

# BiomX

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

INVESTOR PRESENTATION  
SEPTEMBER 2024

NYSE American: PHGE



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# SAFE HARBOR STATEMENT

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# 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

## Therapeutic Focus

- Respiratory – Cystic Fibrosis (CF), Non-Cystic Fibrosis Bronchiectasis (NCFB)
- Diabetic Foot Osteomyelitis (DFO)

## Pipeline Highlights

- BX004 for CF – Positive results in P1b/2a study. P2b results expected in Q3 2025
- BX211 for DFO – Ongoing P2 study, results expected Q1 2025

## Partners



## Key Investors



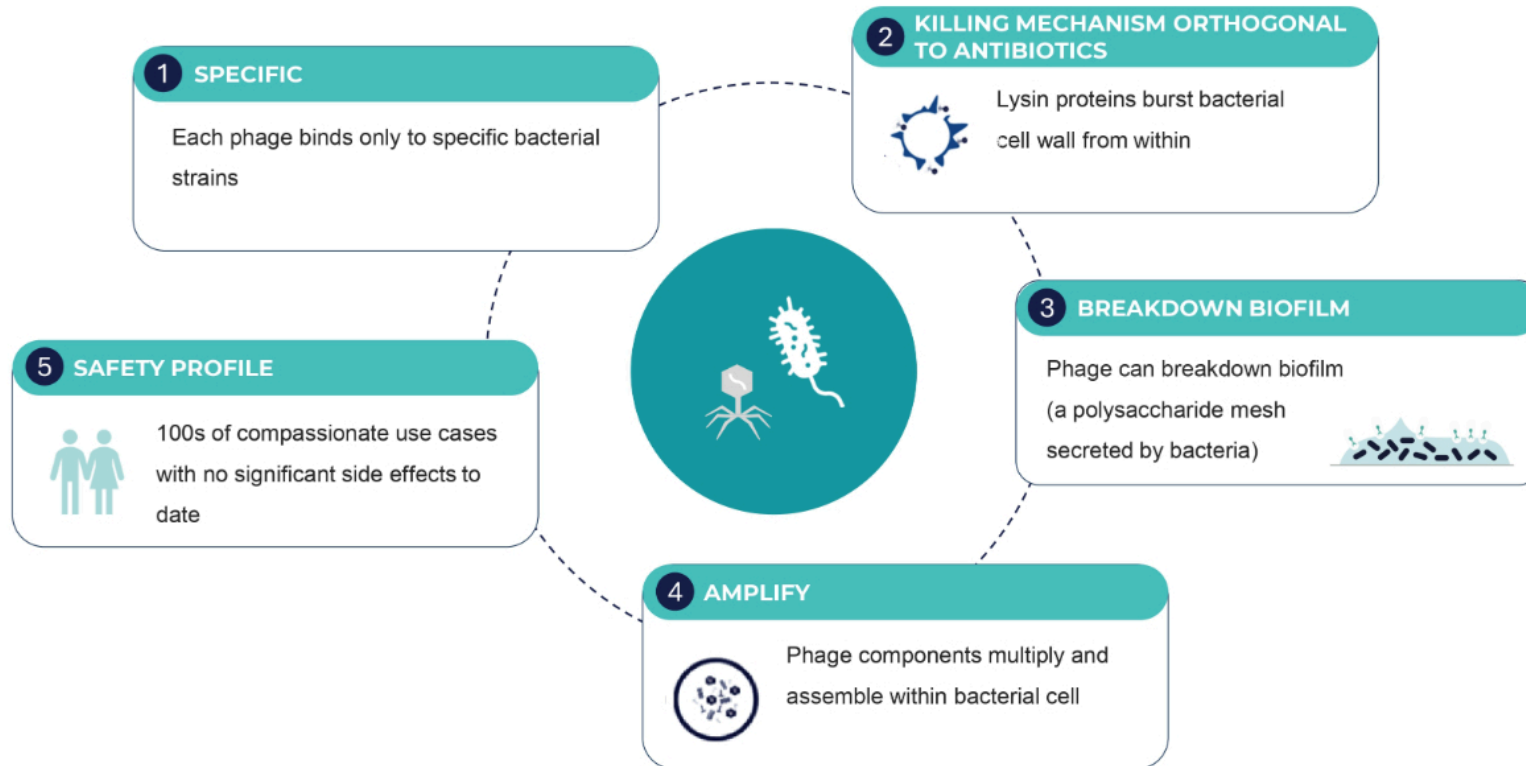


A microscopic view of numerous phages, which are virus-like particles, scattered across the frame. They appear as elongated, cylindrical structures with textured surfaces and distinct heads and tails. The background is a gradient of blue and teal, with some smaller, more spherical particles interspersed among the larger phages.

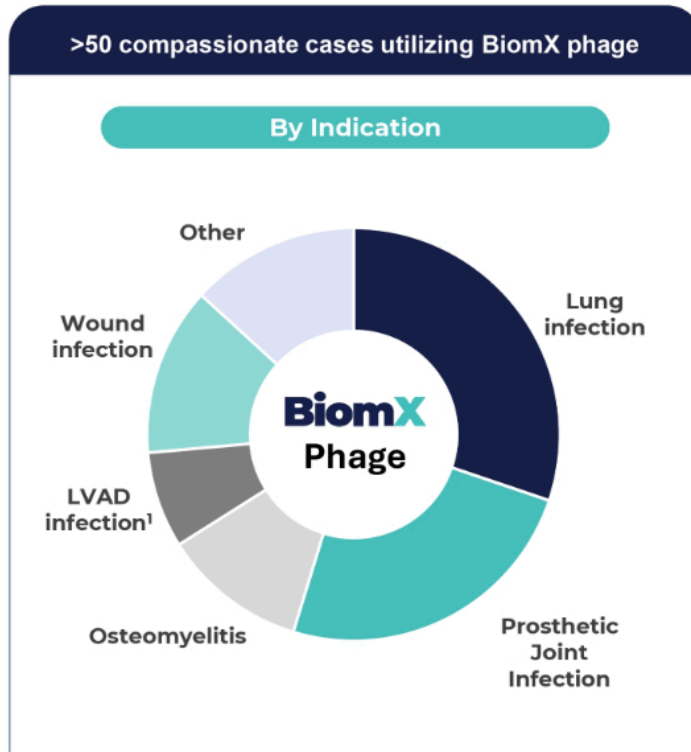
**OUR SCIENCE**  
PHAGE THERAPIES



# Phage: Nature's tool to target bacteria

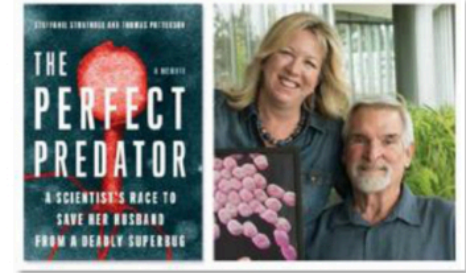


# Phage therapy picking up momentum

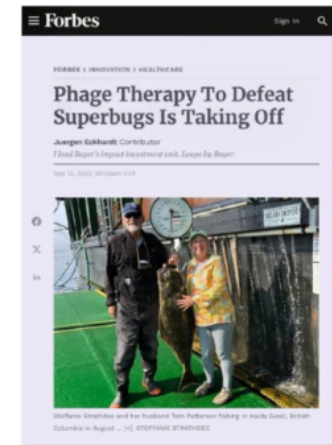


**100 cases** of compassionate phage treatment (Belgian consortium)<sup>2</sup>

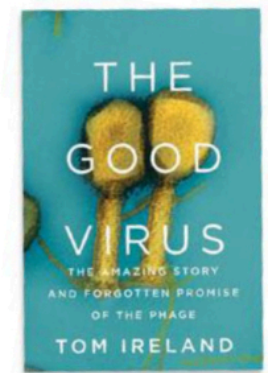
- 35 hospitals, 29 cities
- Clinical improvement reported in **77% of cases**



Feb. 2019

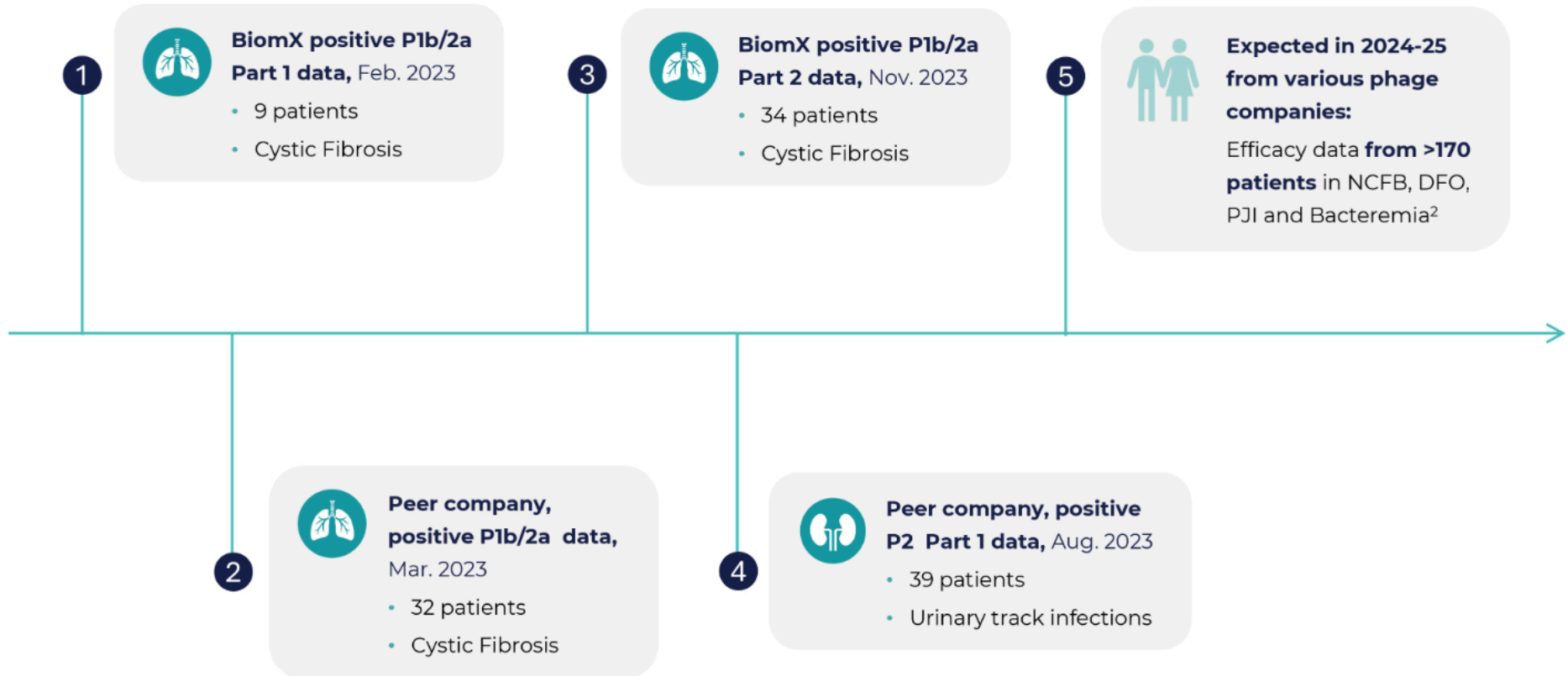


Sept. 2023



Aug. 2023

# Accumulating clinical efficacy and safety data for phage therapy in the industry<sup>1</sup>





# Pipeline

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	Phase I	Phase II	Expected readout	Partners	
Program	Indication						
BX004 <sup>(1)</sup>	Cystic Fibrosis				Ph2b topline expected Q3 2025		
BX004	Non-Cystic Fibrosis Bronchiectasis (NCFB)						
BX211	Diabetic Foot Osteomyelitis				Ph2 topline expected Q1 2025 and Q1 2026		

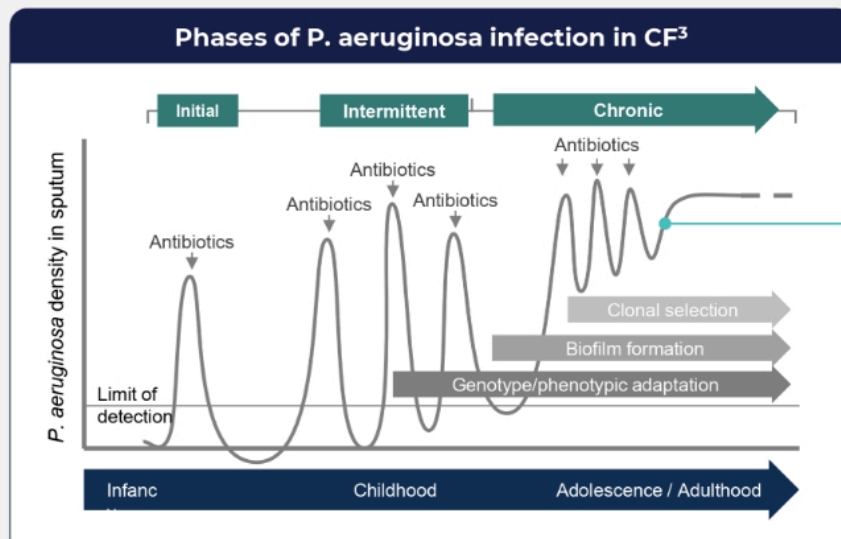
**BX004**  
**CYSTIC FIBROSIS**  
**and NCFB**



# 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 alone<sup>1</sup>

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**<sup>2</sup>



Lack of antibiotic efficacy driven by:

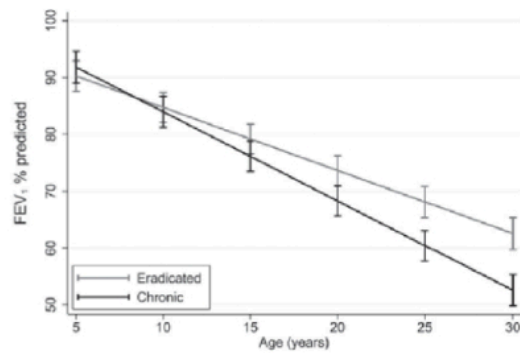
1. *P. aeruginosa* strains with multidrug resistance (MDR)

2. Formation of biofilm => making infection harder to treat



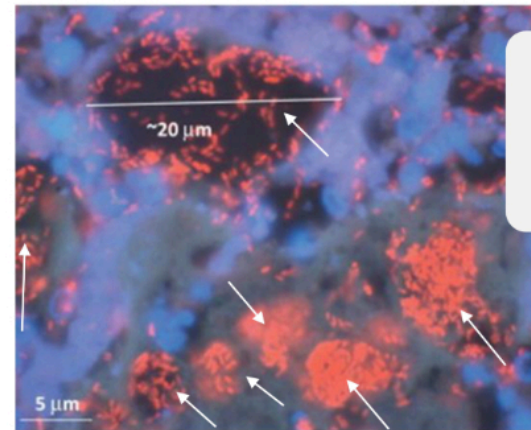
# *Pseudomonas aeruginosa* (PsA) bacteria are associated with decreased lung function (FEV1) in CF patients

## PsA colonization associated with lower FEV1<sup>1</sup>



**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 FEV1<sup>2</sup>



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 design<sup>1</sup>

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



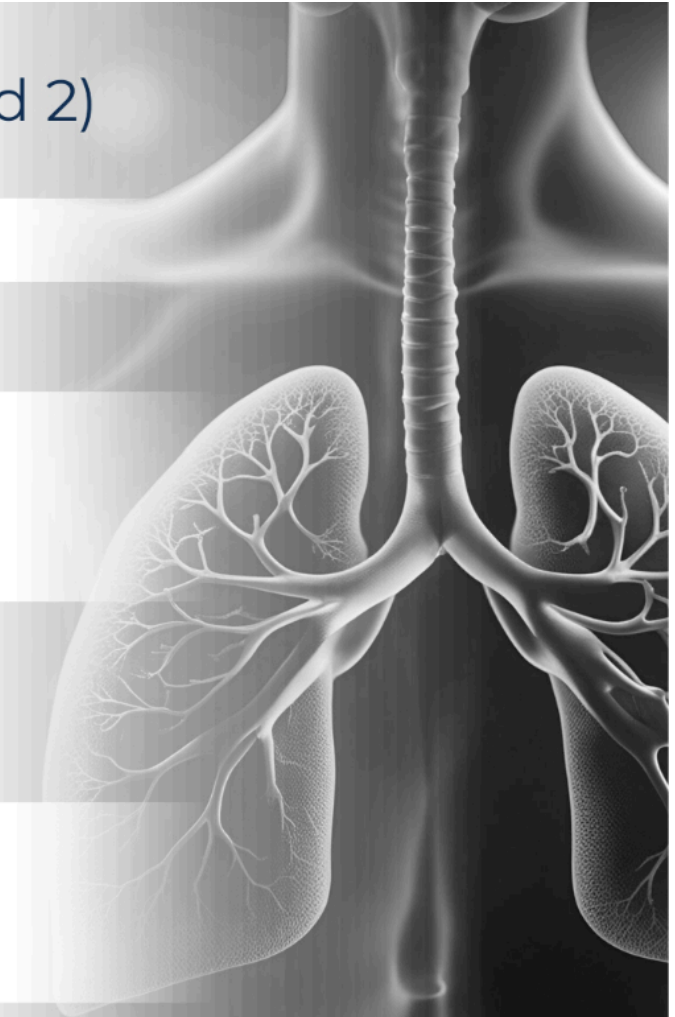
## Key Endpoints:

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

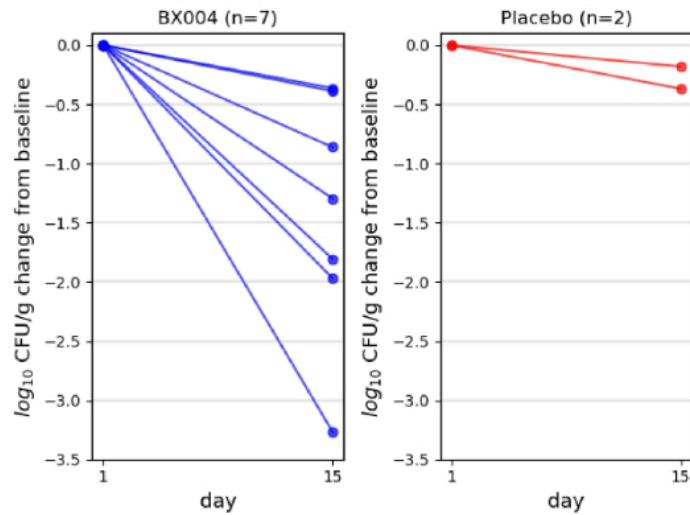


## Phase 1b/2a – Result highlights (Parts 1 and 2)

- Study drug was well-tolerated
- In Part 1, Mean PsA CFU/g<sup>1</sup> reduction at Day 15: -1.42 log<sub>10</sub> CFU/g (BX004) compared to -0.28 log<sub>10</sub> 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 arm<sup>2</sup>. 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 FEV<sub>1</sub><sup>3</sup> improvement (5.67%) and CF Questionnaire-Revised respiratory<sup>3</sup> (8.87 points) at Day 17 (1 week after EOT<sup>3</sup>) in subgroup of patients with reduced lung function<sup>4</sup>
- Part 2: In full population, BX004 vs. placebo PsA levels were more variable. In a prespecified subgroup of patients on SOC<sup>3</sup> inhaled antibiotics on continuous regimen, BX004 vs. placebo showed bacterial reduction of 2.8 log<sub>10</sub> CFU/g at EOT<sup>3</sup>, exceeding Part 1 results



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



	<b>BX004</b>	<b>Placebo</b>
n	7	2
<b>Mean reduction (SD)</b> Log <sub>10</sub> CFU/g	<b>-1.42 (1.03)</b>	<b>-0.28 (0.13)</b>
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)<sup>2</sup>. In the placebo arm 0 out of 10 (0%)<sup>2</sup>

Patients which were converted:

Patient	Duration of PsA infection (years)	Baseline <i>PsA</i> <sup>1</sup> in sputum (CFU/g)
1	18	2.40x10 <sup>5</sup>
2	13	5.60x10 <sup>7</sup>
3*	35	1.09x10 <sup>7</sup>

\*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)

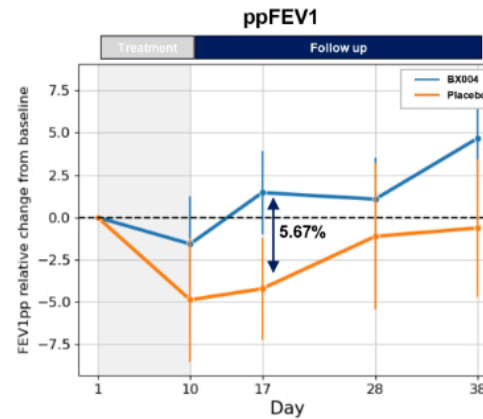
In addition, in Part 1 of the study, one subject in the BX004 arm (1/7: 14.3%) who was persistently positive for PsA for at least 13 years had a 3.3 log reduction at D15 later converted to sputum negative



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

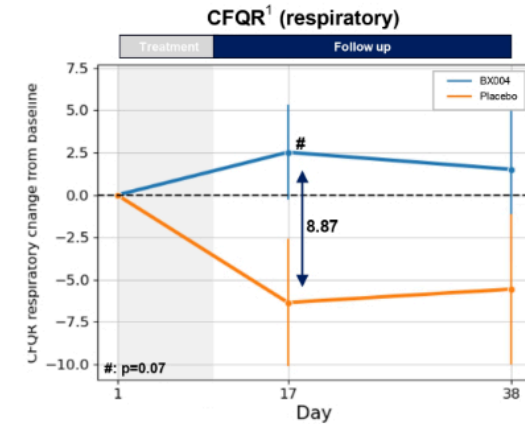
**Clinical improvements were observed on both objective & patient reported outcomes**

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



ppFEV1 change from Baseline: Mean(SE)

	BX004 (N=12) <sup>2</sup>	Placebo (N=8) <sup>2</sup>	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) <sup>3</sup>	Placebo (N=8) <sup>3</sup>	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 CRISS
  - Safety and tolerability

Topline results expected in Q3 2025

# 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)<sup>1</sup>

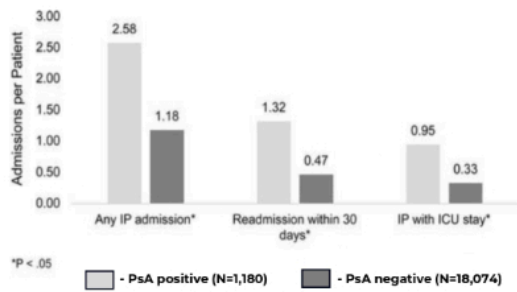
Characterized by permanent dilatation of the bronchi caused by multiple etiologies but with similar symptoms

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

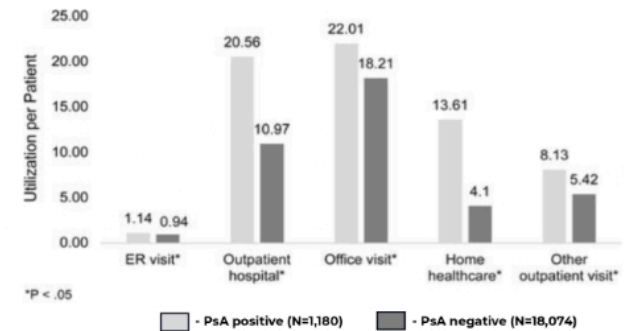
**NCFB patients infected with PsA present worse clinical symptoms compared to non-infected patients**

## More frequent inpatient and outpatient encounters in NCFB patients positive for PsA<sup>2</sup>

### 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  
Osteomyelitis  
(DFO)**



# High unmet need in DFO

DFO is a bacterial infection of the bone in patients with diabetes that is caused by bacteria spreading from adjacent infected soft tissue



1. Superficial ulcer



2. 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 DFO

## Standard of care

- 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

▶ **30-40% of DFO cases result in amputation**



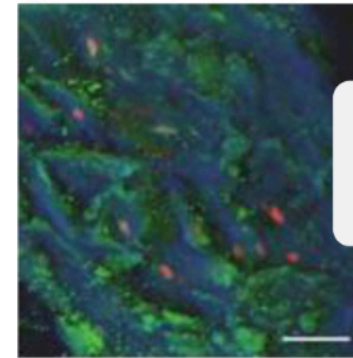
# Biofilm and antibiotic resistance among key drivers of treatment failure

## Key drivers of treatment failure:

- Biofilm - *S. aureus* inhabiting biofilms are 10 to 1,000-fold more resistant to antibiotics, compared to planktonic cells
- Poor blood supply limits effective concentration of IV/oral antibiotics
- Antibiotic resistance

- *S. aureus* present in ~50% of DFO cases
- While other organisms are often present, *S. aureus* is considered the main pathogenic species, due to its rapid doubling time and arsenal of virulence factors

## *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*

# Multiple compassionate treatments of DFO patients demonstrate potential for phage treatment

## 12 DFO cases (*S. aureus*)

9 patients

- Single phage against *S. aureus*
- Topical application or injection to bone, surrounding tissue
- 3-7 weekly applications
- Olympia, Washington

3 patients

- Administration – Direct application
- 6-45 days of application
- Jerusalem, Israel

### Outcome (in 11 out of 12 patients)

- Clearance of soft tissue infection and DFO
- Wound healing
- Prevented amputation

## 11 Osteomyelitis cases (not DFO, various bacteria)

No. of cases	Bacteria	Treatment
1	<i>A.baumannii</i> and <i>K. pneumonia</i>	IV, 11 days
5*	<i>P. aeruginosa</i>	IV 2 weeks or direct application, 7-12 days
2	<i>P. aeruginosa</i> and <i>S. epidermidis</i>	Direct application, 7-10 days
1	<i>E.faecalis</i>	Direct application, 7 days
1	<i>S.agalactiae</i> and <i>S. aureus</i>	Direct application, 9 days
1*	<i>S.aureus</i>	IV

**Outcome - at least 8 reported as clinical recovery**

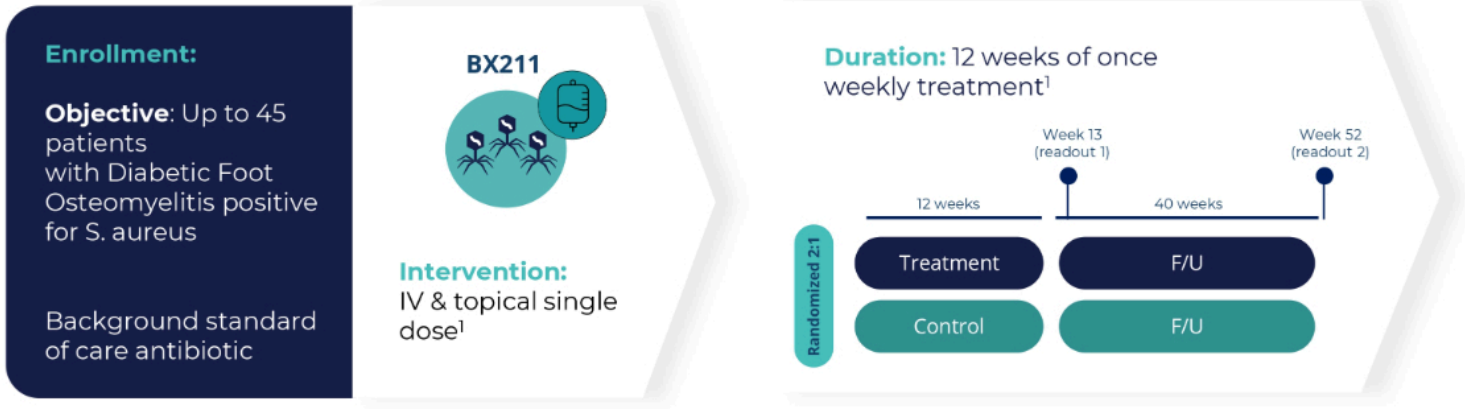
# BX211 phage treatment for DFO patients with *S. aureus*

- **Product** – Phage treatment targeting *S. aureus*. Phage, originating from a 'phage-bank', are personally matched for each patient
- **Patient population** – DFO patients with *S. aureus* infection
- **Delivery** – IV + topical
- **Treatment** - On top of standard of care
- **Key features** – Is potentially effective on antibiotic resistant strains, enables breakdown of biofilm, and improves antibiotic penetration
- **Potential impact:** (1) Prevent amputations (2) Shorten time to healing



# PHASE 1B/2A STUDY – Study design

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



## Key Endpoints:

- Percent area reduction of study ulcer through Week 13
- Time to complete ulcer healing
- Time to 85% CRP<sup>2</sup> reduction
- Percentage of subjects with amputation-free survival at Week 52
- Safety and tolerability

Topline results from week 26 expected in Q1 2025, and from week 52 expected in Q1 2026

# 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 worldwide<sup>1</sup>
- 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 arm<sup>2</sup>
- Phase 2b readout expected 3Q25



## BX211

- Diabetic Foot Osteomyelitis ('DFO') patients represent the majority of 160K lower limb amputations in diabetic patients annually in the US<sup>3</sup>. Potential commercial opportunity of > \$2 billion worldwide<sup>3</sup>
- Phase 2 ongoing, readout expected in 1Q25



## FINANCING AND INVESTORS

- Publicly traded (NYSE American: PHGE)
- \$32.7 million cash and cash equivalents as of June 30, 2024

• Key investors:

**DEERFIELD**  
Advancing Healthcare™





Thank you

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**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 <sup>1</sup>
Potential effect on <i>PsA</i> CFU in lungs	Suppression/eradication of <i>PsA</i> (CFU in sputum)	Magnitude observed under tobramycin Phase 3 study was ~1.5-2 log <sup>2</sup>
Potential impact on lungs	Improved lung function (FEV1)	Magnitude observed under tobramycin Phase 3 study was 8-12% <sup>2</sup>
Potential pricing in the 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 <sup>3</sup>
Market potential	<b>~\$1 Billion in the US alone</b> (worldwide \$1.6 billion) <sup>4</sup>	US patient population times potential pricing

# BX211 DFO addressable market of >\$2B worldwide

	BX211	References/Comments
General patient population	160,000	Lower limb amputations (LLA), diabetic patients annually, US <sup>1</sup>
Assumed relevant population for BX211 treatment	40,000 (25% of 160,000)	Deductions due to <sup>2</sup> : - 85% of amputation are due to DFO - 50% positive for S. aureus - 60% not urgent amputations, enabling biopsy and treatment $85\% \times 50\% \times 60\% = 25\%$
Pricing	\$25,000	Based on 50% of the saved \$50K amputation costs <sup>3</sup>
Relevant market for BX211, US	<b>\$1 Billion</b>	40K times \$25K
Relevant market for BX211, Worldwide	<b>&gt;\$2 Billion</b>	ROW is over \$1 billion, based on the following: . Annual incidence of LLA in the OECD is 3-4 higher than the US <sup>4</sup> Assuming OECD pricing is 50% of US pricing.

## Executive 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, PHD | 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.



### **MARINA WOLFSON | CFO**

Marina Wolfson has served as the Senior Vice President of Finance and Operations of the Company since December 2019. Ms. Wolfson's experience includes working with large pharmaceutical and hi-tech companies, as well as venture capital funds. Prior to joining the Company, Ms. Wolfson worked as Vice President of Finance at BioView Ltd. (TASE) from 2010 to 2019 and a senior auditor at Ernst & Young, an international auditing and business advisory firm 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.

## Executive team (cont'd)



### **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 MBA from Bar-Ilan University and a BA in behavioral science from Ben-Gurion University.



### **MICHAEL BILLARD | General Manager, U.S.**

Mr. Michael Billard has over twenty-years of experience in biotech, pharma, and consumer product development. He served as VP, Project Execution at Adaptive Phage Therapeutic since September 2020, which was acquired by the Company in March 2024. Prior to that, he held senior leadership roles at Propella Therapeutics, Inc., Paragon Bioservices and DSM Nutritional Products (formerly Martek BioSciences) along with project management positions at MedImmune, Inc. and Baxter Healthcare Corporation. Mr. Billard earned his Master of Science in Biotechnology from Johns Hopkins University.



# Board of directors



**RUSSELL G. 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.