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): **January 26, 2023**

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) 72-394-2377**

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\ and one Warrant entitling the holder to receive one half share of Common Stock	PHGE.U	NYSE American
Common Stock, $0.0001 par value	PHGE	NYSE American
Warrants, each exercisable for one-half of a share of Common Stock, 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 7.01 Regulation FD Disclosure.

BiomX Inc., or 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 January 26, 2023, 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 99.1 hereto. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	**Description**
99.1	Investor Presentation dated January 26, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL documents)

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.

January 26, 2023

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

Exhibit 99.1

BiomX

Revolutionizing the treatment of Cystic Fibrosis through our unique BOLT Phage therapy platform

Investor Presentation / Jan 2023

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. For example, when we discuss our expectations regarding the sufficiency of our cash runway 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 delay of certain development programs, our pipeline, our ability to quickly generate clinical proof of concept in patients and the advantages of our BOLT platform 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.

Executive Summary

Unmet need in cystic fibrosis

- Improved treatment has shifted CF from being a disease of childhood to a disease of adulthood. As patients age, *Pseudomonas aeruginosa (PsA)* lung infections become the leading cause of morbidity and mortality.
- Prolonged antibiotic treatments lead to significant resistance, creating a large unmet need - an estimated 17,000 CF patients in the US and Western Europe with chronic *PsA* infections[1].

BX004 – our lead program

- BX004,our proprietary phage cocktail, has the potential to treat CF patients with chronic resistant *PsA* lung infections, providing a significant potential commercial opportunity of > $1 billion[2].
- Part 1 readout of our Phase 1b/2a study - evaluating both safety and efficacy of BX004 - targeting CF patients with chronic *PsA* infections expected in Q1 2023, and part 2 readout in Q3 2023. Study design in collaboration with the CF Foundation.

Our Bolt phage technology

- Our proprietary BOLT phage technology platform - which is based on advanced machine learning – was used to design the BX004 phage cocktail that *in vitro* overcomes antibiotic resistance, biofilms and other bacterial defense systems.

Financing and investors

- Publicly traded **(NYSE American:PHGE).**
- $41.5 million cash and cash equivalents as of September 30, 2022. Expected cash runway until at least middle of 2024.
- Backed by prominent biotech investors such as Orbimed, Johnson & Johnson and the CF Foundation.

1. See slides 11 and 12
2. See slide 22

Strong leadership and scientific team

Management

Jonathan Solomon - Chief Executive Officer, Director
- *Former co-Founder and CEO Proclara*

Merav Bassan, PhD - Chief Development Officer
- *20 years drug and clinical development at Teva*

Assaf Oron - Chief Business Officer
- *Former EVP business development at Evogene*

Marina Wolfson, CPA - Chief Financial Officer
- *Former Bioview, E&Y*

Inbal Benjamini-Elran – Chief HR Officer
- *Former HR roles at Teva and Herzog Law*

Board of Directors

Russell Greig, PhD - Chairman of the Board
- *Former president of GSK Pharma International & SR one, GSK corporate venture group*

Alan Moses, MD - Director
- *Former Global Chief Medical Officer of Novo Nordisk*

Lynne Sullivan - Director
- *Former Senior Vice President of Finance for Biogen*

Scientific Team

Prof. Rotem Sorek
- *Head of microbial genomics group at Weizmann Institute*
- *Phage genomics and CRISPR research*

Prof. Eran Elinav
- *Principal investigator at Weizmann Institute*
- *Immune system and intestinal microbiome interactions*

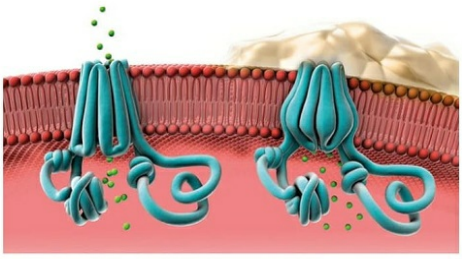
Prof. Timothy K. Lu
- *Associate professor leading synthetic biology group, MIT*
- *Synthetic biology, biochemical engineering*

Prof. Eitan Kerem
- *Former Chairman of Pediatric Pulmonology Unit, Hadassah Medical Center*
- *World leader in CF care and research*

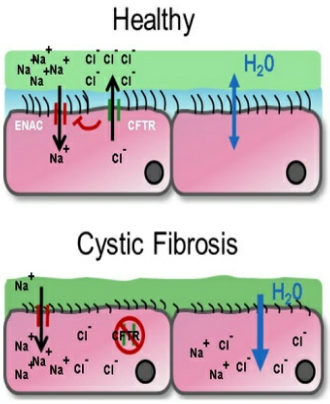
CYSTIC FIBROSIS
The Unmet Need

CF is an inherited disease caused by a mutation on the CFTR protein

- The CFTR protein is present on epithelial cells throughout the body. It is a chloride ion channel involved in maintaining water and ion homeostasis on cell surfaces
- The disease 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



Normal (left) and abnormal CFTR proteins (right)



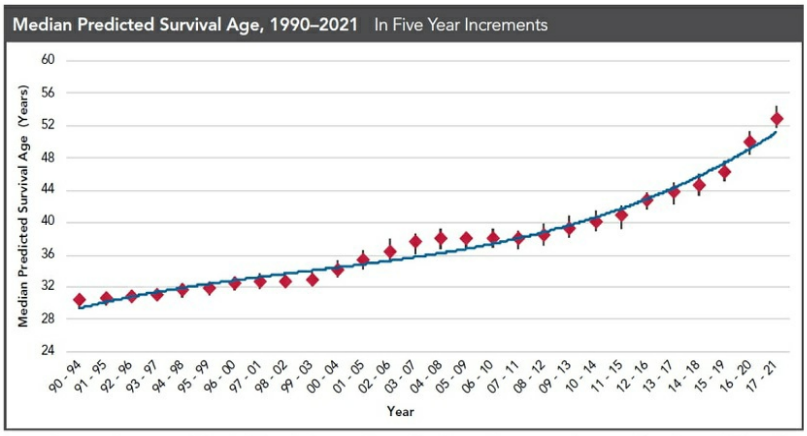
Light blue – periciliary layer

Green – mucus layer

In CF lungs, mutations cause thick and sticky mucus that provides environment for bacteria to infect and propagate. In the less hydrated periciliary layer, the cilia are flattened and the ability to clear bacterial infection reduced.

CF Foundation estimates across 94 countries (https://www.cff.org/intro-cf/about-cystic-fibrosis)
Plackett, Nature 2020
Gibson et al., 2003; Stuart et al., 2010

Declining incidence is offset by increased survival through improved treatment resulting in CF being shifted from being a disease of childhood to being a disease of adulthood



**Using the currently recommended method for calculating median predicted survival. For more information about the methodology, please see the Technical Supplement available at cff.org.*

Improvements driven by introduction of life-changing medicines

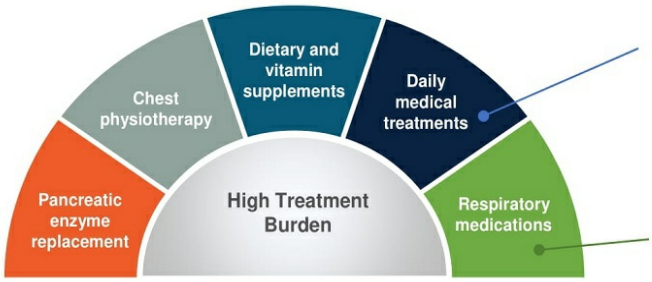
CFF 2021 patient registry annual data report , NACFC (North American CF Conference) Oct. 2021 plenary session

BiomX

From the patient perspective, CF treatment is complex and requires a high degree of adherence to schedules and treatment

- Daily treatment burden for adults includes 7 daily medications, from CF antibiotics that are inhaled or IV to oral CFTR modulators that are designed to correct the malfunctioning protein made by the CFTR gene
- Trikafta, the main CF drug combination used today, costs ~$300K annually per patient in the US, while a lung transplant costs -$1M
- **The global CF therapeutic market was estimated at $10 billion in 2021**

COMPLEXITY OF CF TREATMENT



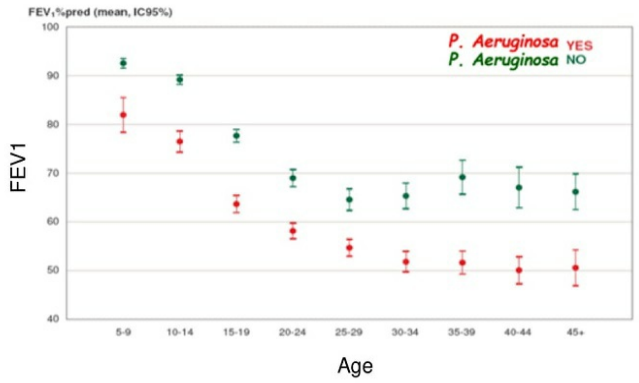
- **CFTR modulators** (Trikafta)
- **Anti inflammatory** (e.g. Azithromycin)
- **Treatment of complications** (drugs for diabetes or liver disease, osteoporosis)

- **Inhaled antibiotics** (e.g. Tobramycin)
- **Inhalations to improve mucociliary clearance** (e.g. Pulmozyme)

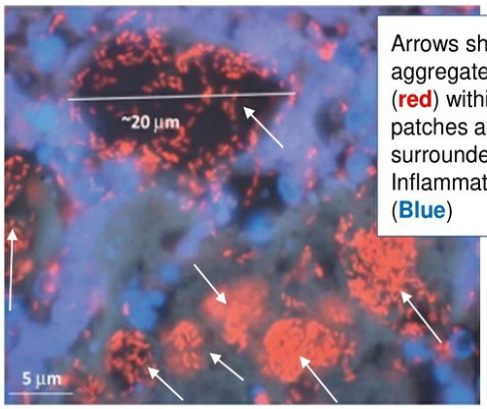
CFF 2021 patient registry annual data report
2021 market size based on Vertex earnings, Cystic Fibrosis Therapeutics Market and Forecast 2020-2027 report (iHealthcaseAnalyst)

Pseudomonas aeruginosa (*PsA*) bacteria are associated with decreased lung function (FEV1) and damaged lung epithelium

PsA colonization associated with lower FEV1 at all ages[1]



PsA forms biofilm patches in the lungs[2]



Arrows show aggregates of PsA (**red**) within biofilm patches and surrounded by Inflammatory cells (**Blue**)

PsA bacteria and biofilm lead to persistent inflammation causing tissue damage and eventually necrosis of lung tissue

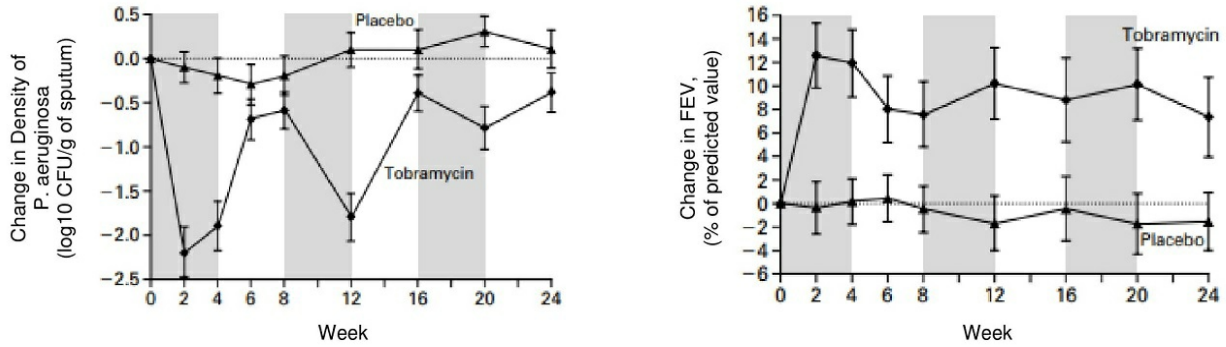
1. Kerem et al., ECFS unpublished data, 2013
2. Bjarnshol at al., Trends in Microbiology 2013

BiomX

Antibiotics were effective 2 decades ago in treating *PsA* infections

Tobramycin showed (study conducted 1995-96) up to **2.2 log bacterial reduction** and **8-12% FEV1 improvement** (compared to placebo)

Phase 3 Efficacy and Safety Study of Tobramycin Inhaled Solution (1995-96)*



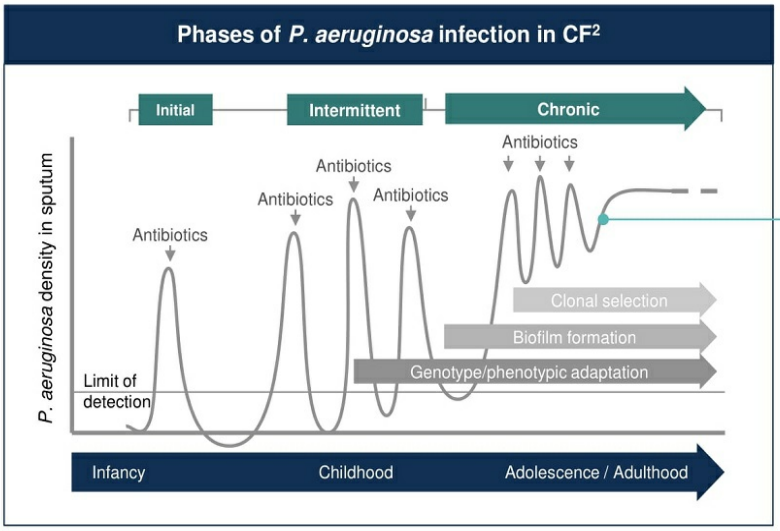
Over the last 2 decades, with the rise of antibiotic resistance, benefits of inhaled antibiotics have diminished

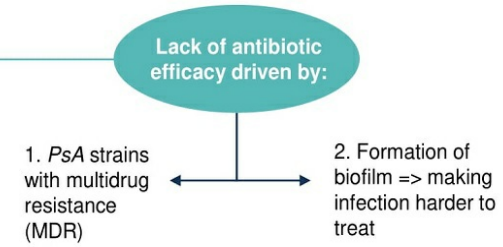
*n=520; 52% >18 yrs; treated in 28 day on/off cycles
B.W. Ramsey et al., (N Engl J Med 1999;340:23-30.

BiomX

Chronic *PsA* infections have become a persistent problem due to antibiotic resistance driving morbidity and mortality in CF

- Chronic respiratory infections and the resulting robust but ineffective inflammatory response, culminating in respiratory failure, are the primary causes of death in CF patients
- After prolonged and repeated antibiotic courses, increased resistance to antibiotics has lowered efficacy, creating a large unmet need for CF patients suffering from Chronic *PsA* - Estimated at **17,000 patients in the US and Western Europe**[1]

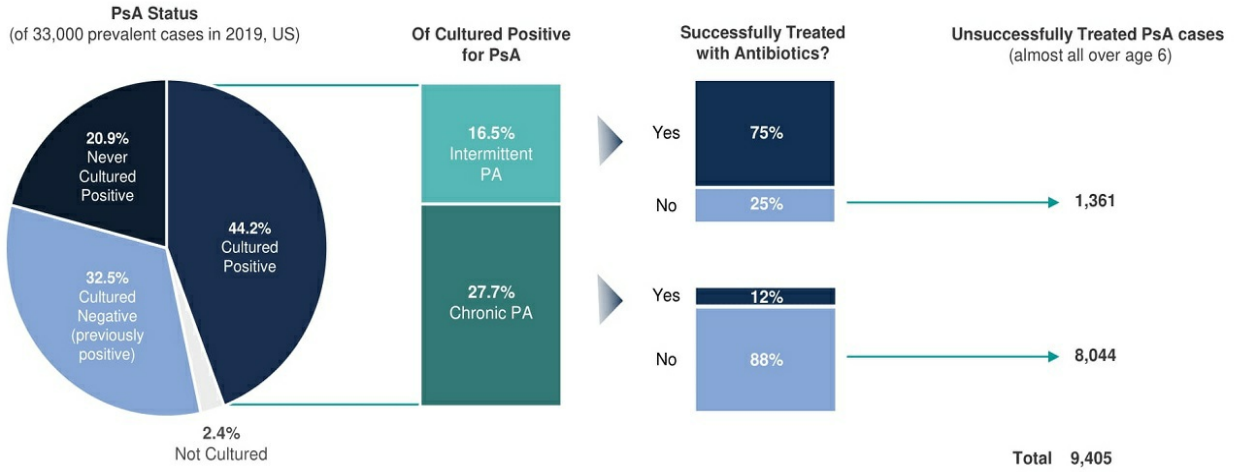




1. CFF Annual Data Report 2019, ECFS patient registry report, 2020
2. Nicole M. Bouvier et al., 2016

BiomX

US Opportunity: Of an estimated 14.6K CF patients who cultured positive for *PsA* (2019), ~9.4K (65%) were not successfully treated with antibiotics



In the US alone, over 8,000 CF patient with chronic *PsA* infections not successfully treated with antibiotics

CFF Annual Data Report 2019

BiomX

BX004 – BiomX's proprietary phage cocktail targeting *PsA* has the potential to treat CF patients with chronic *PsA* lung infections

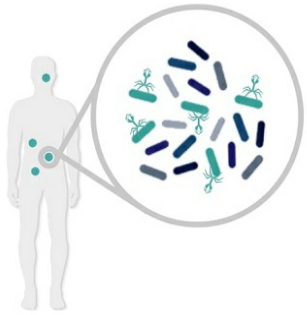
- **Product** – Proprietary phage cocktail targeting *PsA*
- **Patient population** – CF patients with chronic *PsA* lung infections
- **Delivery** – Nebulized
- **Key features** – Potentially effective on antibiotic resistant strains, enables breakdown of biofilm
- **Potential impact:**
  - Suppression/eradication of *PsA* (CFU in sputum)
  - Improved lung function (FEV1)
  - Fewer exacerbations, hospitalizations
  - Increased efficacy of antibiotic treatment
  - Reduce oral, inhaled and IV antibiotic treatments


Intro To
PHAGE

Phage: Nature's precision tool to target bacteria

1. SPECIFIC

Each phage binds only to specific bacterial strains



2. KILLING MECHANISM ORTHOGONAL TO ANTIBIOTICS

Lysin proteins burst bacterial cell wall from within

3. BREAKDOWN BIOFILM

Phage can breakdown biofilm (a polysaccharide mesh secreted by bacteria)

4. AMPLIFY

Phage components multiply and assemble within bacterial cell

5. SAFETY PROFILE

100s of compassionate use cases with no significant side effects to date

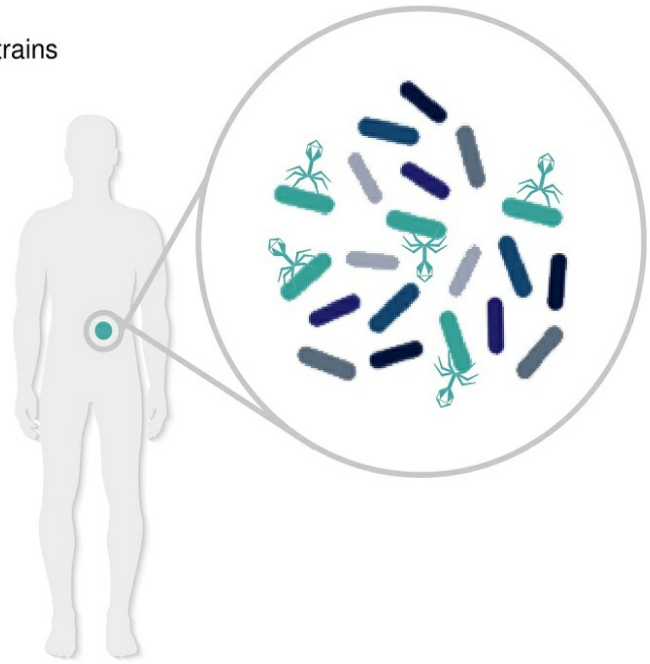
Kortright et al. (2019), Cell Host & Microbe

Key challenges in developing phage therapies

- **Host range -** Narrow specificity to a subset of bacterial strains
- **Resistance -** Bacterial defense systems (e.g. CRISPR)
- **CMC –** Manufacturing (e.g. purity, stability)

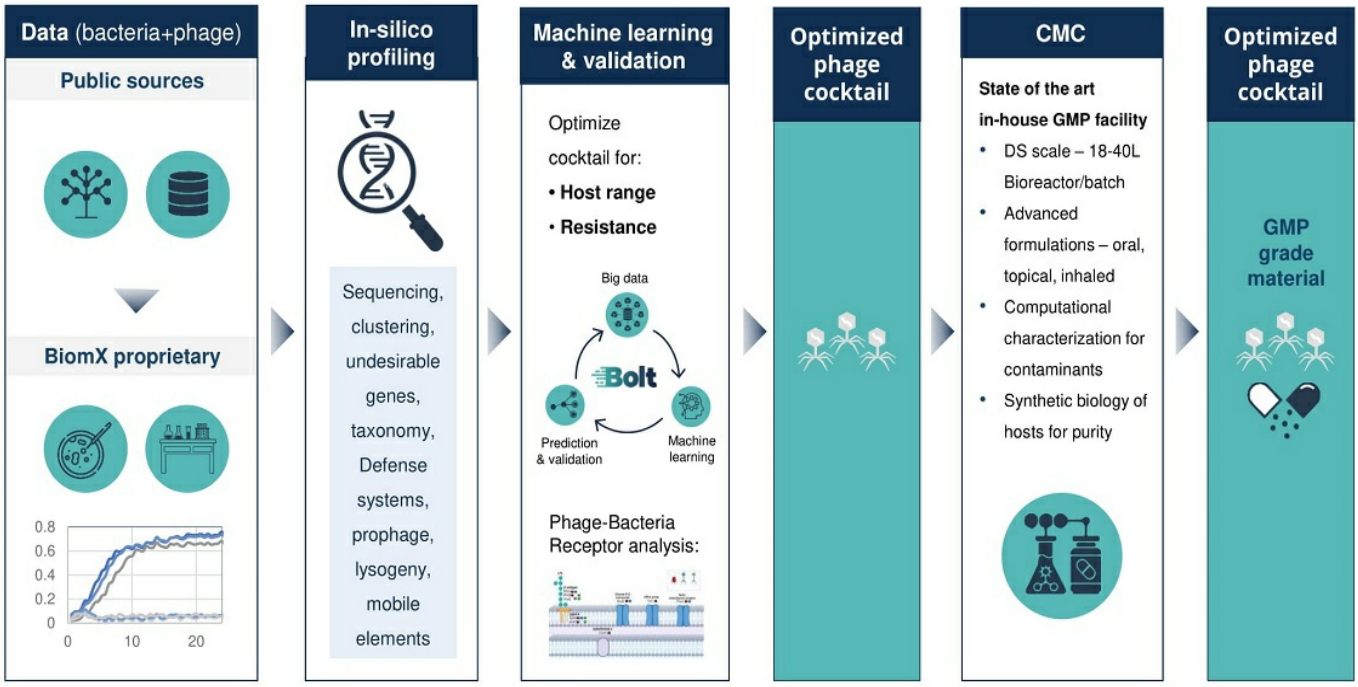
And many other considerations

- Phage titer
- Biofilm breakdown
- Absence of toxic genes
- Other



Phagoburn study The Lancet, inf..Dis.2019 Jan;19(1):35-45.doi: 10.1016/S1473-3099(18)30482-1.
Nestle study: E.BioMedicine 2016 Jan 5;4:124-37. doi: 10.1016/j.ebiom.2015.12.023.
Patterson case: Antimicrob Agents Chemother 2017 Sep 22;61(10):e00954-17. doi: 10.1128/AAC.00954-17.

The BiomX Bolt platform addresses the key challenges in phage therapy development



BX004

Numerous compassionate treatments of CF patients with phage provide strong rationale for the development of BX004

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% increased 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 received nebulized/topical/ other routes

UCSD cases:

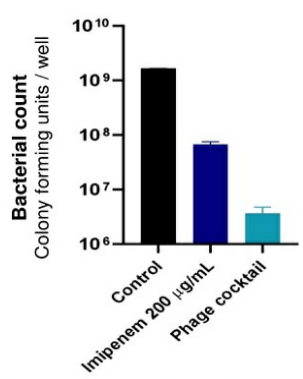
- eIND path for all patients
- IV phage (+ additional nebulized phage for certain patients)
- Twice daily for ~6 months (though a favorable outcome required improvement within 8 weeks)
- **Outcome - Favorable clinical or microbiological responses in 11/20 patients (for 5 patients infection resolved)**

Results demonstrate the 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 has demonstrated *in vitro* penetration of biofilm and activity on antibiotic resistant *PsA* strains

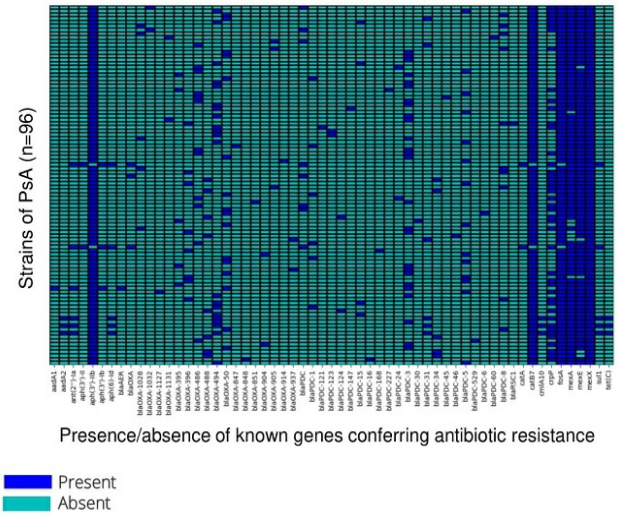
BX004 penetrates biofilm *in vitro*



Biofilm was grown from *PsA* for 24 hours and then treated with BX004 for 6 hours (control-untreated wells). Treatment with antibiotics not shown
Crystal violet – Used for biomass staining of biofilm. Staining substantially reduced following treatment with BX004

BX004 active *in vitro* on antibiotic resistant *PsA* strains

BX004 was active in killing all 96 strains described below displaying multiple antibiotic resistant genes



BiomX internal results

BiomX

Phase 1b/2a study targeting *PsA* with first readout expected in 1Q 2023

Phase 1b/2a – Part 1

Objectives
- Safety, PK and microbiologic/clinical activity

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

Study Population
- CF patients with chronic *PsA* infection

At least 8 Subjects
- 6 receive nebulized BX004 phage therapy
- 2 receive nebulized placebo
- 7 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 *PsA* burden
- Sputum pharmacokinetics
- FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised) and CRISS

Study Population
- CF patients with chronic *PsA* infection

At least 24 subjects
- 16 receive nebulized BX004 phage therapy
- 8 receive nebulized placebo
- 2:1 randomization
- 10 days duration of treatment

Data expected 3Q 2023

Study design informed by input from the CF Foundation

BX004 provides significant commercial opportunity, potentially commanding a market > $1 billion

	BX004	References/Comments
Patient population (US)	~8,000	Number of CF patients with chronic PsA infections[1]
Potential effect on *PsA* CFU in lungs	Suppression/eradication of *PsA* (CFU in sputum)	Magnitude observed under Tobramycin Phase 3 study was ~1.5-2 log[2]
Potential impact on lungs	Improved lung function (FEV1)	Magnitude observed under Tobramycin Phase 3 study was 8-12%[2]
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[3]
Market potential	**~$1 Billion in the US alone** (worldwide $1.6 billion)[4]	US patient population times potential pricing

1. CFF 2019 Patient Registry Annual Data Report
2. See previous slide on Tobramycin study
3. Trikafta and Arikayce – Publicly announced pricing, First Databank, Jan. 8, 2021, public pricing information. for alternating Tobi Podhaler and Cayston solution assumes 65% compliance
4. Assumes rest of the world outside US comprises 40% of total market. Based on current distribution in CF therapeutic market (iVertex annual report, Cystic Fibrosis Therapeutics Market and Forecast 2020-2027 report (iHealthcaseAnalyst)

Regulatory path for BX004

According to FDA guidance under BiomX pre-IND and IND:

- Phage are inert to mammalian cells => considered safe if lytic, do not carry virulent genes and have no generalized transduction. Accordingly:
- **No need for GLP general toxicology** studies
- **No need for healthy volunteer clinical studies** (conducted in target carrier population)
- Phage in cocktail may be exchanged during development provided adequate characterization

According to public communications from the FDA:

- No regulatory hurdles for engineered synthetic phage aimed at improving intrinsic characteristics
- Potentially allows development of personalized therapies based on a dynamic phage library using an approved manufacturing platform

BX004 is potentially eligible for expedited programs/designations: Breakthrough, Priority review, Fast track designation, Accelerated approval, ODD

FDA, NIH, NIAID joint workshop (2017): "Bacteriophage Therapy: Scientific and Regulatory Issues Public Workshop" (https://www.fda.gov/media/108025/download)
Principi N, Silvestri E and Esposito S. Advantages and Limitations of Bacteriophages for the Treatment of Bacterial Infections. Front Pharmacol. 2019 May 8;10:513.

IP protection of phage cocktails

CORE IP APPLICATIONS:

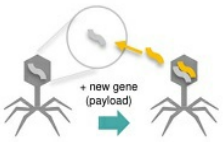
Natural phage cocktails

- Composition claims on combinations of phage in cocktail/s based on additive/synergistic effects (e.g. combinations of phage avoiding development of resistance due to multiple MOAs)
- Method claims for use of the combinations against the infecting bacteria

Novel combination of natural phage

Synthetic phage cocktails

- Composition claims on new synthetic matter on each specific synthetic phage and the phage combination of the cocktail (e.g. a synthetic phage where a heterologous gene was added conferring traits, such as improved biofilm breakdown capabilities)



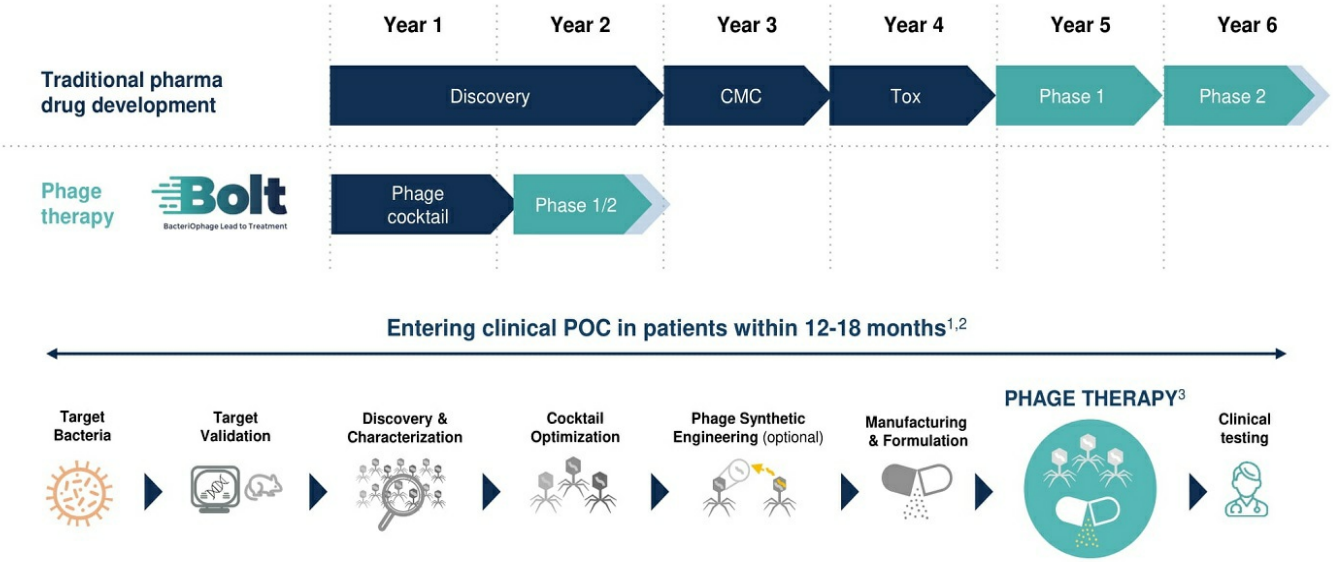
Synthetically engineered phage

SUPPLEMENT IP APPLICATIONS:

- Claim product aspects invented in later product development such as effective formulations, delivery device features, manufacturing methods, synthetic engineering of manufacturing host or other


PIPELINE

Bolt end to end platform allows entering 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 entering clinical validation may be longer depending on indication, identity of target bacteria 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

Pipeline

	Phage discovery	Preclinical	Phase I	Phase II	Phase III
Product Candidates					
Cystic fibrosis • BX004					
Atopic dermatitis • BX005*					

* On May 24, 2022, we announced that we plan to prioritize the CF program and delay the AD program.

Other potential indications

Prosthetic Joint Infections (PJI)[1]

- **Condition** – Chronic infections in patients who underwent hip or knee joint replacement
- **Cause** - Bacterial infection surrounding joint implant (main bacteria – *Staphylococcus aureus*, *Staphylococcus epidermidis*)
- **Patient population (2030 est.) –** Cases of revision surgeries with S. aureus/S. epidermidis: 30K annually in US[2]
- **Existing treatment –** Primarily revision surgery
- **Unmet need –** Primarily: avoid a complex and expensive revision surgery. Secondary: Treat patients not suitable for revision surgery
- **Proposed phage product –** A phage cocktail targeting infecting bacteria (*S. aureus*, *S. epidermidis*), delivered by a local injection and/or during a DAIR procedure

DAIR: Debridement, Antibiotics, Implant Retention

M. avium complex (MAC)[1]

- **Condition** - A rare, progressive & chronic condition
- **Cause** - *Mycobacterium avium* complex (MAC) lung infection
- **Patient population (2022 est.)** – Estimated Number of MAC lung disease patients refractory to treatment (US): 15,000[3]
- **Existing treatment –** Arikayce, other standard antibiotic therapy with up to 29% success rate[4].
- **Unmet need –** Treatment with higher success rates and/or reduced adverse effects.
- **Proposed phage product –** An oral/inhaled phage cocktail targeting MAC

1. Potential indications are for illustrative purposes only. Potential indications referred to on this slide are at a preliminary stage and subject to further evaluation.
2. Integration of data including from 10.3390/jcm8050673, 10.1186/s13018-021-02850-3, 10.3390/diagnostics12071654 and 10.1016/j.arth.2020.02.030, 10.3899/jrheum.170990 and AAOS annual report 2022.
3. Internal analysis, Q1 2023, BiomX Inc. [doi:10.1513/AnnalsATS.201804-236OC; 10.1513/AnnalsATS.201611-860OC; 10.1378/chest.13-2538]; Insmed Form10-K, 2021
4. Success defined as culture converted by Month 6 (at least 3 consecutive monthly negative sputum cultures), https://www.arikaycehcp.com/culture-conversion//

Thank you

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