

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): **November 9, 2022**

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
Units, each consisting of one share of Common Stock, \$0.0001 par value, and one Warrant entitling the holder to receive one half share of Common Stock	PHGE.U	NYSE American
Shares of Common Stock, \$0.0001 par value	PHGE	NYSE American
Warrants, each exercisable for one-half of a share of common stock, \$0.0001 par value, at an exercise price of \$11.50 per share	PHGE.WS	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 2.02 Results of Operations and Financial Condition.

On November 9, 2022, BiomX Inc., or the Company, issued a press release announcing its financial results for the third quarter ended September 30, 2022. A copy of the press release issued in connection with the announcement is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Item 7.01 Regulation FD Disclosure.

The Company from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On November 9, 2022, 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 pursuant to Item 7.01 as Exhibit 99.2 hereto. 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 November 9, 2022

SIGNATURE

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.

November 9, 2022

By: /s/ Jonathan Solomon

Name: Jonathan Solomon

Title: Chief Executive Officer

BiomX Reports Third Quarter 2022 Financial Results and Provides Business Update

Continued Progress Enrolling Patients in Phase 1/2 Trial of BX004 for Treatment of Lung Infections in Cystic Fibrosis; Results from Part 1 of the Trial Now Expected in Q1 2023

Announced Publication in Cell of Research Demonstrating Proof-of-Concept Assessment of Orally Administered Phage Treatment in Preclinical Model of Inflammatory Bowel Disease

Cash Runway Through at Least Mid-2024

Company Will Host a Conference Call and Webcast Today at 8:00 am ET

NESS ZIONA, Israel – November 9, 2022 – BiomX Inc. (NYSE American: PHGE) (“BiomX” or the “Company”), a clinical-stage microbiome company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the third quarter ended September 30, 2022.

“Despite encountering challenges early in the quarter in recruiting cystic fibrosis patients following the COVID-19 pandemic, we have recently put in place important mechanisms to accelerate screening and enrollment and are encouraged by the recent increased enrollment into BX004 that will impact both parts of the trial,” said **Jonathan Solomon**, Chief Executive Officer of BiomX. “Based on these latest trends, we now anticipate that enrollment for Part 1 of the study will be complete by year-end. Factoring in a modest impact from the U.S. holiday season and the time required for data analysis following each patient’s treatment period, we now expect to announce results from Part 1 of the trial in the first quarter of 2023, followed by results from Part 2 in the third quarter of 2023. We believe that we remain financially and operationally positioned to execute on our business plan with respect to our CF program, with cash runway anticipated to take us through at least mid-2024. We appreciate the continued support of our shareholders and look forward to providing our initial data from the CF program.”

Clinical Program Updates

Cystic Fibrosis (BX004)

- BiomX has dosed the first patients in the Company’s Phase 1b/2a study evaluating BX004 for the treatment of chronic respiratory infections in patients with cystic fibrosis (“CF”).
- BX004 is being developed for the treatment of chronic respiratory infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with CF.
- The Phase 1b/2a trial is composed of two parts. Part 1 of the study will evaluate the safety, pharmacokinetics, and microbiologic/clinical activity of BX004 in eight CF patients in a single ascending dose and multiple dose design, with results expected in the first quarter of 2023. Part 2 of the study will evaluate the safety and efficacy of BX004 in 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 are expected in the third quarter of 2023.

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- As previously announced, BiomX has received a Therapeutics Development Award of up to \$5 million from the Cystic Fibrosis Foundation (“CF Foundation”). The award is structured as an equity investment in which the CF Foundation has agreed to purchase up to \$5 million of BiomX common stock across two separate tranches. The first tranche was received on December 21, 2021, with the CF Foundation making an initial equity investment of \$3 million. Upon completion of all patient dosing in Part 1 of the Company’s Phase 1b/2a study of BX004, BiomX would have the right to receive the second tranche of \$2 million, also as an equity investment.

Atopic Dermatitis (BX005)

- The Company is collaborating with Maruho Co. Ltd., a leading dermatology-focused pharmaceutical company in Japan, supporting a range of pre-clinical activities to move this program forward, and working on evaluating timelines for a clinical trial.

RECENT CORPORATE HIGHLIGHTS

- In August, the Company announced the publication of a scientific paper titled “*Targeted suppression of human IBD-associated gut microbiota commensals by phage consortia for treatment of intestinal inflammation*” in the journal, *Cell*. The research was conducted across several organizations, including BiomX and the Weizmann Institute of Science, and presents phage proof of concept in preclinical models of inflammatory bowel disease as well as highlights from the clinical study. The paper is available online at [https://www.cell.com/cell/fulltext/S0092-8674\(22\)00850-9](https://www.cell.com/cell/fulltext/S0092-8674(22)00850-9).

Third Quarter 2022 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of September 30, 2022, were \$41.5 million, compared to \$63.1 million as of December 31, 2021. The decrease was primarily due to net cash used in operating activities. Based upon the Company’s strategic focus on the CF program, the existing cash and cash equivalents are expected to be sufficient to fund the current operating plan until at least the middle of 2024.
- **Research and development expenses, net** were \$3.5 million for the three months ended September 30, 2022, compared to \$6.6 million for the same period in 2021. The decrease is primarily due to a decrease in salaries and related expenses and stock-based compensation expenses driven by a reduction in personnel, as part of the corporate restructuring the Company announced in May of this year, as well as pausing the development of BX003, the product candidate for the treatment of Inflammatory Bowel Disease and Primary Sclerosing Cholangitis, pausing the development of the Company’s colorectal cancer product candidate, and the discontinuation of the Company’s product candidate for the treatment of acne, BX001. The decrease was partially offset by a decrease in grants from the Israel Innovation Authority.
- **General and administrative expenses** were \$2.6 million for the three months ended September 30, 2022, compared to \$2.8 million for the same period in 2021. The decrease is primarily due to a decrease in salaries and related expenses and stock-based compensation expenses due to a reduction in workforce.

- **Net loss** for the third quarter of 2022 was \$6.8 million, compared to \$10 million for the same period in 2021.
- **Net cash used in operating activities** for the nine months ended September 30, 2022 was \$21.9 million, compared to \$18.5 million for the same period in 2021.

Conference Call and Webcast Information

BiomX management will host a conference call and webcast today at 8:00 am ET to report financial results and business updates for the third quarter 2022. To participate in the conference, please dial 1-877-407-0724 (U.S.), 1-809-406-247 (Israel), or 1-201-389-0898 (International). A live and archived webcast of the call will be available on the Investors section of the Company's website at www.biomx.com.

About BiomX

BiomX is a clinical-stage microbiome company developing both natural and engineered phage cocktails designed to target and destroy bacteria in the treatment of chronic diseases. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at 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 discusses future updates on its CF and Atopic Dermatitis programs, its expectations regarding the timing of the completion of enrollment and results of the CF trial, the potential safety, tolerability and potential treatment effect of its product candidates, the potential to achieve the applicable clinical milestones required to receive an additional \$2 million investment from CFF, and its cash runway and financial and operational position, BiomX is making 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. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. 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 30, 2022 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.

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BIOMX INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(USD in thousands, except share and per share data)
(unaudited)

Note	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expenses, net	3,536	6,608	13,049	16,102
Amortization of intangible assets	380	380	1,139	1,139
General and administrative expenses	2,633	2,845	7,471	8,436
Operating loss	6,549	9,833	21,659	25,677
Other income	(52)	-	(52)	-
Interest expenses	555	172	1,504	172
Financial expenses (income), net	(280)	16	(706)	(96)
Loss before tax	6,772	10,021	22,405	25,753
Tax expenses	8	10	26	16
Net loss	6,780	10,031	22,431	25,769
Basic and diluted loss per share of Common Stock	6	0.23	0.37	1.03
Weighted average number of shares of Common Stock outstanding, basic and diluted	29,907,812	27,077,903	29,812,542	25,120,037

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BIOMX INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)
(unaudited)

Note	As of	
	September 30, 2022	December 31, 2021

ASSETS**Current assets**

Cash and cash equivalents	37,067	62,099
Restricted cash	960	996
Short-term deposits	3,500	-
Other current assets	1,003	3,543
Total current assets	42,530	66,638

Property and equipment, net	5,034	5,694
Intangible assets, net	382	1,519
Operating lease right-of-use assets	3,955	4,139
Total non-current assets	9,371	11,352

51,901 77,990

LIABILITIES AND STOCKHOLDERS' EQUITY**Current liabilities**

Trade accounts payable	1,781	2,795
Other accounts payable	2,023	5,453
Contract liability	-	1,976
Current portion of operating lease liabilities	687	819
Current portion of long-term debt	4 2,989	-
Total current liabilities	7,480	11,043

Non-current liabilities

Contract liability	1,976	-
Long-term debt, net of current portion	4 11,799	14,410
Operating lease liabilities, net of current portion	3,882	4,787
Other liabilities	206	215
Total non-current liabilities	17,863	19,412

Commitments and Contingencies	3	
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Stockholders' equity	5	
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Preferred Stock, \$0.0001 par value; Authorized - 1,000,000 shares as of September 30, 2022 and December 31, 2021.

No shares issued and outstanding as of September 30, 2022 and December 31, 2021.

- -

Common Stock, \$0.0001 par value; Authorized - 120,000,000 shares as of September 30, 2022 and 60,000,000 shares as of December 31, 2021. Issued - 29,982,282 shares as of September 30, 2022 and 29,753,238 shares as of December 31, 2021. Outstanding - 29,976,582 shares as of September 30, 2022 and 29,747,538 shares as of December 31, 2021.

2 2

Additional paid in capital	157,471	156,017
Accumulated deficit	(130,915)	(108,484)

Total stockholders' equity	26,558	47,535
	51,901	77,990

BiomX Contacts**Investor Relations:**

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Corporate Project Manager

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Source: BiomX Inc.

The background of the slide features a detailed illustration of a bacteriophage, a virus that infects bacteria. The phage is shown with its hexagonal head, tail, and tail fibers. It is positioned as if it is about to inject its genetic material into a large, textured bacterial cell. The entire scene is set against a dark blue background with a subtle grid pattern. The BiomX logo is prominently displayed in the upper left corner, with 'Biom' in white and 'X' in a vibrant orange.

BiomX

Company Introduction

ADVANCING MEDICINE.
PRECISELY.

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 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 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.



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

Broad platform based on computational and synthetic biology capabilities

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



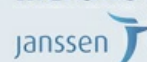
Pipeline

- Focusing on cystic fibrosis; Expected to produce clinical data in 1Q23
- Additional programs in atopic dermatitis, IBD / PSC¹ & Cancer



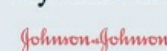
Partnerships

- Therapeutics Development Award from the Cystic Fibrosis Foundation.
- Biomarker discovery collaborations in IBD: Janssen (J&J) & Boehringer Ingelheim
- Maruho ROFO² for rights in Japan to atopic dermatitis product candidate



Financing and investors

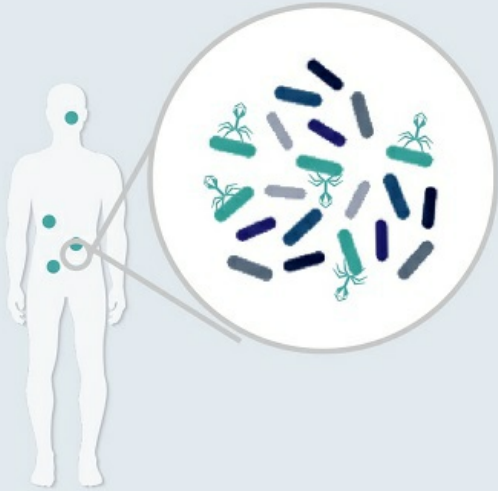
- Publicly traded (**NYSE:PHGE**)
- Equity raised: \$146M
- Grants received: \$6.3M
- Current debt facility: \$15M
- Expected cash runway until at least middle of 2024



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

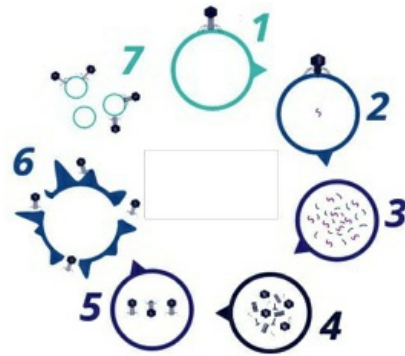
Phage: Nature's precision tool to target bacteria

Each phage binds only to specific bacterial strains

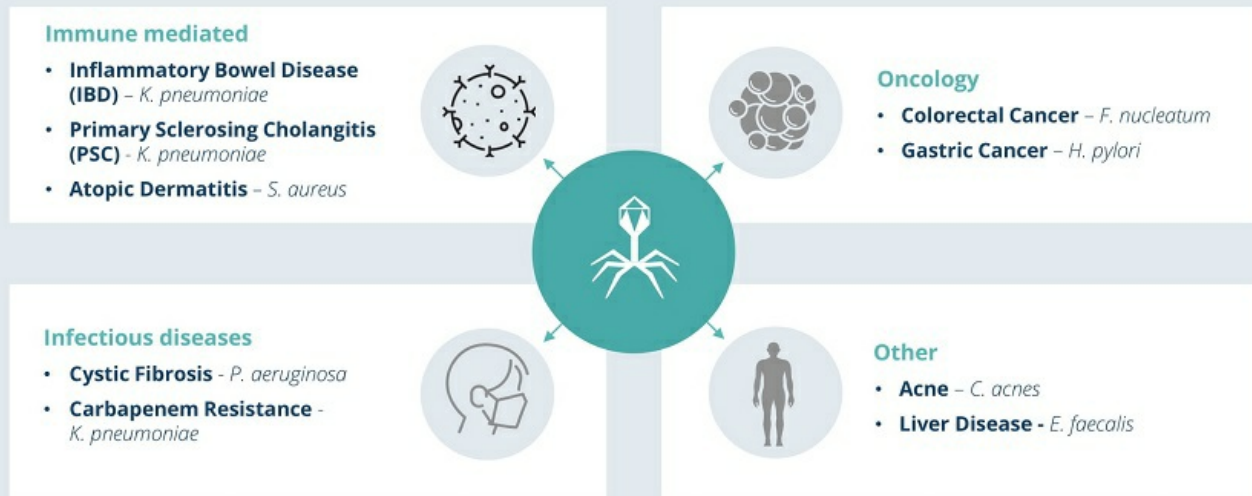


Phage have an amplifying lifecycle

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



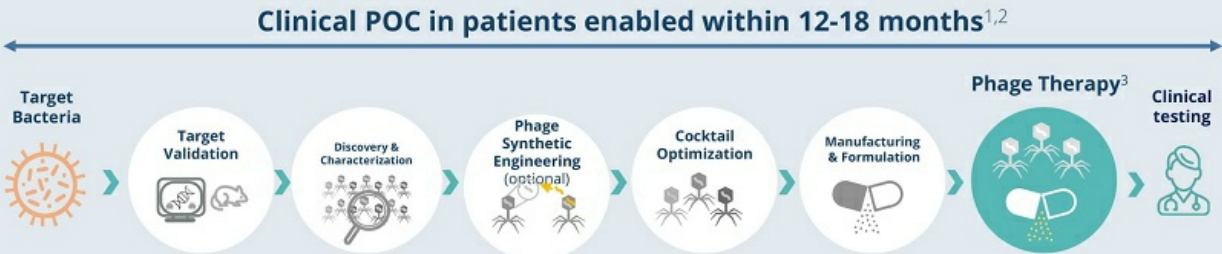
Multiple potential applications of phage therapy



Pipeline



Our Bolt platform allows clinical POC within 12-18 months



1.

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.

2.

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.

3.

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



Cystic Fibrosis

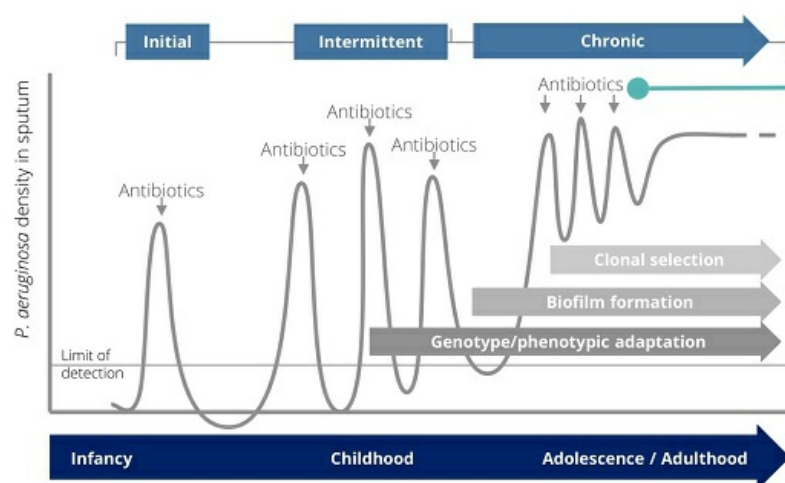
Upcoming milestone: Phase 1b/2a part 1 data expected in 1Q 2023

Program is supported by Cystic Fibrosis Foundation

BiomX

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

Phases of *P. aeruginosa* infection in CF¹



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

- CF patients regularly use multiple therapies – CFTR modulators, anti-infectives, mucolytic agents, bronchodilators and other
- **Worldwide CF therapeutic market in 2020 was approximately \$8.5B²**

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 ± 0.76 log reduction)**
- **Outcome - FEV1% changed in a range of 0 to 8.9%**

14 CF patients treated for *Mycobacterium* (20 patient total) ⁵

- 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:

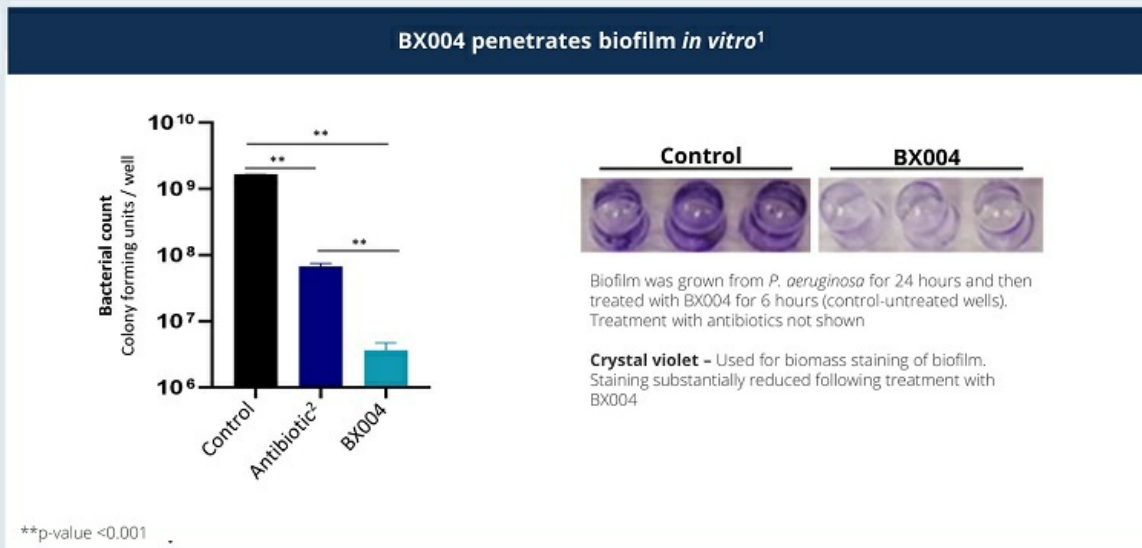
- eIND path for all patients
- IV phage (+ additional for certain patients)
- Twice daily for ~6 months (though a favorable outcome required improvement within 8 weeks)
- **Outcome - Favorable clinical or microbiological responses in 11/20 patients (for 5 patients infection was resolved)**

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
5. 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

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 CRIS

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 1Q 2023

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 CRIS

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 3Q 2023



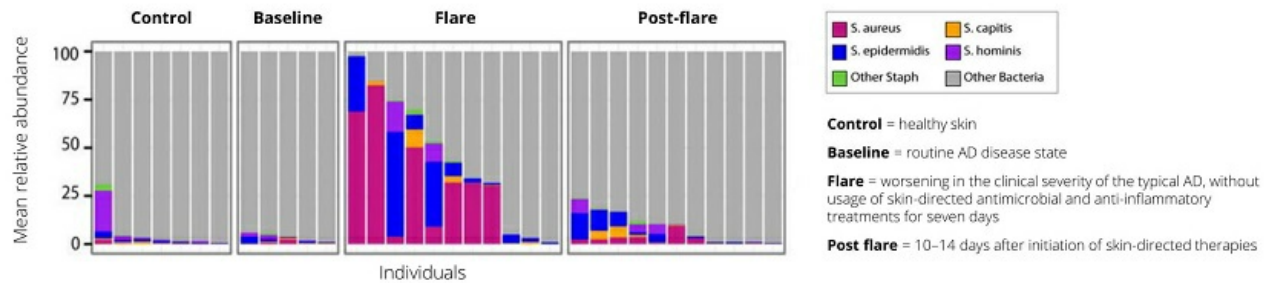
Atopic Dermatitis

Upcoming milestone: TBD

BiomX

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

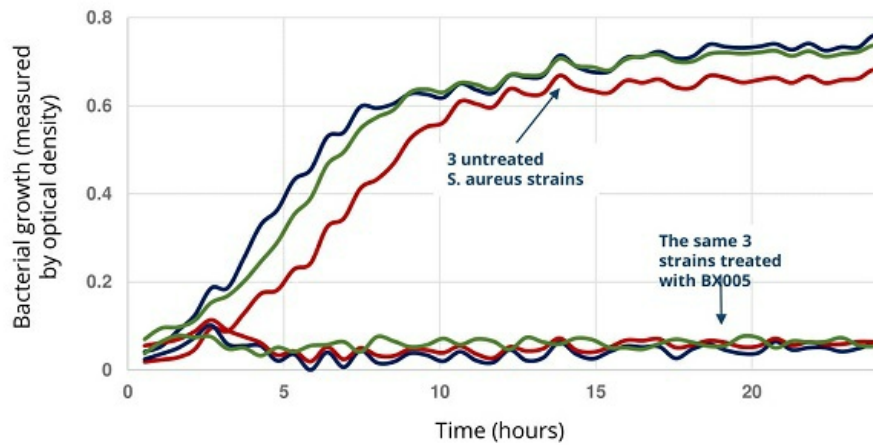
Relative abundance of staphylococcal species on skin during AD disease stages (metagenomics analysis)



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

BX005 eradicates *S. aureus* (in vitro assay with 3 strains)



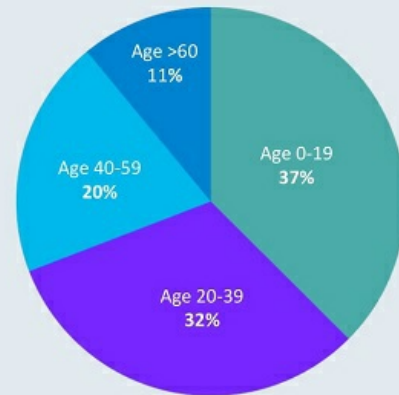
In vitro, BX005 eradicated **over 90%** of *S. aureus* strains¹

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

- Atopic dermatitis, a rapidly growing market¹:
 - > \$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, stretch marks, and corticosteroid addiction
- Based on clinical experience of using natural phage topically³, 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)²



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
3. 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

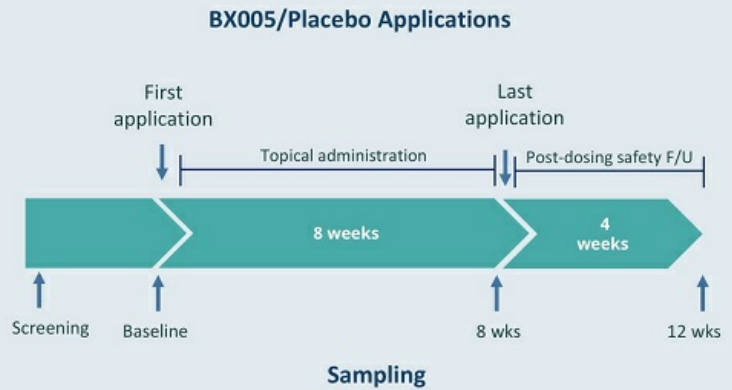
- Safety and tolerability
- Decrease in target bacteria
- Clinical improvement (e.g. change in EASI / IGA / SCORAD scores)

• 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





THANK YOU

BiomX
