. "Building upon the strong scientific rigor of our clinical program and our findings in patients showing meaningful bacterial reduction where antibiotics have failed, we have initiated our Phase 2b trial of BX004, with topline results expected in the first quarter of 2026."

The peer-reviewed results of Part 1 of BiomX's BX004 Phase 1b/2a study include new analyses showing that BX004 achieved a substantially greater improvement of approximately 500-fold (additional improvement of 2.7 log_{10}) in bacterial reduction compared with placebo in CF patients. Notably, the data highlights that no bacterial resistance to BX004 emerged during the trial, addressing a critical limitation of traditional antibiotics. Findings from Part 1 of the Phase 1b/2a study were consistent with the results observed in Part 2.

"Drawing on decades of experience in large-scale genomic analysis and bacterial defense mechanisms, the study demonstrates how large-scale data analysis can be used to optimize bacteriophage cocktails for treating chronic infection associated with cystic fibrosis," said Rotem Sorek, Ph.D., Professor of Genetics, Weizmann Institute of Science. "By combining experimental and computational methods, we've developed a design approach that broadens bacterial strain coverage, lowers the likelihood of resistance, and enhances activity against bacterial biofilms, establishing an effective framework for designing next-generation bacteriophage therapeutics."

Key Highlights from the Study

Part 1 of BiomX's Phase 1b/2a study evaluated the safety, tolerability, pharmacokinetics, and anti-microbiologic activity of BX004 over a 7-day treatment period in nine CF patients (seven on BX004, two on placebo) with chronic *P. aeruginosa* pulmonary infection. The Part 1 data demonstrated:

- **Strong Safety Profile:** BX004 was safe and well-tolerated with no treatment-related safety events across all patients and dose levels tested.
- **Successful bacterial reduction achieved:** At day 15, BX004-treated patients showed a negative 1.42 log_{10} reduction in *P. aeruginosa* bacteria from baseline, while patients receiving placebo worsened by +1.26 log_{10} CFU/g. This 2.7 log_{10} CFU/g treatment effect (which represents approximately a 500-fold, or 99.8%[1], greater bacterial reduction with BX004 versus placebo) was achieved on top of standard of care inhaled antibiotics. These findings resulted from an additional *post hoc* analysis and are being reported for the first time. Results at day 4 during BX004 treatment showed *P. aeruginosa* burden reduction (1.9 log_{10} CFU per gram of sputum difference between groups).
- **Therapeutic phages successfully reached and persisted at infection site:** Phages were detected in all patients treated with BX004 during the dosing period, including in several patients up to day 15 (one week after end of therapy). As expected, no phages were detected in patients receiving placebo.
- **No bacterial resistance to treatment:** There was no emerging treatment-related resistance to BX004 during or after treatment with BX004, addressing efficacy of phage against bacteria where resistance is common amongst traditional antibiotics.
- **Favorable shifts in microbiome composition post treatment:** Microbiological signals included a reduction in *P. aeruginosa* relative abundance and an increase in microbiome alpha diversity in the phage-treated group, in contrast to the placebo group.

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

The *Nature Communications* publication describes the full translational path from laboratory discovery to clinical testing. Environmental phages were isolated and screened using *P. aeruginosa* grown under conditions mimicking the CF lung environment. *In silico* screening confirmed the absence of known genes associated with antibiotic resistance or virulence.

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 patients in a randomized, placebo-controlled 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 U.S. Food and Drug Administration 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 plans to initiate and enroll patients in the Phase 2b trial and timing of topline results thereof, enrollment of patients in a Phase 2b trial of BX004, the Company’s leadership in developing natural and engineered phage cocktails and personalized phage treatments for chronic diseases, the potential safety, efficacy and toleration of BX004, the potential benefits of BX004, future clinical development of BX004, and the potential of its candidates to address the substantial unmet needs of patients with intractable 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; 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:

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Ben Cohen
Head Corporate Communications
benc@biomx.com

Exhibit 99.2


Clinical Stage Programs Addressing Urgent Need for Overcoming Antibiotic Resistance
Corporate Presentation
July 2025
BiomX
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 ("FDA") and foreign regulatory agencies, including timing thereof, the use of Real World Evidence and potential to obtain accelerated approval, among others, potential commercial opportunities, the potential to use our product candidates for new indications, 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 FDA. 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.

Antimicrobial Resistance: Rising concerns and limited treatment options underscore the urgent need for novel therapies

35% ➡ Resistance Rate of *S. Aureus to antibiotic Methicillin*[1]

70% ➡ Increase in Death Associated with Antimicrobial Resistance Expected by 2050[2]

>2x ➡ Increase in Death Associated with Antibiotic Resistant *S. aureus* from 1990 to 2021[2]

10M

Annual Deaths by 2050
WHO projected Antimicrobial Resistance Mortality[3]

$100T

Drug Resistant Infection Cumulative Economic Loss by 2050[4]

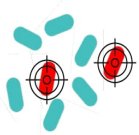
1. World Health Organization (2022). Global antimicrobial resistance and use surveillance system (GLASS) report: 2022.
2. GBD 2021 Antimicrobial Resistance Collaborators (2024). *Lancent*. Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050
3. World Health Organization. (2019, April 29). New report calls for urgent action to avert antimicrobial resistance crisis
4. O'Neill, J. (2016). Tackling drug-resistant infections globally: Final report and recommendations. Review on Antimicrobial Resistance

Phage Therapy: A century-old solution with renewed promise

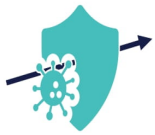
Key Advantages

Active against Antibiotic Resistant Strains

Safe Modality, Inert to Human Cells, and Supported by FDA



Targets Only Harmful Bacteria – No Disruption to Microbiome



Penetrates and Disrupts Biofilm

Self-Amplifying Phages Increase Efficacy of Each Dose

Ability to Launch Straight into Early/Mid Clinical Development

Though first discovered >100 years ago, phage therapy struggled to gain traction—now, with rising antibiotic resistance and recent positive clinical data, we believe that its breakthrough moment has finally arrived

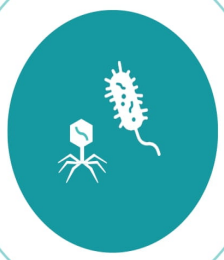
Phage Therapy Momentum: Growing clinical data signal a pivotal moment ahead[1]

March 2025: BiomX positive P2 data
41 patients
Diabetic Foot Osteomyelitis
BiomX

Nov. 2023: BiomX positive P1b/2a data
43 patients
Cystic Fibrosis
BiomX

Aug. 2024: Peer company reported positive P2 Part 1 data[2]
39 patients
Urinary tract infections

May 2025: Peer company reported Positive P2 data[3]
50 patients
Bacteremia



Phage Therapy Clinical Trails

- Emergence of first well-controlled, double-blind, placebo-controlled phage therapy trials
- BiomX – the first to show statistically significant clinical efficacy in a chronic bacterial infection
- Phage therapy – added benefits on top of standard-of-care, including antibiotics
- Phage therapeutics targeting high-need indications—some with no approved treatments

1. Press releases of BiomX and other companies developing phage therapies. Disclaimer: BiomX is not responsible for, and expressly disclaims responsibility for, the content of third party press releases
2. Locus Biosciences. Locus Biosciences Announces Positive Results from Part 1 of ELIMINATE Phase 2 Trial of the Engineered Bacteriophage Therapy LBP-EC01 Published in The Lancet Infectious Diseases. GlobeNewswire. August 12, 2024.
3. Armata Pharmaceuticals Announces Positive Topline Data from the Phase 1b/2a diSArm Study of Intravenously Administered AP-SA02 in Complicated Staphylococcus aureus Bacteremia. PR Newswire. May 19, 2025

Company Overview:

BiomX's Phage Therapy Solutions

Alarming rise in antimicrobial resistance signals urgent need for better treatment

Phage therapy emerging as a powerful solution for persistent infections, supported by growing body of efficacy and safety data

BX211 – *S. aureus* infections

Positive efficacy and safety data **(Phase 2)** in DFI & DFO with *S. aureus* infection, showing **sustained ulcer reduction** and **superior recovery outcomes** in bone-depth ulcers

Planned Phase 2/3 pending regulatory discussions

Potential additional Phase 2 ready indications: **PJI**

BX004 – *P. aeruginosa* infections

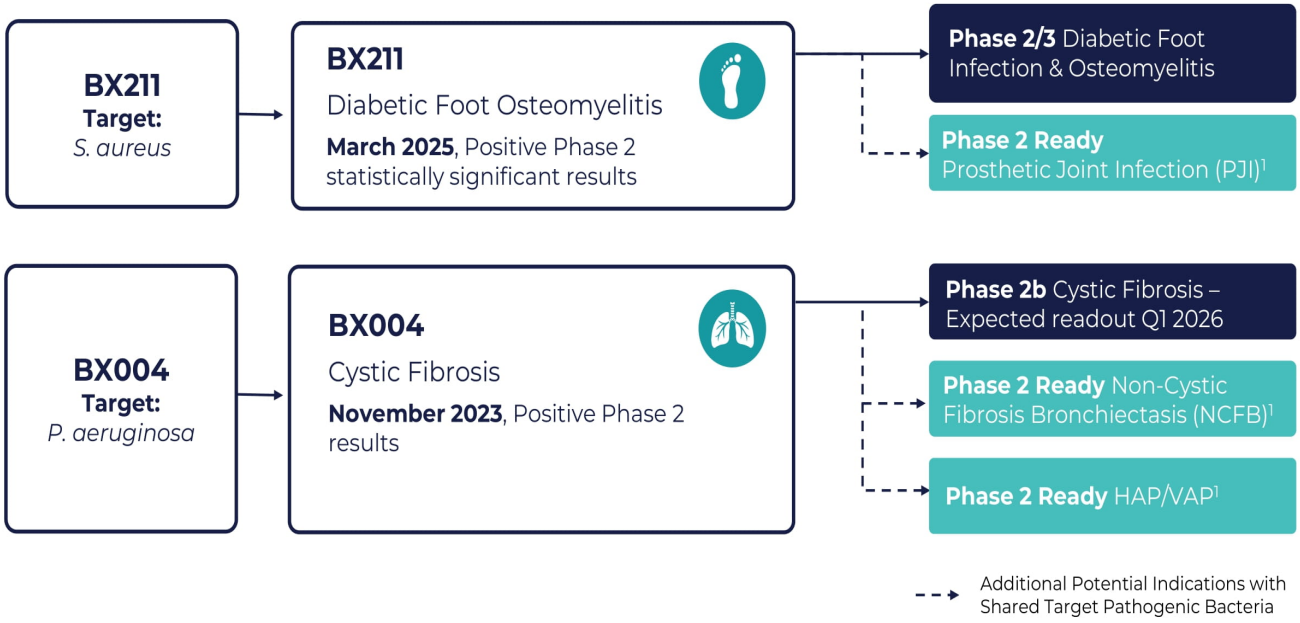
Positive Phase 1b/2a data in CF patients with *P. aeruginosa* infection, demonstrating **sputum culture conversion**, **improved lung function,** and **bacterial reduction**

Phase 2b study ongoing

Potential additional Phase 2 ready indications: **NCFB, HAP/VAP**

DFI: Diabetic Foot Infection; DFO: Diabetic Foot Osteomyelitis; PJI: Prosthetic Joint Infection
CF: Cystic Fibrosis; NCFB: Non-cystic Fibrosis Bronchiectasis; HAP/HVP: Hospital-acquired / Ventilator-associated Pneumonia

Shared Targets, Expanded Potential: Clinical efficacy opens the door to potential additional Phase 2 studies across related infections

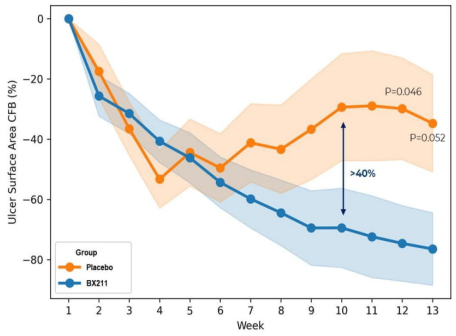


1. Additional potential indications that could be pursued with shared target bacteria as parent program

BiomX's Groundbreaking Phase 2 Results

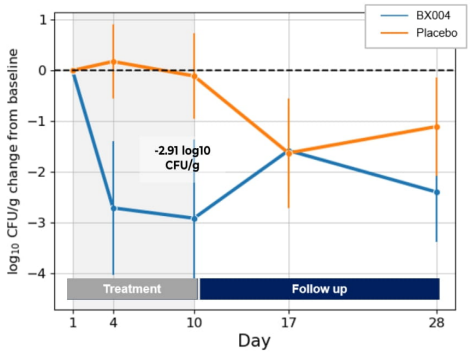
Efficacy of phage therapy across indications

Diabetic Foot Osteomyelitis (BX211): On top of antibiotic SoC



The 1st multi-center, double-blind, placebo-controlled clinical study to demonstrate statistically significant efficacy of a phage therapy in a clinical endpoint for a chronic bacterial infection

Cystic Fibrosis (BX004): On top of antibiotic SoC



Demonstration of ability of phage to convert chronic lung infections (13-35 yrs, >10^7 PFU/g) to sputum culture negative with 10 days of phage treatment & signals of improvement vs placebo in pulmonary function and PROs

- Two positive phase 2 trials in separate indications
- Two different bacterial targets
- Two routes of administration

BiomX

CFB – Change From Baseline; SoC – Standard of Care; CFU – Colony Forming Units; PFU – Plaque Forming unit;

BiomX—Built on a Strong Foundation: Backed by leaders in science, industry, and capital

Strong Science & Scientific Founders

Prof. Rotem Sorek
Head of microbial genomics group at Weizmann Institute
Phage genomics and CRISPR research
nature | Cell | Science | nature reviews immunology

Prof. Eran Elinav
Principal investigator at Weizmann Institute
Immune system and intestinal microbiome interactions
nature medicine | Cell | npj | biofilms and microbiomes

Prof. Timothy K. Lu
Associate professor leading synthetic biology group, MIT
Synthetic biology, biochemical engineering
nature | nature biotechnology | Cell Host & Microbe | Cell Genomics

Dr. Carl Merril
National Institutes of Health, Adaptative Phage Therapeutics
nature | Journal of Bacteriology | WILEY | PNAS

Trusted by top biotech and healthcare investors

DEERFIELD Advancing Healthcare™ | AMR ACTION FUND | OrbiMed Healthcare Fund Management

≥ $215 M Raised[1]

Working with mission-aligned global leaders

CYSTIC FIBROSIS FOUNDATION® | WRAIR

~$40 M Non-diluted Funding from U.S. Navy

BiomX

1. >$200M raised from the investors listed, among others

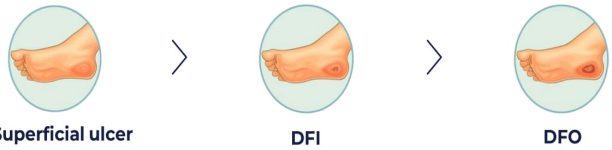
BX211

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

BiomX

Disease Burden: DFI & DFO drive diabetic amputations, burdening the healthcare system

DFI to DFO
Bacterial infection spreading from soft tissue to bone



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

Standard of Care
Suboptimal efficacy leading to high rate of amputation

Moderate-to-severe DFI & DFO SoC: 4 – 6 weeks of IV/oral antibiotics / debridement / offloading

Approved Therapy: Last drug approved for DFI in 2005 with no approved drugs for DFO in the US

Poor Prognosis: 20-40% of cases result in amputation, increasing 5-year mortality rate up to 50%

Economic Burden
Significant burden on both patients and healthcare system

>38M
Diagnosed diabetes, US 2024[1]

~160K
Lower limb amputations due to DFI/DFO[2]

~8B
Annual cost to US healthcare system (~$50K direct cost per patient)

BiomX

1. CDC National Diabetes Statistics Report, last visited March 2025 based on crude estimates for 2021
2. American Diabetes Association. (n.d.). *Amputation Prevention Alliance*. Retrieved June 8, 2025Nilsson, 2018 & Brooks 2021

Phase 2 Study Design: Multicenter, double blind, placebo-controlled study to assess improvement of clinical outcomes

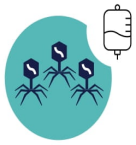
Primary Endpoint:
Percent area reduction of study ulcer through Week 13

Enrollment:

41 patients with Diabetic Foot Osteomyelitis positive for S. aureus

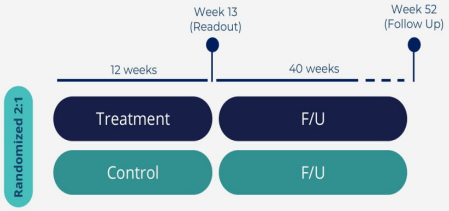
Background standard of care antibiotic

BX211



Intervention:
IV & topical

Duration: 12 weeks of once weekly treatment
IV in week 1, topical for 12 weeks



Primary Endpoints:
- 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

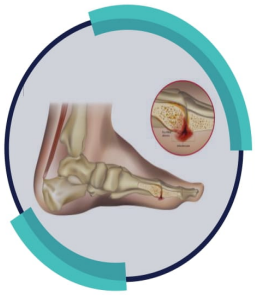
BiomX

Results Highlight: Phase 2 diabetic foot osteomyelitis

Safe and **well-tolerated**

Sustained and statistically significant **PAR ulcer size reduction**[1]

- ✓ Separation from placebo starting at week 7 with a difference greater than 40% by week 10



Statistically significant **improvements in ulcer depth** in patients with ulcers at **bone depth**

Favorable trends compared to placebo across **several additional clinical parameters**

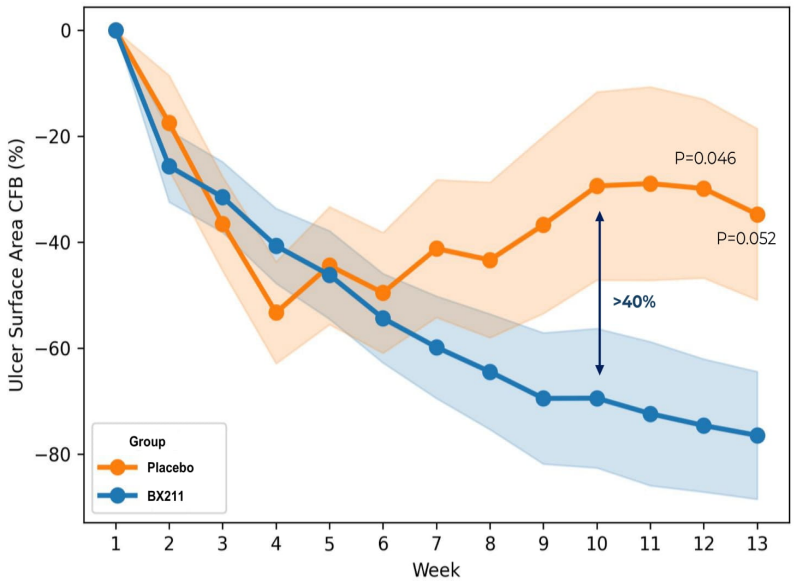
BiomX

1. Ulcer depth was classified according to deepest tissue involved as measured by swab)

PAR- Percentage Area Reduction

Efficacy (1): BX211 showed clinically relevant, statistically significant[1], reduction in ulcer surface area

Percent Area Reduction (PAR) from baseline of ulcer surface area (LS Mean ± SE)[2]
(See detailed data in next slide)



1. Not adjusted
2. Areas colored in orange and blue reflect the standard error. Full Analysis Set (FAS) population, all data are MMRM (Mixed Model Repeated Measure) LS mean and SEs (Standard Error)

PAR – Percent Area Reduction, CI - Confidence Interval, CFB – Change From Baseline

Efficacy (2): BX211 showed clinically relevant, statistically significant[2], 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%** (-83.80, 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 13[3]:	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

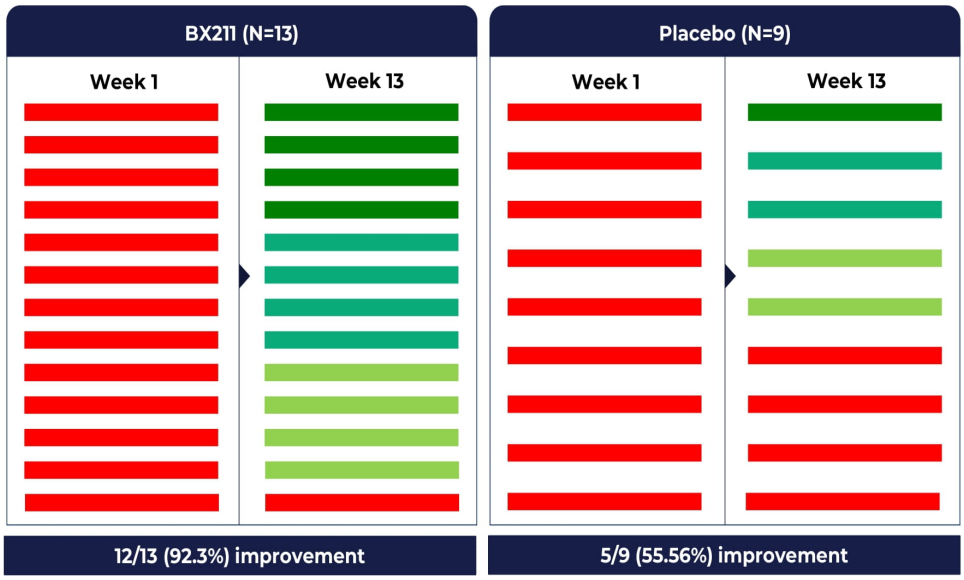
Week	1	2	3	4	5	6	7	8	9	10	11	12	13
BX211 (N)	26	23	23	25	24	23	22	19	23	23	22	22	20
Placebo (N)	14	14	13	12	14	12	12	12	12	12	12	12	12

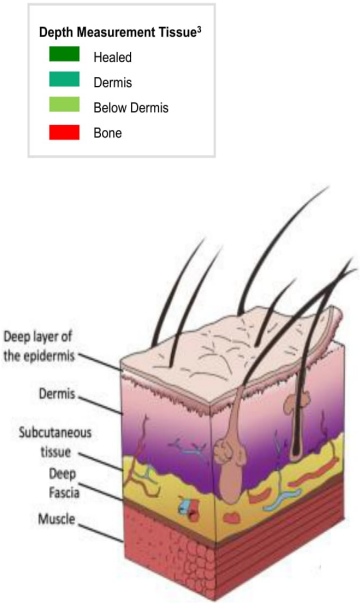
1. Full Analysis Set (FAS) population, all data are MMRM (Mixed Model Repeated Measure) LS mean and SEs (Standard Error)
2. Not adjusted
3. Primary endpoint

PAR – Percent Area Reduction, CI - Confidence Interval, CFB – Change From Baseline

Efficacy (3): Patients with ulcers at bone depth[1] displayed statistically significant[2] better recovery in the BX211 group

Change in tissue involvement of the ulcer for weeks 1 and 13[1]

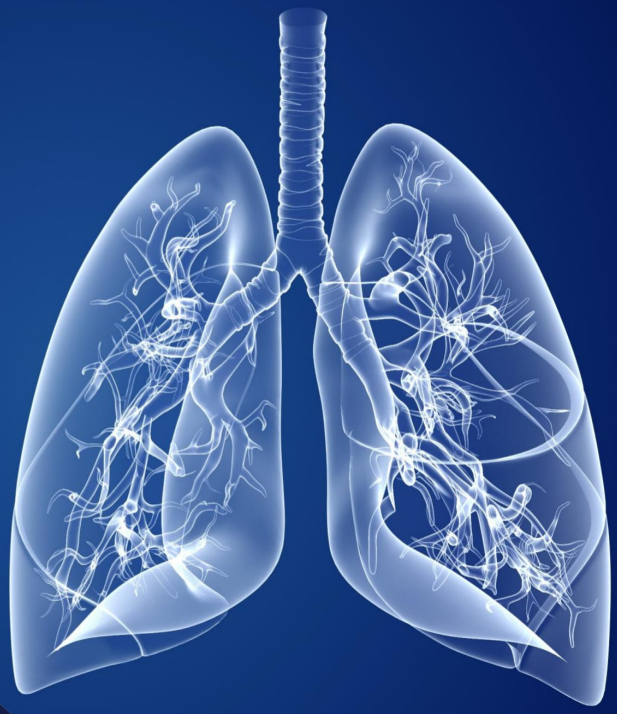




1. For all patients at FAS (Full Analysis Set) population that had measured bone involvement at baseline and have a measured tissue involvement at week 13 as measured by a swab
2. The statistical test performed is Miettinen-Nurminen test, with p= 0.048, not adjusted
3. In the figure, to avoid unblinding, Subcutaneous, Fascia and muscle were placed in the same group.

BX004

Cystic Fibrosis and NCFB



BiomX

Cystic Fibrosis: Chronic pulmonary infections and the inflammatory response are primary causes of death in CF

Cystic Fibrosis
Thick mucus promotes chronic bacteria infections

Thick, sticky mucus traps bacteria and hinders normal airway clearance, fostering **chronic lung infections**, **often driven by *Pseudomonas aeruginosa***

Standard of Care
Antibiotic resistance is associated with worse outcomes

Chronic management: Inhaled antibiotics, CFTR[1] modulators, airway clearance therapies, azithromycin

Drug-resistance: After prolonged and repeated antibiotic courses, increased resistance to antibiotics lowers efficacy and drives lung function decline and mortality in CF

Large Unmet Need
A significant number of CF patients suffer from chronic PsA infections

~105K
Prevalent CF Patients, Worldwide[2]

~33K
Prevalent CF Patients, US[2]

~17K
CF Patients Suffering from Chronic PsA infections, US and Western EU[3]

1. CFTR- Cystic fibrosis transmembrane conductance regulator
2. CF Foundation estimates across 94 countries (https://www.cff.org/intro-cf/about-cystic-fibrosis)
3. CFF Annual Data Report 2019, ECFS patient registry report, 2020

Phase 1b/2a Study Design: Multicentered, double blind, placebo-controlled study to assess safety, reduction of PsA burden and improvement in clinical outcomes

Enrollment:

43 CF patients with chronic PsA infections

Standard of care antibiotic, no restriction on CFTR modulators

BX004

Intervention:
Nebulized dosing

Part 1[1]
7 days - Single ascending dose followed by multiple doses[2]

- Treated – 7 subjects
- Control – 2 subjects

Part 2
10 days of same dose, twice daily

- Treated – 23 subjects
- Control – 11 subjects

Key Endpoints:

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

Topline results from Part 1 and 2 available

CFTR - cystic fibrosis transmembrane conductance regulator;
Image of phage product is intended as an illustration only, and may not represent the number of phages administered
1. Study design informed by input from the CF Foundation
2. 7 days duration - 3 ascending, 4 multiple dosing

Results Highlight: Phase 1b/2a cystic fibrosis (Part 1 and 2)

Study drug was well-tolerated

Reduction in bacterial load

Part 1, at Day 15: 2.7 log_{10} CFU/g treatment effect (represents approximately a 500-fold, or 99.8% , greater bacterial reduction with BX004 versus placebo)

In Part 2, in a prespecified subgroup of patients on SOC inhaled antibiotics on continuous regimen, BX004 vs. placebo showed bacterial reduction of 2.8 log10 CFU/g at EOT, exceeding Part 1 results

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 arm[1]

In Part 1, 1 of 7 (14.3%) treated patients also had converted based on physician report

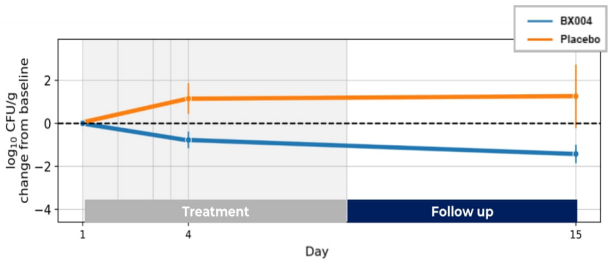
Clinical efficacy

BX004 showed signals of improvement in pulmonary function vs. placebo: Relative FEV1[2] improvement (5.67%) and CF Questionnaire-Revised respiratory[2] (8.87 points) at Day 17 (1 week after EOT) in subgroup of patients with reduced lung function[3]

CFU– Colony forming units; SOC – standard of Care: EOT – End of treatment,
1. In patients that had quantitative CFU levels at study baseline
2. FEV1 (or ppFEV1) – percent predicted forced expiratory volume in 1 second, CF Questionnaire-Revised Respiratory – a PRO (Patient reported outcome) for respiratory parameters in CF patients
3. Predefined group with Baseline FEV1<70%

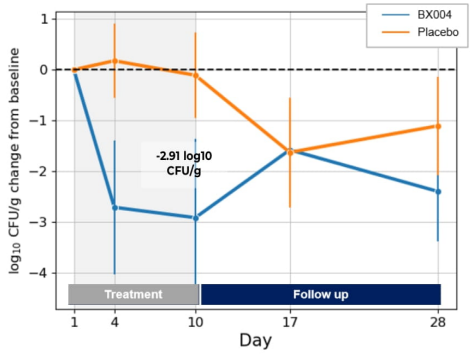
Efficacy (1): BX004 demonstrated greater reduction in PsA levels compared to placebo

PART 1 (on top of antibiotic SoC):



	BX004 (N=7)[1]	Placebo (N=2)	Difference
D4	-0.77 (0.32)	1.15 (0.47)	-1.9
D15	-1.42 (0.36)	1.26 (1.02)	-2.7

PART 2 (on top of antibiotic SoC, continuous subgroup):



CFU/g log change from Baseline: Mean (SE)

	BX004 (N=7)[1]	Placebo (N=5)	Difference
D4	-2.71 (1.21)	0.18 (0.64)	-2.89
D10	-2.91 (1.4)	-0.11 (0.73)	-2.8
D17	-1.58 (0.77)	-1.63 (0.95)	0.05
D28	-2.4 (0.9)	-1.1 (0.85)	-1.3

CFU– Colony forming units

1. BX004-A: D10 N=6

Efficacy (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:

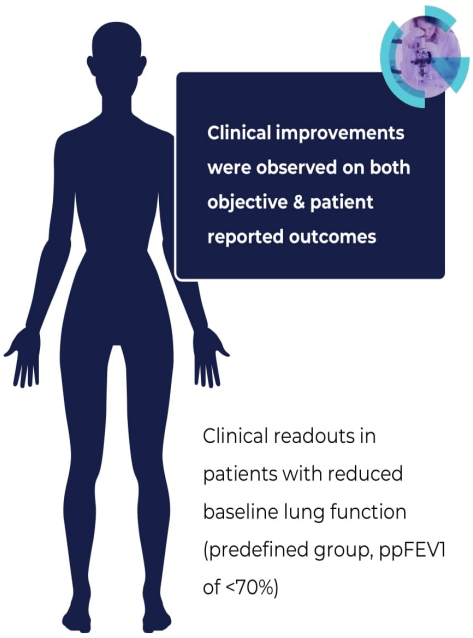
Patient	Duration of PsA infection (years)	Baseline *PsA*[1] in sputum (CFU/g)
1	**18**	**$2.40x10^3$**
2	**13**	**$5.60x10^7$**
3	**35**	**$1.09x10^7$**

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

BiomX

1. PsA – Pseudomonas aeruginosa, CFU/g – Colony forming units per gram
2. In patients that had quantitative CFU levels at study baseline

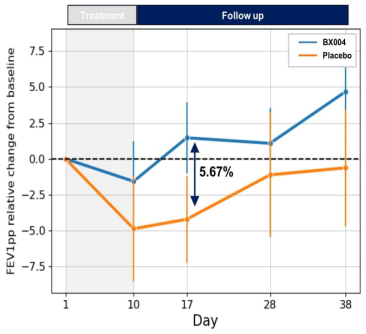
Efficacy (3): BX004 shows meaningful clinical improvement after 10 days of treatment in multiple clinical readouts



Clinical improvements were observed on both objective & patient reported outcomes

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

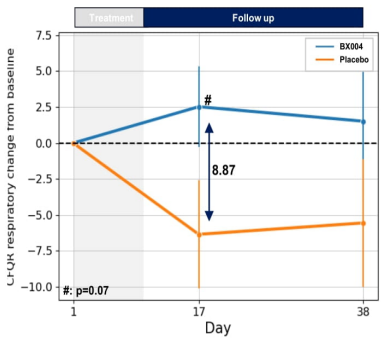
ppFEV1



ppFEV1 change from Baseline: Mean(SE)

	BX004 (N=12)[2]	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[1] (respiratory)



CFQR respiratory change from Baseline: Mean(SE)

	BX004 (N=12)[3]	Placebo (N=8)[3]	Difference
D17	2.52 (2.61)	-6.35 (3.45)	8.87
D38	1.51 (5.1)	-5.56 (4.05)	7.07

BiomX

1. PRO (Patient reported outcome) - CF Questionnaire-Revised for respiratory parameter
2. BX004: D38 N=7, Placebo: D28 N=7, D38 N=6
3. BX004: D17 and D38 N=11, Placebo: D17 and D38 N=7

Phase 2b Study: Study design

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

Enrollment:

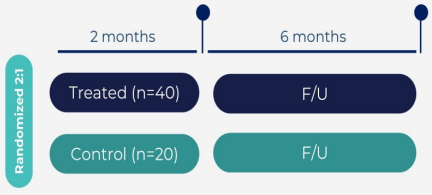
Objective: ~60 CF patients[1] with chronic PsA infections

Standard of care antibiotic, no restriction on CFTR modulators

BX004

Intervention:
Nebulized dosing

Part 2b
2 months of same dose, twice daily



Key Endpoints:

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

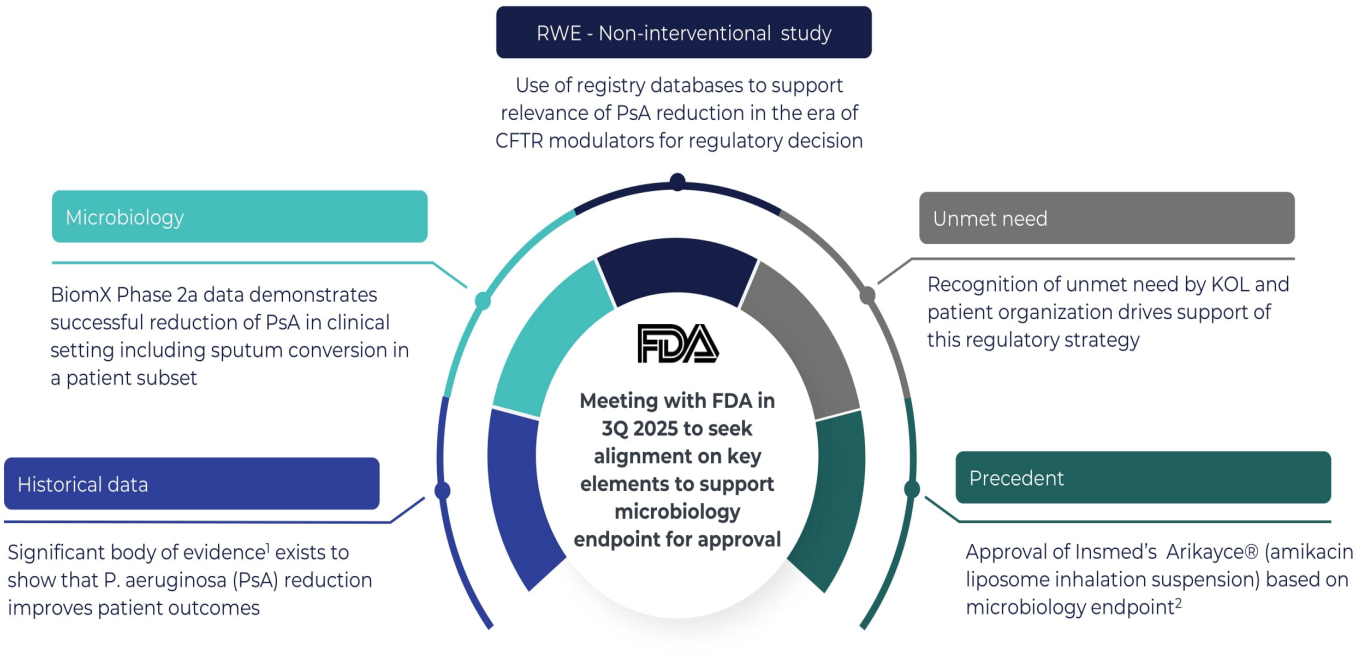
Topline results expected in Q1 2026

BiomX

1. Subject to discussions with FDA, and further consultation. Number of subjects under the study stated is an objective and actual numbers may vary
Image of phage product is intended as an illustration only, and may not represent the number of phages administered

BiomX Regulatory Strategy

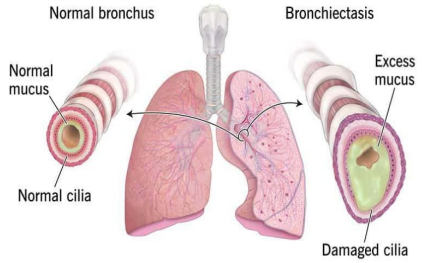
P. aeruginosa (PsA) reduction improves patient outcomes, and ongoing real-world evidence (RWE) analysis may support approval based on this microbiology endpoint



1. Journal of Cystic Fibrosis 22 (2023) 98–102; Pediatric Pulmonology 47:44–52 (2012)
2. Arikayce (amikacin liposome inhalation suspension) received accelerated approval from the FDA in September 2018 for treating Mycobacterium avium complex (MAC) lung disease in adults with limited or no alternative treatment options. This approval was based on the drug's ability to achieve sputum culture conversion (defined as 3 consecutive negative monthly sputum cultures) by Month 6, when combined with a multidrug therapy regimen. Continued approval is contingent upon the results of ongoing confirmatory trials verifying clinical benefit.

NCFB: A promising next candidate given its medical similarity to cystic fibrosis

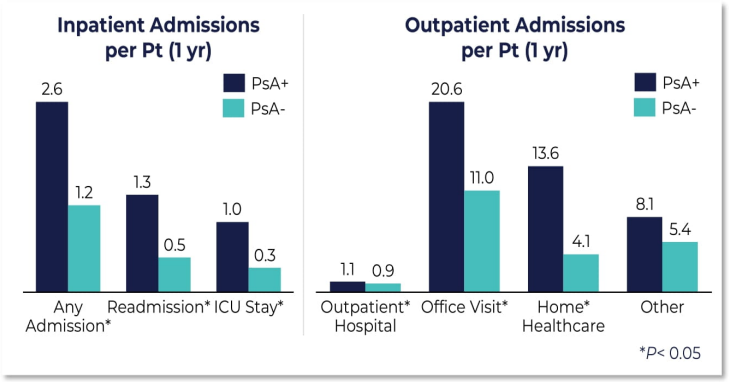
Non-Cystic Fibrosis Bronchiectasis (NCFB)



A chronic progressive inflammatory lung disease with:

>1 M	Diagnosed patients (US, EU5, Japan)[1]
0	Approved treatments

Worse Clinical Symptoms and More Inpatient / Outpatient Encounters Associated with *PsA* Infections[2]



Bacteria linked to CF and NCFB are largely the same — highlighting strong scientific rationale and disease overlap that support **pursuing NCFB**

1. .Weycker, Chron Respir Dis. 2017, Quint, European Respiratory Journal, 2016, Ringshausen, European Respiratory Journal, 2019, Henkle, Chest, 2018, Asakura, American Journal of Respiratory and Critical Care Medicine 2024, Insmed Commercial Presentation June 4th, 2024
2. Franklin et. al, JME, Apr 2024
Image source: Cleveland Clinic: Bronchiectasis

Summary

BiomX

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2 Phage Therapy Programs

2 Phase 2 Studies

Reputable Investors & Partners

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