

## Safe Harbor Statement

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. When we discuss our expectations regarding the sufficiency of cash, cash equivalents and short-term deposits to fund the our current operating plan until at least the middle of 2024, the ability of our products to address unmet medical needs, the potential to receive up to \$15 million in additional loan tranches if certain milestones are met, the design, aim, expected timing and results of our preclinical and clinical trials and studies, including resumption of certain development programs, including whether we will be able to obtain funding for such programs, as well as our pipeline and the potential of our product candidates, our ability to quickly generate clinical proof of concept in patients and the advantages of our BOLT platform as well as our leadership position in phage technology we are making forward-looking statements. 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 <u>www.sec.gov</u>. 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.



## What we do



We develop disease modifying therapies based on natural or engineered phage cocktails as precision medicines to target and specifically destroy harmful bacteria



Our R&D platform enables generation of clinical proof of concept in patients within 12-18 months from project initiation\*



# Unique position as leader in phage technology

## Only clinical stage phage company focusing on chronic indications

## **Technology**

- BOLT phage therapy platform –
  Rapid path from discovery to clinic
- Scalable in-house manufacturing can support annually over 50 different phage at a clinical grade



### **Partnerships**

- Therapeutics Development Award from the Cystic Fibrosis Foundation.
- Maruho ROFO<sup>2</sup> for rights in Japan to atopic dermatitis product candidate
- Biomarker discovery collaborations in IBD: Janssen (J&J) & Boehringer Ingelheim







### **Pipeline**

- Focusing on cystic expected to produce clinical data in 3Q22
- Additional programs in atopic dermatitis, IBD / PSC<sup>1</sup> & Cancer



### **Financing and investors**

- Publicly traded (NYSE:PHGE)
- Equity raised: \$146M
- Grants received: \$6.3M
- Secured debt of up to \$30M
- Expected cash runway until at least middle of 2024





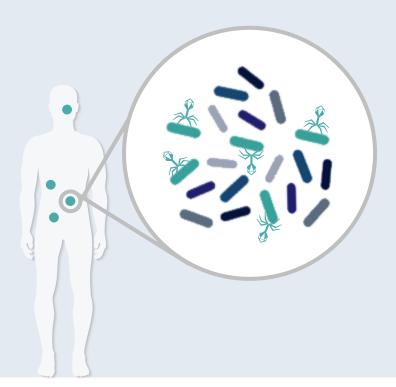




- I. Inflammatory Bowel Disease (IBD), Primary Sclerosing Cholangitis (PSC)
- 2. Right Of First Offer

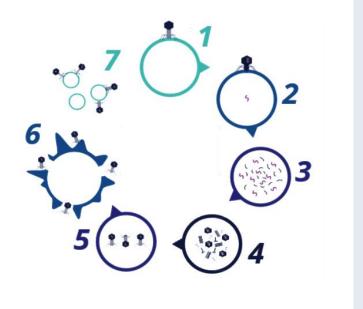
# Phage: Nature's precision tool to target bacteria

# Each phage binds only to specific bacterial strains



## Phage have an amplifying lifecycle

- Locate
- 2 Inject
- 3 Infect
- 4 Multiply
- 5 Assemble
- **6** Eradicate
- Seek

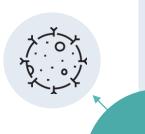




# Multiple potential applications of phage therapy

#### Immune mediated

- Inflammatory Bowel Disease (IBD) K. pneumoniae
- Primary Sclerosing Cholangitis (PSC) K. pneumoniae
- **Atopic Dermatitis** *S. aureus*





- Colorectal Cancer F. nucleatum
- Gastric Cancer H. pylori

#### **Infectious diseases**

- **Cystic Fibrosis** *P. aeruginosa*
- Carbapenem Resistance K. pneumoniae





#### Other

- Acne C. acnes
- **Liver Disease** *E. faecalis*



# Pipeline

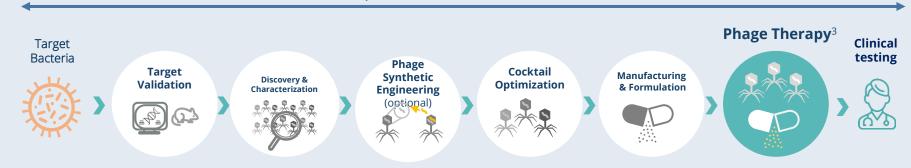
	Phage discovery	Preclinical	Phase I	Phase II	Phase III
Product Candidates					
Cystic fibrosis • BX004					
Atopic dermatitis • BX005					
IBD / PSC • BX003					
Colorectal cancer					



# Our **Bolt** platform allows clinical POC within 12-18 months

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Traditional pharma drug development	Discovery		смс	Тох	Phase 1	Phase 2
Phage Bolt therapy BacteriOphage Lead to Treatment	Phage cocktail	nase 1/2				

## Clinical POC in patients enabled within 12-18 months<sup>1,2</sup>

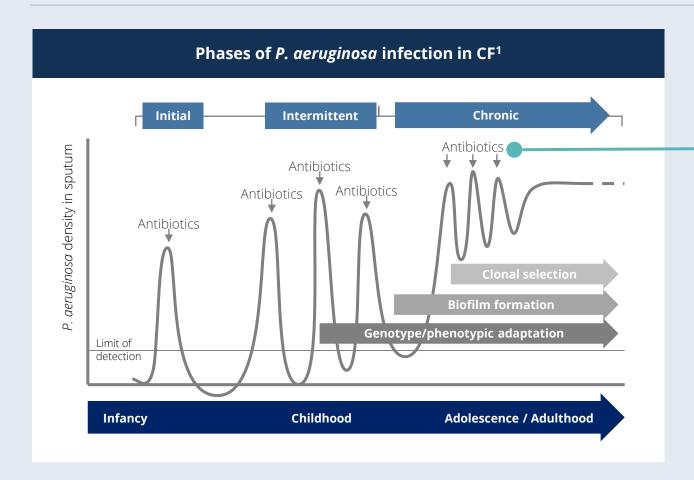




- Strong safety profile of naturally occurring phage supported by regulatory feedback allows proceeding to Phase 1/2 studies without preclinical safety studies or Phase 1 studies in healthy volunteers.
- In certain indications the length of clinical validation may be longer depending on indication, identity of target bacteria, recruitment rate, cohort size and other factors.
- Usually, we would develop an optimized phage therapy, which is comprised of several phage (a phage cocktail) optimized to address multiple characteristics such as bacterial host range, emergence of resistance and other factors. In some cases, we may alternatively develop personalized phage cocktails tailored to target specific strain/s of a given patient. We may complete a clinical POC by treating multiple patients with either an optimized phage cocktail or personalized cocktails



# Recurring infections leading to antibiotic resistance are a main cause of death in CF



Repeated antibiotic courses lead to nonmucoid and mucoid multidrug-resistance (MDR) of P. aeruginosa strains

- CF patients regularly use multiple therapies – CFTR modulators, antiinfectives, mucolytic agents, bronchodilators and other
- Worldwide CF therapeutic market in 2020 was approximately \$8.5B<sup>2</sup>



- 1. CF Foundation, Bomberg et al., 2008
- . Vertex 10K filing 2020, internal estimates

# 25 CF patients already treated with phage under compassionate use

### 11 CF patients treated for P. aeruginosa 1-4

- Indication P. aeruginosa AMR lung infections
- Location 8 Yale University, 2 Georgia, 1 San-Diego
- Administration 10 nebulized, 1 IV phage

#### Yale cases:

- eIND path for 8 CF patients
- Nebulized phage
- 7-10 days, single or multiple rounds
- Post phage therapy P. aeruginosa CFU titers decreased significantly (2.2  $\pm$  0.76 log reduction)
- Outcome FEV1% changed in a range of 0 to 8.9%

# 14 CF patients treated for Mycobacterium (20 patient total) <sup>5</sup>

- Indication Non-tuberculous Mycobacterium infections. Lung infections in all CF patients
- Location San Diego (UCSD)
- Administration 20 IV, certain patient also nebulized/topical/ other

#### **UCSD** cases:

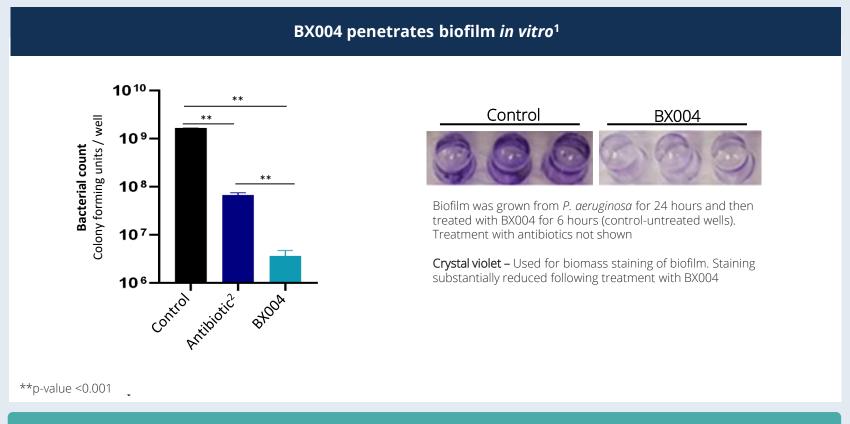
- eIND path for all patients
- IV phage (+ additional for certain patients)
- Twice daily for ~6 months (though a favorable outcome required improvement within 8 weeks)
- Outcome Favorable clinical or microbiological responses in 11/20 patients (for 5 patients infection was resolved)

Results demonstrate the safety of phage therapy and potential to decrease bacterial burden and improve clinical outcome



- 1. Kutateladze et al., 2008
- 2. Kvachadze et al., 2011
- 3. Law et al., 2019
- 4. Stanley et al., 2020
- . Dedrick et al. 2022

# BX004 is active on antibiotic resistant *P. aeruginosa* strains and penetrates biofilm *in vitro*



BX004 displays enhanced biofilm penetration compared to antibiotics



- 1. Internal data. A *P. aeruginosa* strain sensitive to antibiotics was grown to form biofilm
- .. Imipenem 200 micrograms/ml (X100 MIC), (β-lactam antibiotic with activity against P. aeruginosa)

# Phase 1b/2a study targeting *P. aeruginosa* with first readout expected in 3Q 2022

#### Phase 1b/2a - Part 1

#### **Objectives**

• Safety, PK and microbiologic/clinical activity

#### Endpoints

- Safety and tolerability
- Decrease in *P. aeruginosa* burden
- Sputum pharmacokinetics
- FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised) and CRISS

## **Study Population**

• CF patients with chronic *P. aeruginosa* infection

#### 8 Subjects

- 6 receive nebulized BX004
- 2 receive nebulized placebo
- 6 days duration of treatment

#### **Key Design Features**

Single ascending dose followed by multiple doses

Data expected 3Q 2022

#### Phase 1b/2a - Part 2

#### **Objectives**

Safety and efficacy

#### **Endpoints**

- Safety and tolerability
- Decrease in *P. aeruginosa* burden
- FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised) and CRISS

#### **Study Population**

• CF patients with chronic *P. aeruginosa* infection

#### 24 subjects

- Nebulized BX004 phage therapy or placebo
- 2:1 randomization
- 10 days duration of treatment

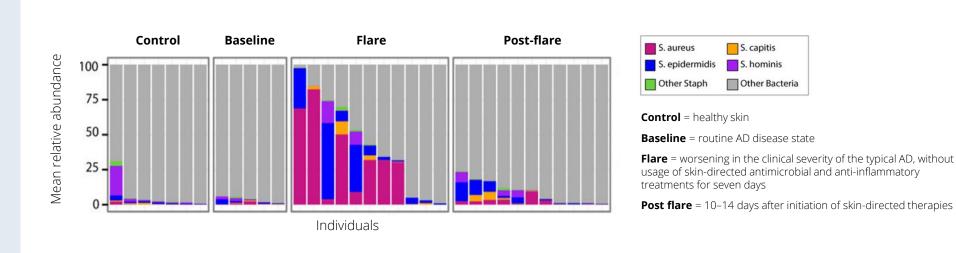
Data expected 1Q 2023





# Atopic Dermatitis (AD) flares are associated with presence of *S. aureus*

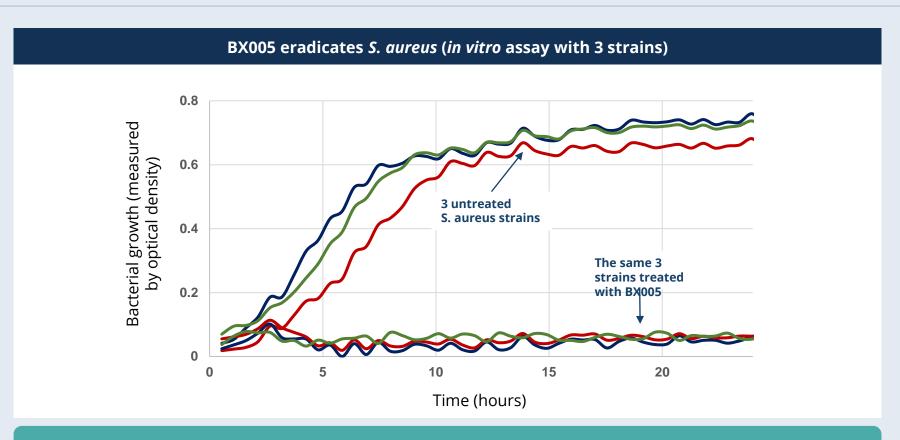




S. aureus becomes the dominant bacterial species during AD flares and is correlated with SCORAD



# BX005 phage cocktail shows broad host range targeting of *S. aureus in vitro*



In vitro, BX005 eradicated **over 90%** of *S. aureus* strains<sup>1</sup>



Source: Internal data

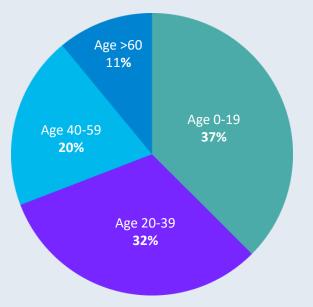
1. Panel of 120 strains isolated from skin of subjects from the US and Europe

# BX005 has the potential to be an efficacious and safe topical treatment for long-term use

- Atopic dermatitis, a rapidly growing market<sup>1</sup>:
  - > \$5 billion in 2020
  - Expected to surpass \$15 billion in 2027
- Over 35% of atopic dermatitis patients are children
- Parents are seeking efficacious topical treatments with a better safety profile
  - Calcineurin inhibitors and recently approved topical JAK inhibitor carry a black box warning for cancer risks in the US
  - Corticosteroids limited for short term use. Long-term use has been associated with skin atrophy, starch marks, and corticosteroid addiction
- Based on clinical experience of using natural phage topically<sup>3</sup>, BX005 is expected to have **fewer side effects** and a **safer profile** compared to existing treatments

## Children are the largest atopic dermatitis patient group

### Atopic dermatitis patients by age group (US)<sup>2</sup>





- 1. Atopic dermatitis Market forecast, trend analysis & competition tracking, Fact Mr. report
- 2. Atopic dermatitis: Global drug forecast and market analysis to 2027, GlobalData report
  - Based on safety data from BiomX's clinical studies using a topical phage cocktail for acne-prone skin

# Phase 1b/2a atopic dermatitis study targeting *S. aureus*

## Study design - A double-blind, randomized, multicenter, vehicle-controlled study

### Objectives

• Safety, efficacy and pharmacodynamics

#### Endpoints

- Safety and tolerability
- Decrease in target bacteria
- Clinical improvement (e.g. change in EASI / IGA / SCORAD scores)

## Study Population

- Adults with moderate-to-severe atopic dermatitis
- S. aureus colonized

## Approximately 48 subjects

- BX005 or placebo (vehicle) administered topically twice daily
- 8-week duration of treatment

## **BX005/Placebo Applications**

