

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **June 14, 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

(IRS Employer
Identification No.)

**22 Einstein St., 5th Floor
Ness Ziona, Israel**

(Address of Principal Executive Offices)

7414002

(Zip Code)

(972) 72 394 2377

(Registrant's telephone number, including area code)

Not applicable

(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 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 5.08 Shareholder Director Nominations.

BiomX Inc. (the "Company") expects to hold its 2022 Annual Meeting of Stockholders (the "Annual Meeting") on Wednesday, August 24, 2022 and has fixed the closing of business on June 29, 2022 as the record date for the Annual Meeting. Because the date of the Annual Meeting has been changed by more than 30 days from the anniversary date of the 2021 Annual Meeting of Stockholders, the Company is providing the due date for submission of any qualified stockholder proposal.

In accordance with Rule 14a-5(f) and Rule 14a-8(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the deadline for receipt of stockholder proposals for inclusion in the Company's proxy statement for the Annual Meeting pursuant to Rule 14a-8 will be no later than 5:00 p.m., Eastern Time, June 24, 2022. Stockholder proposals must comply with all of the applicable requirements set forth in the rules and regulations of the Securities and Exchange Commission, including Rule 14a-8 under the Exchange Act and the Company's Bylaws.

Item 7.01. Regulation FD Disclosure.

On June 14, 2022, BiomX Inc. posted to its website an updated investor presentation, a copy of which is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

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.

By: /s/ Jonathan Solomon

Name: Jonathan Solomon

Title: Chief Executive Officer

Date: June 14, 2022

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, a long 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 quadrant, with 'Biom' in white and 'X' in a bright blue color.

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 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 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

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



Pipeline

- Focusing on cystic expected to produce clinical data in 3Q22
- Additional programs in atopic dermatitis, IBD / PSC¹ & Cancer



Partnerships

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



Financing and investors

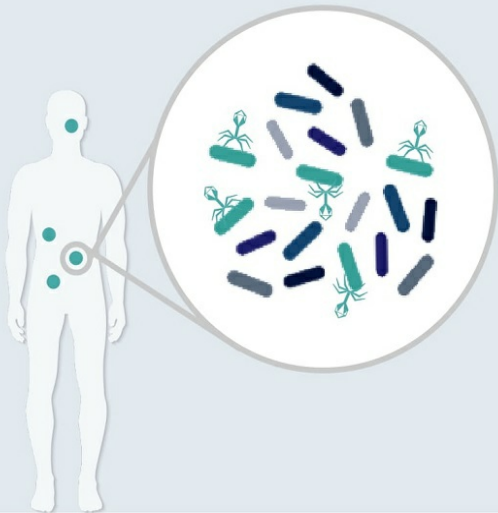
- Publicly traded (**NYSE:PHGE**)
- Equity raised: \$146M
- Grants received: \$6.3M
- Secured debt of up to \$30M
- Expected cash runway until at least middle of 2024



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

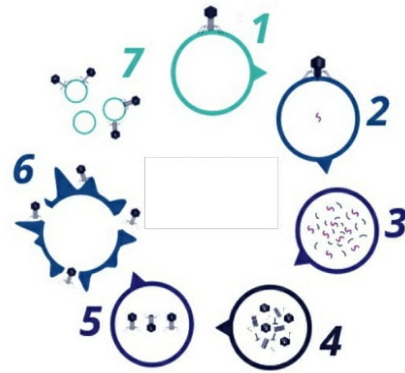
Phage: Nature's precision tool to target bacteria

Each phage binds only to specific bacterial strains

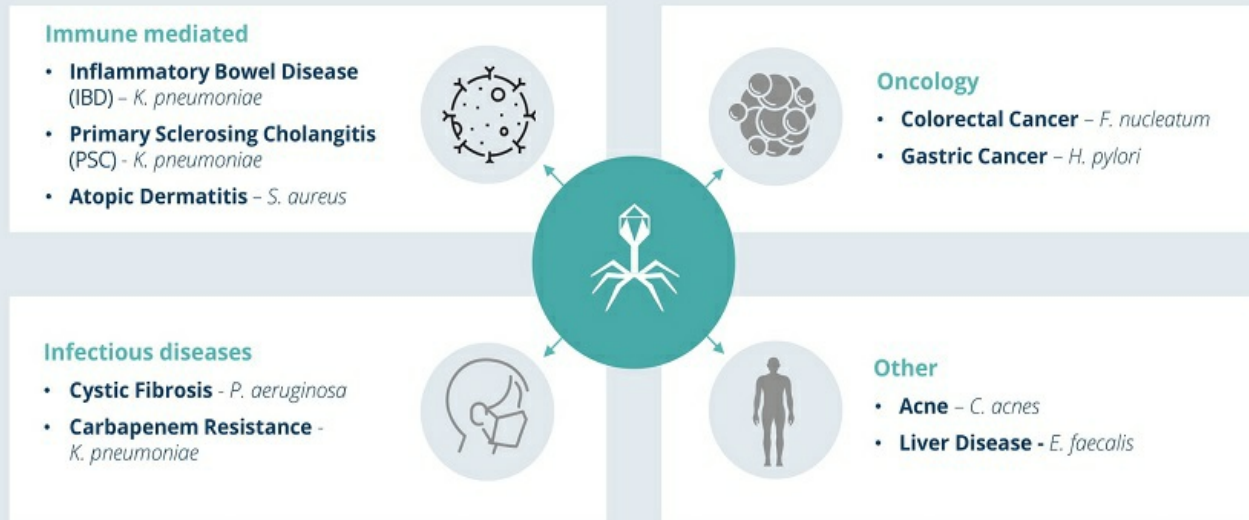


Phage have an amplifying lifecycle

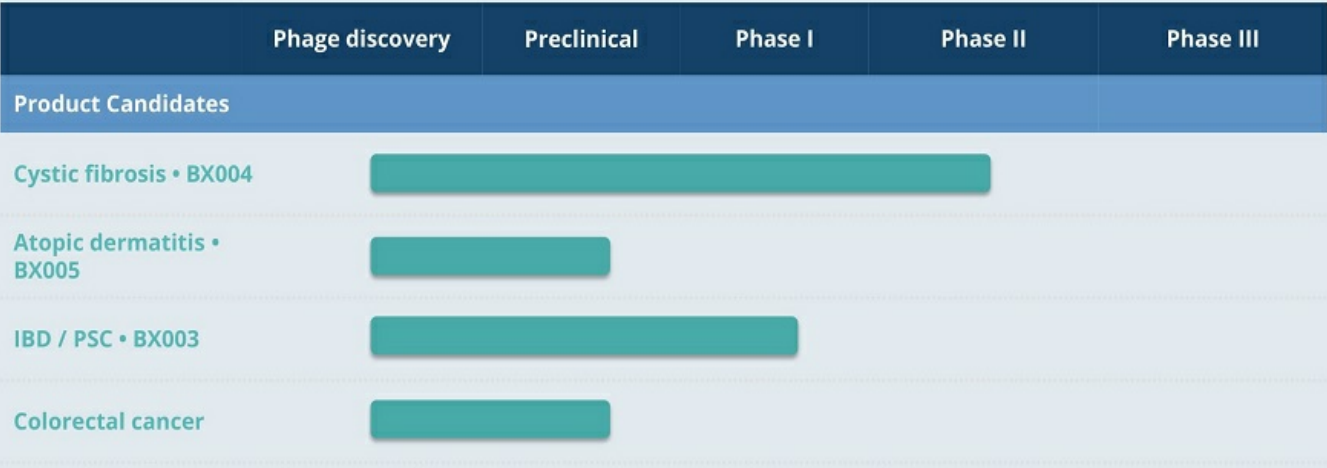
- 1 Locate
- 2 Inject
- 3 Infect
- 4 Multiply
- 5 Assemble
- 6 Eradicate
- 7 Seek



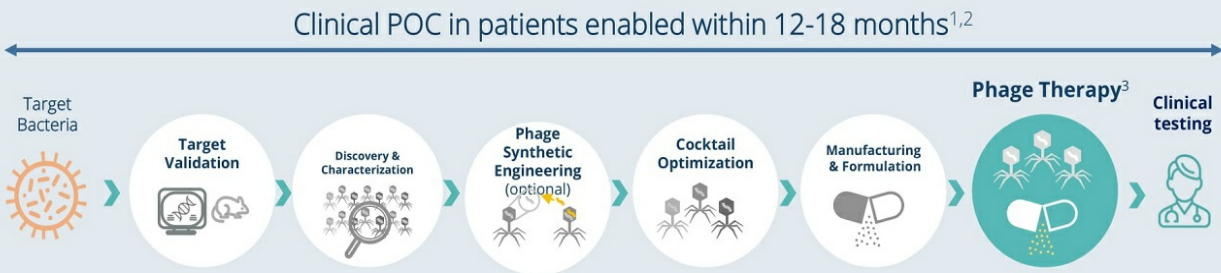
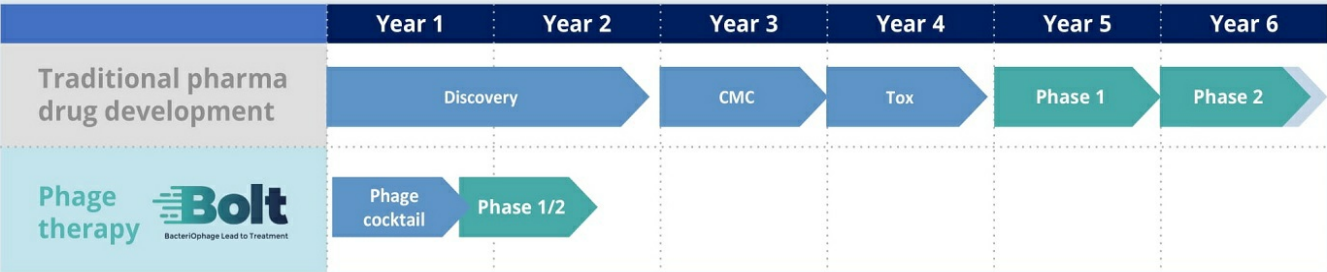
Multiple potential applications of phage therapy



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

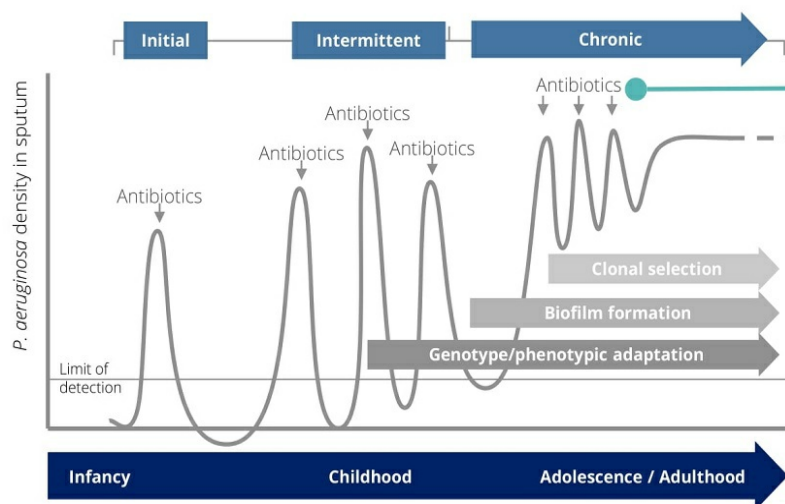
Upcoming milestone: Phase 1b/2a part 1 data expected in 3Q 2022

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

Selected cases of compassionate use of phage therapy targeting *P. aeruginosa*

11 CF patients treated with phage targeting *P. aeruginosa*

2 CF patients, Georgia ^{1,2}

- 5 yr old & 7 yr old
- Nebulized phage
- Combined with antibiotics
- 9 courses with 4-6 week intervals
- Reduction in sputum bacterial burden ($10^7 \rightarrow 10^4$ CFU/g) ²
- Patient gained weight, clinical improvement observed ¹

CF patient, San Diego, US ³

- 26 yr old
- Phage administered IV
- Combined with antibiotics
- No exacerbation within 100 days following the end of phage therapy

8 CF patients, Yale University, US ⁴

- 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)
- Post phage therapy FEV1% changed in a range between 0 to 8.9%

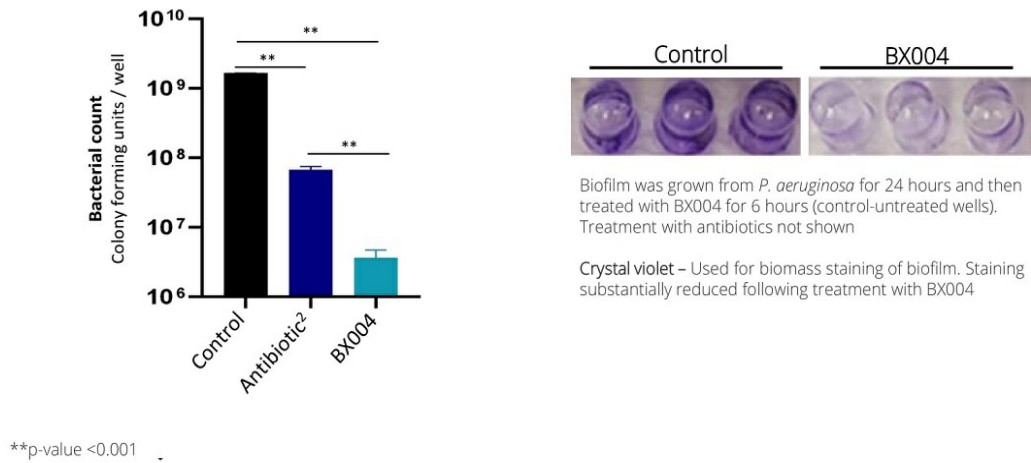
Results demonstrate the potential of phage therapy to decrease bacterial burden and improve FEV1



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

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

BX004 penetrates biofilm *in vitro*¹



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	Phase 1b/2a – Part 2
<p>Objectives</p> <ul style="list-style-type: none">• Safety, PK and microbiologic/clinical activity <p>Endpoints</p> <ul style="list-style-type: none">• Safety and tolerability• Decrease in <i>P. aeruginosa</i> burden• Sputum pharmacokinetics• FEV1 (forced expiratory volume)• CFQ-R (CF Questionnaire-Revised) and CRIS <p>Study Population</p> <ul style="list-style-type: none">• CF patients with chronic <i>P. aeruginosa</i> infection <p>8 Subjects</p> <ul style="list-style-type: none">• 6 receive nebulized BX004• 2 receive nebulized placebo• 6 days duration of treatment <p>Key Design Features</p> <ul style="list-style-type: none">• Single ascending dose followed by multiple doses <p>Data expected 3Q 2022</p>	<p>Objectives</p> <ul style="list-style-type: none">• Safety and efficacy <p>Endpoints</p> <ul style="list-style-type: none">• Safety and tolerability• Decrease in <i>P. aeruginosa</i> burden• FEV1 (forced expiratory volume)• CFQ-R (CF Questionnaire-Revised) and CRIS <p>Study Population</p> <ul style="list-style-type: none">• CF patients with chronic <i>P. aeruginosa</i> infection <p>24 subjects</p> <ul style="list-style-type: none">• Nebulized BX004 phage therapy or placebo• 2:1 randomization• 10 days duration of treatment <p>Data expected 1Q 2023</p>



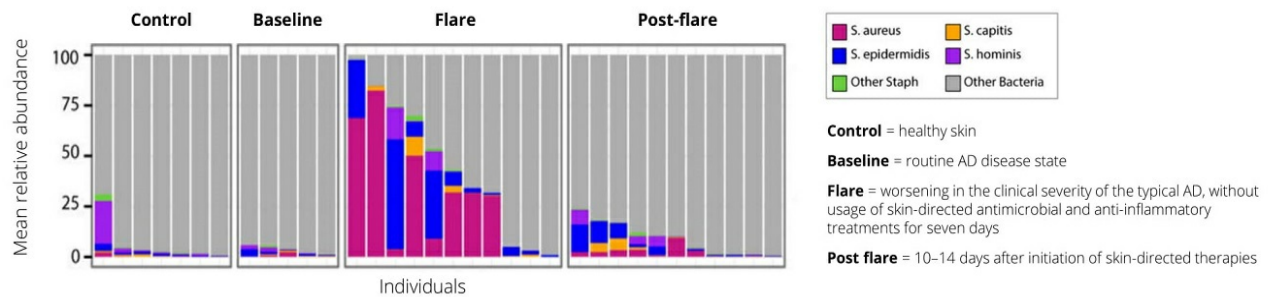
Atopic Dermatitis

Upcoming milestone: TBD

BiomX

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

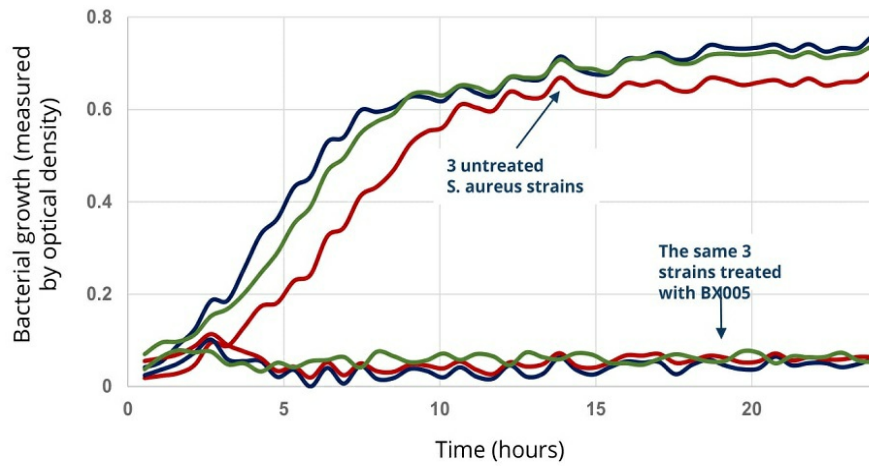
Relative abundance of staphylococcal species on skin during AD disease stages (metagenomics analysis)



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)



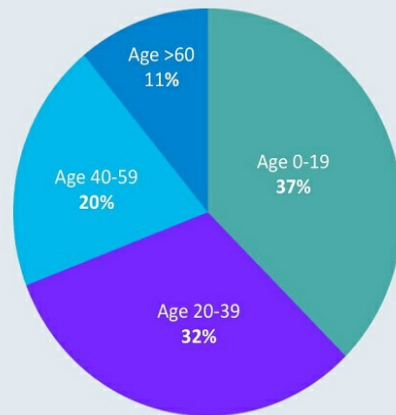
In vitro, BX005 eradicated **over 90%** of *S. aureus* strains¹

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

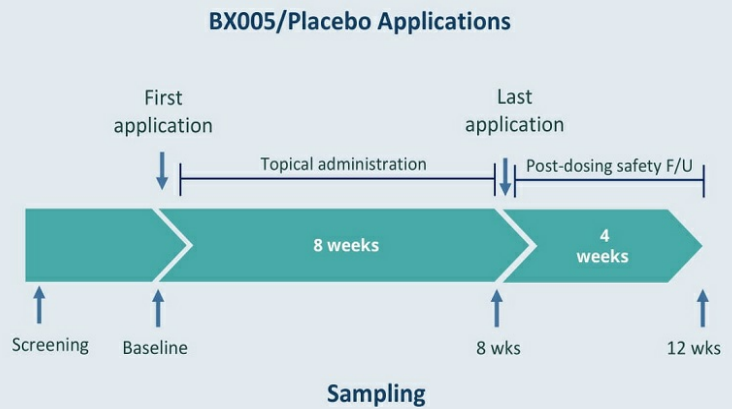
- Safety and tolerability
- Decrease in target bacteria
- Clinical improvement (e.g. change in EASI / IGA / SCORAD scores)

• 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
