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 15, 2021**

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 5 Ness Ziona, Israel	**7414003**
(Address of Principal Executive Offices)	(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 15, 2021, BiomX Inc., or the Company, issued a press release announcing its financial results for the third quarter ended September 30, 2021. 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 15, 2021, 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 15, 2021
99.2	Investor Presentation dated November 15, 2021
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.

November 15, 2021

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

BiomX Reports Third Quarter 2021 Financial Results and Provides Business Update

Announces Strategic Focus on Cystic Fibrosis and Atopic Dermatitis Programs Based on Potential Proof-of-Concept Clinical Data Readouts in 2022

Cash Runway Now Extended to End of 2023, Well Beyond Key 2022 Data Readouts

FDA Clears BiomX to Begin Phase 1b/2a Trial in Cystic Fibrosis; Trial to Start Imminently

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

BRANFORD, Conn. and NESS ZIONA, Israel – November 15, 2021 -- 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, reported today financial results and provided a business update for the third quarter ended September 30, 2021.

"In planning for the years ahead, BiomX has made the decision to prioritize the development of our cystic fibrosis and atopic dermatitis product candidates, as each has the potential to generate proof-of-concept clinical data readouts in 2022. BiomX will also discontinue development of its acne program," said Jonathan Solomon, Chief Executive Officer of BiomX. "We believe that by focusing on the efficient use of BiomX's capital on selected programs that can generate clinically meaningful, proof-of-concept data, will best position our company to drive value creation for shareholders. With this decision, we intend to also postpone our development efforts temporarily in inflammatory bowel disease and colorectal cancer until 2023.

"Importantly, our new strategic focus will have a positive impact on our balance sheet. This new focus may allow us to extend our cash runway by up to 6 months, until at least the end of 2023, and additional tranches that may become available to us under our venture debt facility upon satisfaction of certain specified milestones may further extend our cash runway to the first half of 2024." We therefore believe that we remain well-positioned financially through our expected clinical data readouts in cystic fibrosis and atopic dermatitis."

RECENT CORPORATE HIGHLIGHTS

- In October 2021, BiomX reported topline results of the cosmetic Phase 2 acne study showing statistically significant improvement from baseline observed in the appearance of acne-prone skin but with no meaningful difference demonstrated for BX001 relative to vehicle.
- In October 2021, BiomX entered into an agreement with Maruho Co. Ltd., Japan's largest dermatology-focused pharmaceutical company, for a right of first offer to license BiomX's atopic dermatitis product candidate, BX005, in Japan. The right of first offer will commence following the availability of results from the Phase 1/2 study of BX005 expected in 2022. Maruho also entered into a binding agreement for an equity investment in BiomX, intended primarily to support the Phase 1/2 study, of $3 million at a premium to the market share price.

- In September 2021, BiomX was cleared by the U.S. Food and Drug Administration (FDA) to initiate a Phase 1b/2a trial of BX004 in cystic fibrosis patients with chronic respiratory infections caused by *Pseudomonas aeruginosa.*
- In August 2021, the Company announced that it entered into a debt financing agreement of up to $30 million with Hercules Capital, Inc. (NYSE:HTGC). In July 2021, BiomX announced it raised $15 million in a registered direct offering of common stock and warrants.

Clinical Program Updates

Cystic Fibrosis ("CF") (BX004)

- 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.
- In September 2021, BX004 was cleared by the FDA to initiate a Phase 1b/2a trial in CF patients with chronic respiratory infections caused by *Pseudomonas aeruginosa.*
- The Phase 1b/2a trial is composed of two parts and is expected to start imminently. Part 1 of the trial 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 second quarter of 2022. Part 2 of the trial 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 by the third quarter of 2022.

Atopic Dermatitis ("AD") (BX005)

- BX005 is designed to shift the skin microbiome composition of AD patients to its "pre-flare" state by reducing *Staphylococcus aureus* burden, potentially resulting in clinical improvement.
- BX005 is currently in the final stages of GMP production. Due to delays in communications with the FDA attributable to COVID-related matters, the Company now expects results from its Phase 1/2 proof-of-concept trial evaluating the safety and efficacy of BX005 in the third quarter of 2022 instead of the first half of 2022.

Inflammatory Bowel Disease ("IBD") and Colorectal Cancer Programs

- Consistent with the new strategic focus on CF and AD programs and the efficient deployment of BiomX capital, the Company plans to temporarily pause its development efforts in IBD and colorectal cancer until early 2023, as neither program would otherwise be expected to yield proof-of-concept data in patients through the end of 2022.

Acne-Prone Skin (BX001)

- Based upon the topline results of the cosmetic Phase 2 acne trial previously announced in October 2021, the Company has now determined that it is discontinuing this program to focus resources on the CF and AD programs.

Third Quarter 2021 Financial Results

- **Cash balance and short-term deposits** as of September 30, 2021, were $68.3 million, compared to $57.1 million as of December 31, 2020. The increase was primarily due to net cash provided by financing activities partially offset with net cash used in operating activities. During the third quarter, the Company completed a $15 million registered direct equity financing and debt financing agreement of up to $30 million. Based upon the BiomX's new strategic focus on its cystic fibrosis and atopic dermatitis programs, the Company now expects its existing cash, cash equivalents and short-term deposits to be sufficient to fund the Company's current operating plan until the end of 2023. Additional tranches that will become available to the Company under its venture debt facility upon satisfaction of certain specified milestones can further extend the Company's cash runway to the first half of 2024.

- **Research and development (R&D) expenses, net** were $6.6 million for the three months ended September 30, 2021, compared to $6.1 million for the same period in 2020. The increase was primarily due to increased expenses related to conducting pre-clinical and clinical trials of our product candidates and an increase in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees in R&D and clinical activities.

- **General and administrative expenses** were $2.8 million for the three months ended September 30, 2021, compared to $2.4 million for the same period in 2020. The increase was primarily due to increases in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees, due to an increase in expenses associated with operating as a public company, such as directors' and officers' insurance and due to expenses resulted from moving into new premises.

- **Net loss** for the third quarter of 2021 was $10.0 million, compared to $8.8 million for the same period in 2020.

- **Net cash used in operating activities** for the nine months ended September 30, 2021 was $18.5 million, compared to $17.3 million for the same period in 2020.

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 2021 ended September 30, 2021. 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, such as cystic fibrosis, atopic dermatitis, inflammatory bowel disease, primary sclerosing cholangitis, and colorectal cancer. 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 its expectations regarding the sufficiency of cash, cash equivalents and short-term deposits to fund the Company's current operating plan until at least the end of 2023, or even later, the ability of its 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 its preclinical and clinical trials and studies, including resumption of certain development programs, as well as its pipeline and the potential of its product candidates, 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 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 31, 2021 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.

BIOMX INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

USD in thousands, except share and per share data

	Note	Three Months Ended September 30,		Nine Months Ended September 30,	
		2021	2020	2021	2020
Research and development ("R&D") expenses, net		6,608	6,056	16,102	13,302
Amortization of intangible assets		380	380	1,139	1,139
General and administrative expenses		2,845	2,394	8,436	6,749
Operating loss		9,833	8,830	25,677	21,190
Financial expenses (income), net		188	5	76	(248)

Loss before tax		10,021	8,835	25,753	20,942
Tax expenses		10	-	16	-
Net Loss		10,031	8,835	25,769	20,942
Basic and diluted loss per share of Common Stock	6	0.37	0.38	1.03	0.91
Weighted average number of shares of Common Stock outstanding, basic and diluted		27,077,903	23,150,253	25,120,037	23,013,790

BIOMX INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

USD in thousands

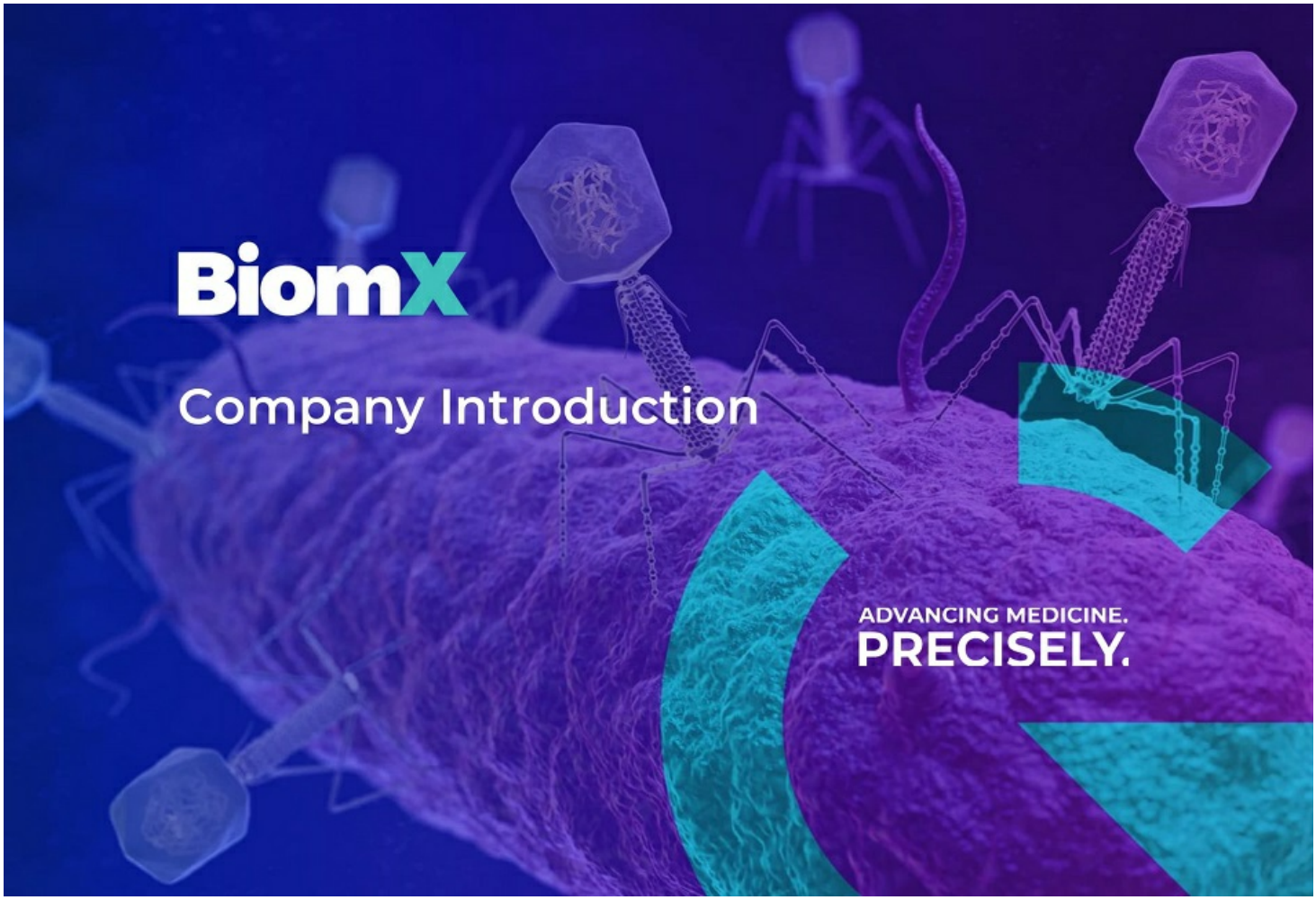
	Note	As of September 30, 2021	As of December 31, 2020
ASSETS			
Current assets			
Cash and cash equivalents		67,346	36,477
Restricted cash		985	763
Short-term deposits		-	19,851
Other current assets		1,467	3,576
Total current assets		69,798	60,667
Property and equipment, net		5,863	2,228
Intangible assets, net		1,899	3,038
Operating lease right-of-use assets		4,239	4,430
Total non-current assets		12,001	9,696
		81,799	70,363

	Note	As of September 30, 2021	As of December 31, 2020
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Trade account payables		1,879	2,320
Other account payables		6,321	3,978
Current portion of operating lease liabilities		799	863
Total current liabilities		8,999	7,161
Non-current liabilities			
Long-term debt	4	14,225	-
Operating lease liabilities, net of current portion		4,728	5,032
Other liabilities		420	701
Total non-current liabilities		19,373	5,733
Commitments and Collaborations	3		
Stockholders' equity	5		
Preferred Stock, $0.0001 par value; Authorized - 1,000,000 shares as of September 30, 2021 and December 31, 2020. No shares issued and outstanding as of September 30, 2021 and December 31, 2020.		-	-
Common Stock, $0.0001 par value; Authorized - 60,000,000 shares as of September 30, 2021 and December 31, 2020. Issued – 28,206,229 shares as of September 30, 2021 and 23,270,337 shares as of December 31, 2020. Outstanding – 28,200,529 shares as of September 30, 2021 and 23,264,637 shares as of December 31, 2020.		3	2
Additional paid in capital		151,451	129,725
Accumulated deficit		(98,027)	(72,258)
Total stockholders' equity		53,427	57,469
		81,799	70,363

BiomX, Inc.
Anat Primovich
Corporate Project Manager
+972506977228
anatp@biomx.com

Source: BiomX Inc

Exhibit 99.2


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 end of 2023, or even later, 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, as well as its pipeline and the potential of its 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

Bolt
BacteriOphage Lead to Treatment

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

BiomX

* 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.

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

Bolt

Pipeline

- Focusing on cystic fibrosis & atopic dermatitis. Both expected to produce POC data in 2022[1]
- Additional programs in IBD / PSC[2] & Cancer to resume in 2023

Partnerships

- Maruho ROFO[3] for rights in Japan to atopic dermatitis product candidate
- Biomarker discovery collaborations in IBD
  - Janssen (J&J)
  - Boehringer Ingelheim

maruho

Janssen

Boehringer Ingelheim

Financing and investors

- Publicly traded (**NYSE:PHGE**)
- Equity raised: $143M
- Secured debt of up to $30M
- Expected cash runway until at least end of 2023

OrbiMed

SymBiosis

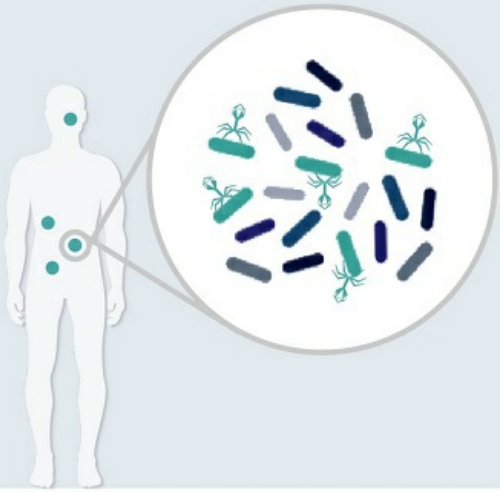
Johnson & Johnson

BiomX

1. Phase 1/2 results in cystic fibrosis,, Phase 1/2 results in atopic dermatitis
2. Inflammatory Bowel Disease (IBD) , Primary Sclerosing Cholangitis (PSC)
3. Right Of First Offer

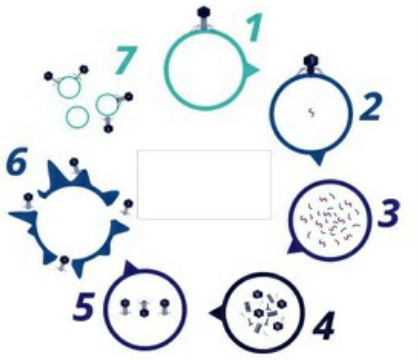
Phage: Nature's precision tool to target bacteria

Each phage binds only to specific bacterial strains



Phage have an amplifying lifecycle

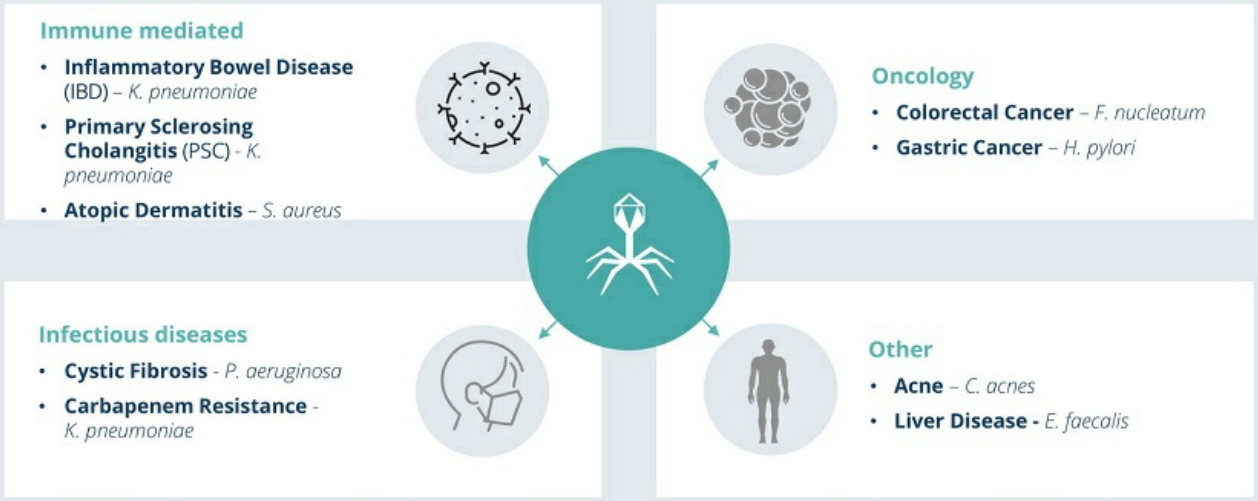
1. Locate
2. Inject
3. Infect
4. Multiply
5. Assemble
6. Eradicate
7. Seek



BiomX

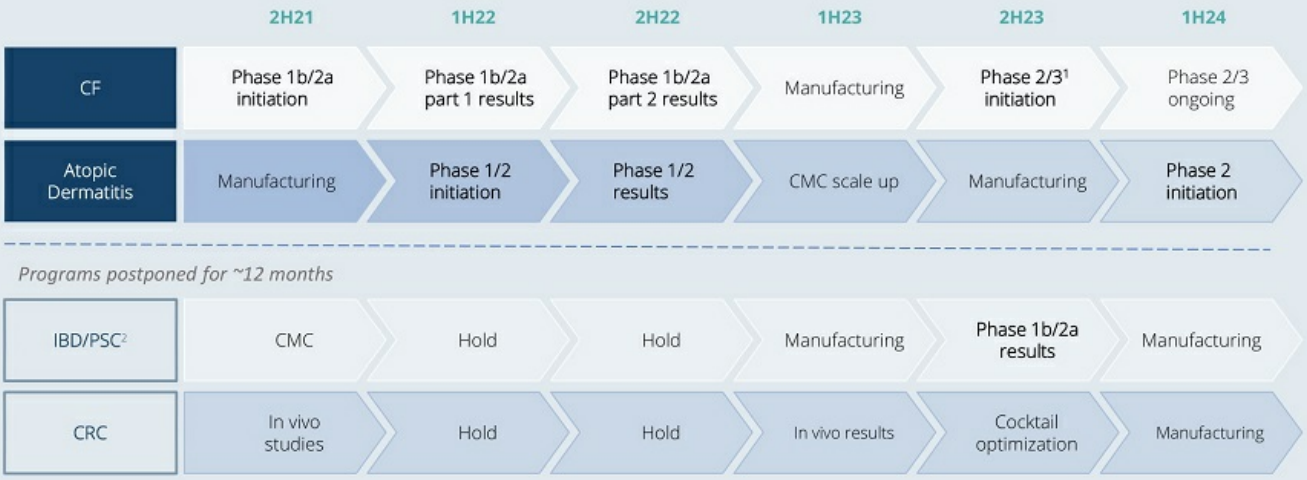
Source: Kortright et al. (2019), Cell Host & Microbe

Multiple potential applications of phage therapy



BiomX

Pipeline: 2 Phase 2 readouts expected by end of 2022 [1]



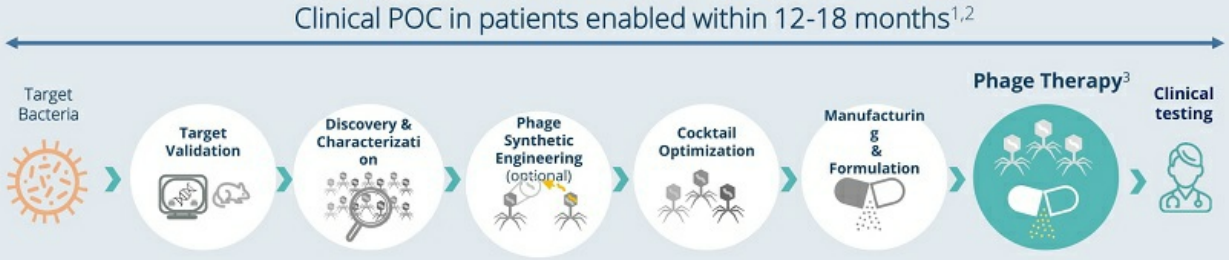
Cash and equivalents as of Sep 30th , 2021 were $68.3M million;

Cash runway expected at least until end of 2023, with additional venture debt tranches – mid-24

BiomX

1. Phase 1b/2a results in cystic fibrosis, Phase 2 results in atopic dermatitis,
2. As the IBD and PSC programs share the same bacterial target, Klebsiella pneumoniae, we currently anticipate that the BX003 phage cocktail will be developed for both indications. Accordingly, the Phase 1 study is expected to support progress of both indications.

Our Bolt platform allows clinical POC within 12-18 months

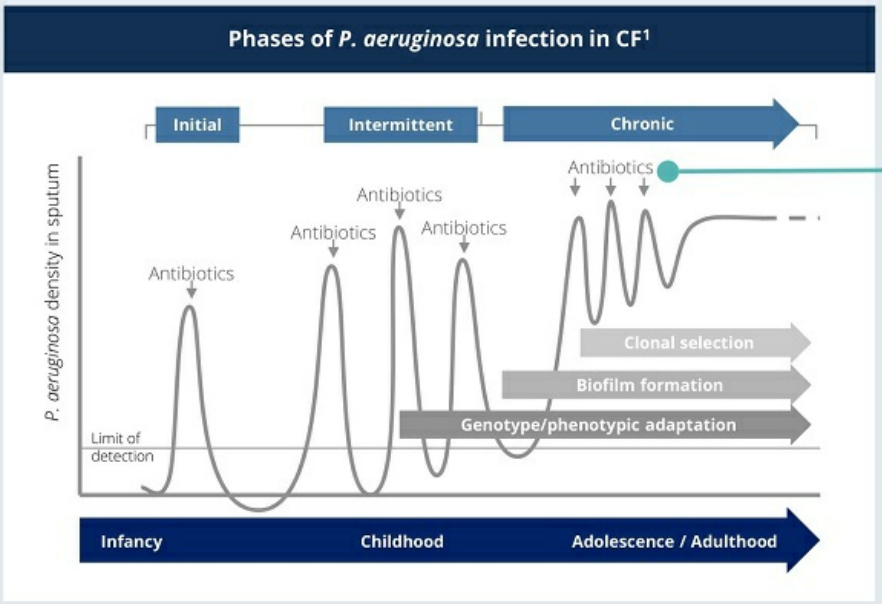


BiomX

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


whitley A35 anaerobic workstation
Cystic Fibrosis
Upcoming milestone: Phase 1b/2a part 1 data expected in 2Q 2022
BiomX

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, anti-infectives, mucolytic agents, bronchodilators and other
- Worldwide CF therapeutic market in 2020 was approximately $8.5B[2]

BiomX

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

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 → 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%

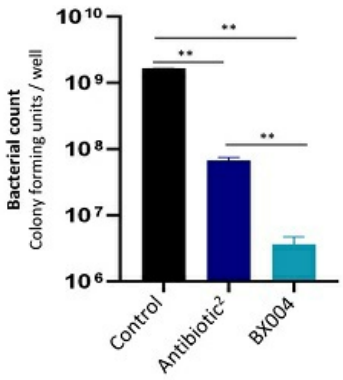
Results demonstrate the potential of phage therapy to decrease bacterial burden and improve FEV1

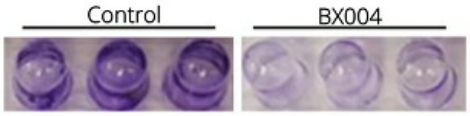
BiomX

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]





Biofilm was grown from *P. aeruginosa* 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

**p-value <0.001

BX004 displays enhanced biofilm penetration compared to antibiotics

BiomX

1. Internal data. A *P. aeruginosa* strain sensitive to antibiotics was grown to form biofilm
2. 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 2Q 2022

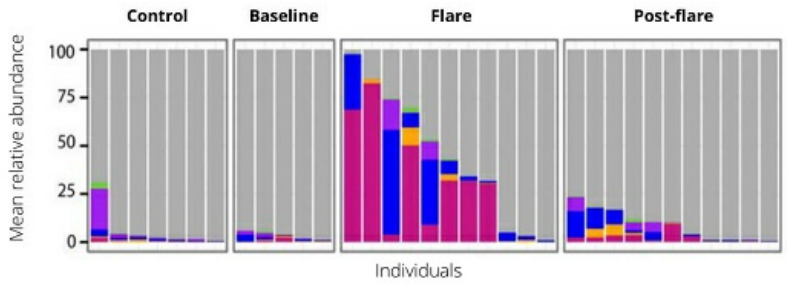
Phase 1b/2a – Part 1	Phase 1b/2a – Part 2
Objectives • Safety, PK and microbiologic/clinical activity **•Endpoints** • Safety and tolerability • Decrease in *P. aeruginosa* burden • Sputum pharmacokinetics • FEV1 (forced expiratory volume) • CFQ-R (CF Questionnaire-Revised) and CRISS **Study Population** • 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 2Q 2022**	**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 3Q 2022**

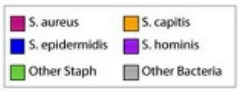
BiomX


Atopic Dermatitis
Upcoming milestone: Phase 2 data expected in 3Q 2022
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)





Control = healthy skin

Baseline = routine AD disease state

Flare = worsening in the clinical severity of the typical AD, without usage of skin-directed antimicrobial and anti-inflammatory treatments for seven days

Post flare = 10–14 days after initiation of skin-directed therapies

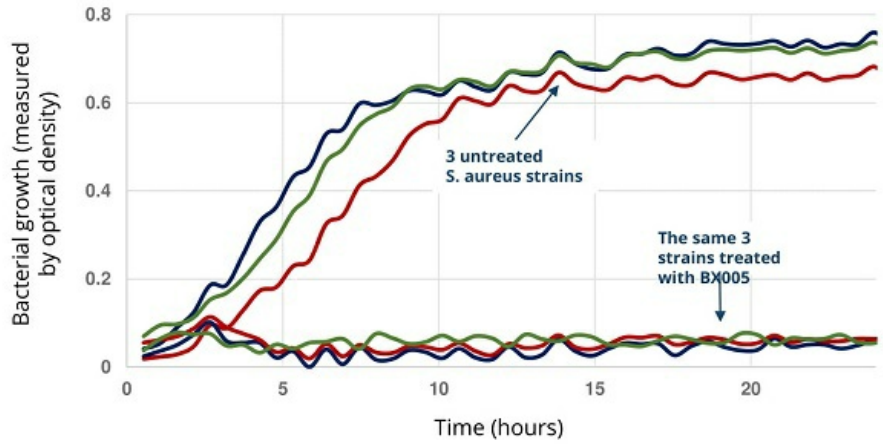
S. aureus becomes the dominant bacterial species during AD flares and is correlated with SCORAD

BiomX

Byrd and Kong (2017) Sci Transl Med. 05 9(397)

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* strains[1]

BiomX

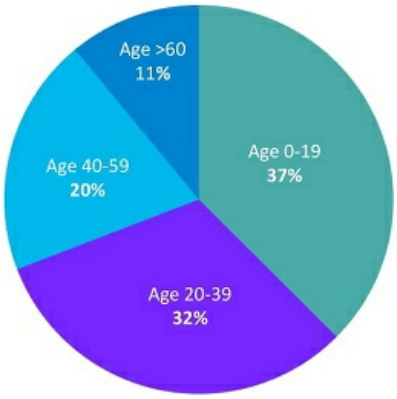
Source: Internal data
1. Panel of 120 strains isolated from skin of subjects from the US and Europe

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

- Atopic dermatitis, a rapidly growing market[1]:
  - > $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[3], 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]



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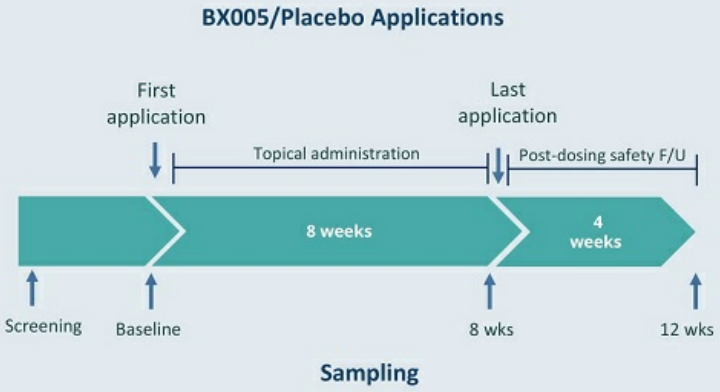
1. Atopic dermatitis Market forecast, trend analysis & competition tracking, Fact Mr. report
2. Atopic dermatitis: Global drug forecast and market analysis to 2027, GlobalData report
3. Based on safety data from BiomX's clinical studies using a topical phage cocktail for acne-prone skin

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

Data expected 3Q 2022



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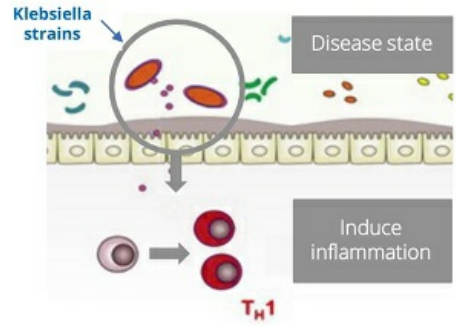
wk: week; F/U: Follow-Up


Inflammatory Bowel Disease (IBD), Primary Sclerosing Cholangitis (PSC)
Upcoming milestone: Phase 1b/2a data expected in 2H 2023
BiomX

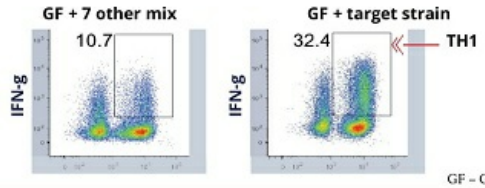
IBD · Identifying potential disease causing pro-inflammatory *Klebsiella* strains

Science

Pro-inflammatory *Klebsiella* strains affect IBD pathology



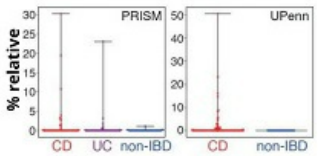
Inflammatory induction is seen in GF mice*



GF – Germ Free

Higher abundance of *Klebsiella* strains in IBD patients

Abundance of *Klebsiella* strains



CD – Crohn's disease
UC – Ulcerative colitis

Activity of bacterial target confirmed by BiomX

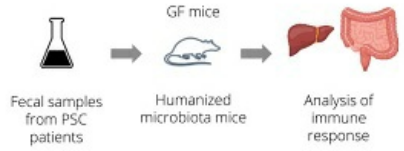
BiomX

Source: Atarashi et al. (2017), Science
** TH1 – A lineage of CD4+ effector T cell secreting IFNg and TNF. In IBD, TH1 cells accumulate in the intestinal tract of IBD patients and are directly associated with disease*

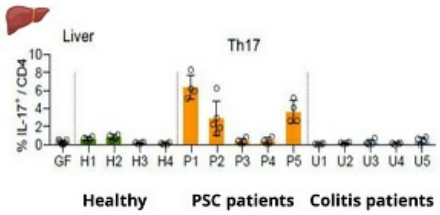
PSC • *Klebsiella* identified as possible driver of "leaky gut"

nature microbiology

Discovery approach



Th17* is induced in livers of GF mice inoculated with fecal samples from PSC patients



KP isolated from mice's lymph nodes colonized with patient samples

	Liver	MLN	Spleen
SPF mice	ND		ND
HC-gnotobiote	ND		ND
PSC/UC-gnotobiote	ND		ND

***Klebsiella pneumoniae* plays a gating role**

SPF – Specific-pathogen-free
HC – Healthy Controls
PSC/UC – PSC and ulcerative colitis

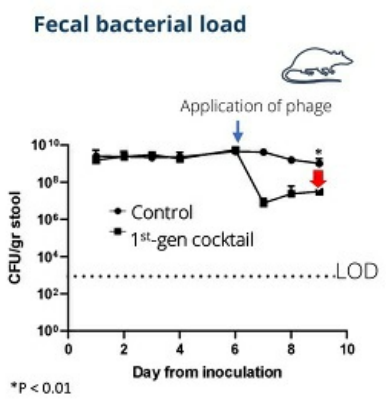
Klebsiella pneumoniae (KP) is a specific gut pathobiont of PSC that is an intestinal barrier disrupter and is pro-inflammatory ("*leaky gut*")

BiomX

Source: Nakamoto et al. (2019), Nature Microbiology
**TH17 – A lineage of CD4+ effector T cell secreting IL17A+, promoting inflammation and fibrosis within the liver*

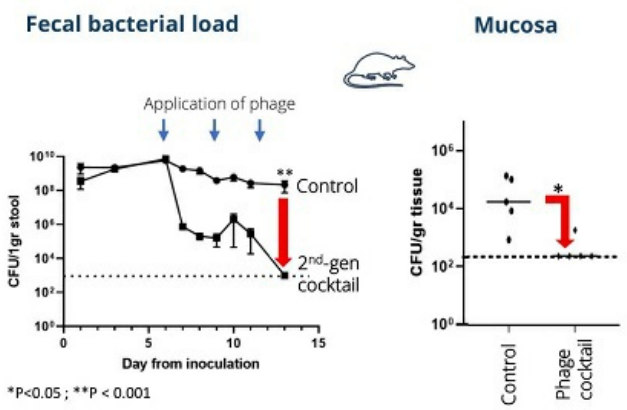
Phage cocktail composition drives activity

1st-generation phage cocktail (in-vivo)



Adding 2 phage with new MOA

2nd-generation phage cocktail (in-vivo) reduces bacterial load



Phage cocktails are optimized to prevent appearance of resistant bacteria by targeting multiple bacterial receptors and defense mechanisms

BiomX

Source: Internal data

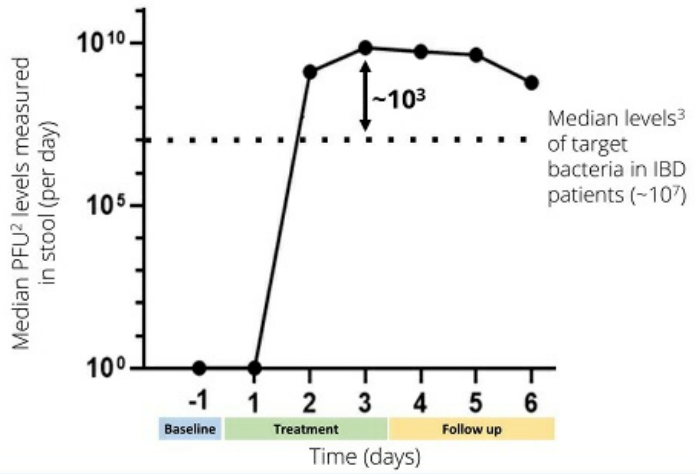
BX002: Phase 1a pharmacokinetic results demonstrate delivery of high levels of viable phage to the gut[1]

Phase 1a study design

3-day multiple-dose study (placebo-controlled)

- **Objectives**
  - Safety and pharmacokinetics
- **Endpoints**
  - Safety and tolerability
  - Detection of viable phage in stool
- **Study Population:** Healthy volunteers
- **18 subjects**
  - Oral delivery
  - 14 phage treatment + 4 placebo

Results - Median levels of viable phage detected in stool prior and following oral delivery of phage



- BX002 was safe and well tolerated
- Viable phage delivered is ~1,000 times higher compared to bacterial burden of *K. pneumoniae* in IBD patients

BiomX

1. Study conducted with BX002, a phage therapy candidate for oral administration targeting K. pneumoniae. In November 2020, BiomX announced the consolidation of its IBD and PSC programs to develop one broad host range product candidate for both indications, designated BX003.
2. PFU – Plaque forming units.
3. Value is based on median levels of K. Pneumoniae measured in clinical stool samples collected by BiomX from IBD patients.

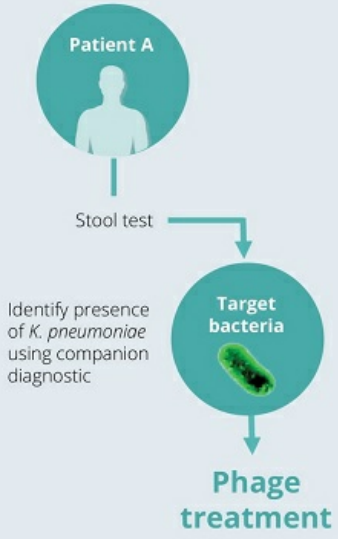
Phase 1b/2a study results expected in 2H 2023

Phase 1b/2a study design
Proof-of-Principle

4-week dosing study (placebo-controlled)

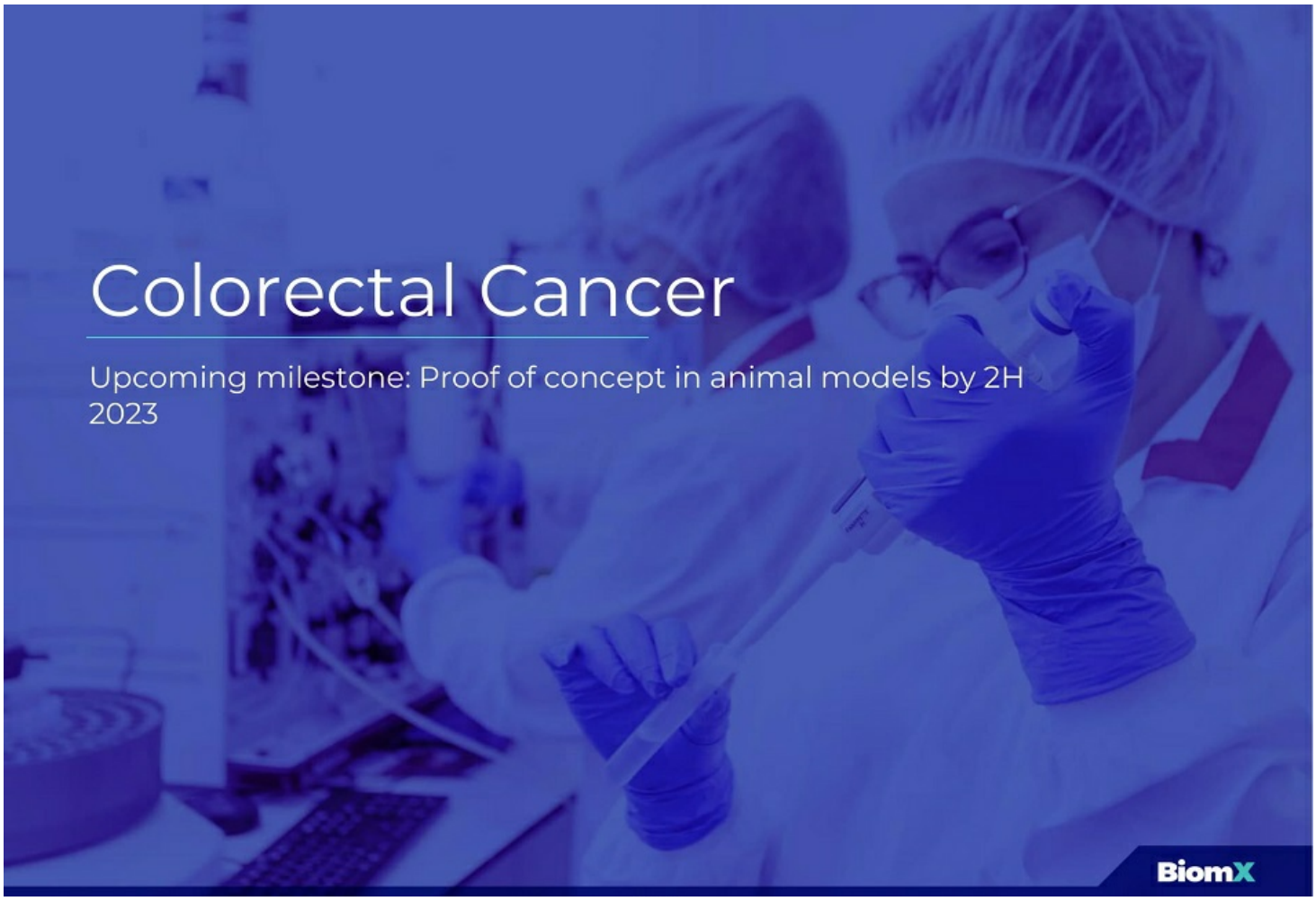
- **Objectives**
  - Safety and efficacy
- **Endpoints**
  - Safety and tolerability
  - Reduction of *K. pneumoniae* (efficacy)
  - Stool microbiome evaluation
- **Study Population:** Target bacteria carriers (Healthy volunteers or IBD/PSC patients)
- **60 subjects total**
  - Oral delivery
  - BX003 or placebo
  - 30 subjects per cohort

Data expected 2H 2023

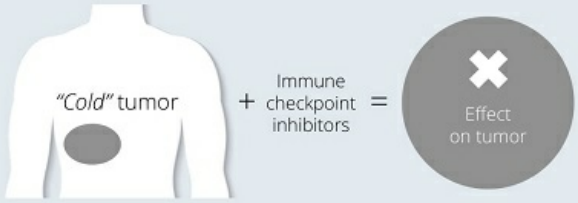


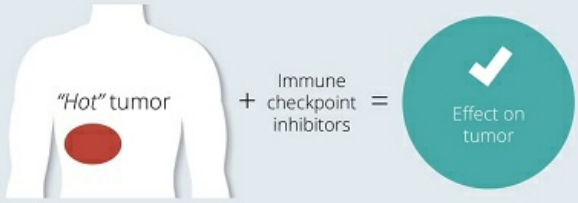
BiomX

In November 2020, BiomX announced the consolidation of its IBD and PSC programs to develop one broad host range product candidate for both indications, designated BX003.


Colorectal Cancer
Upcoming milestone: Proof of concept in animal models by 2H 2023
BiomX

Most colorectal cancer (CRC) patients do not respond to immunotherapy





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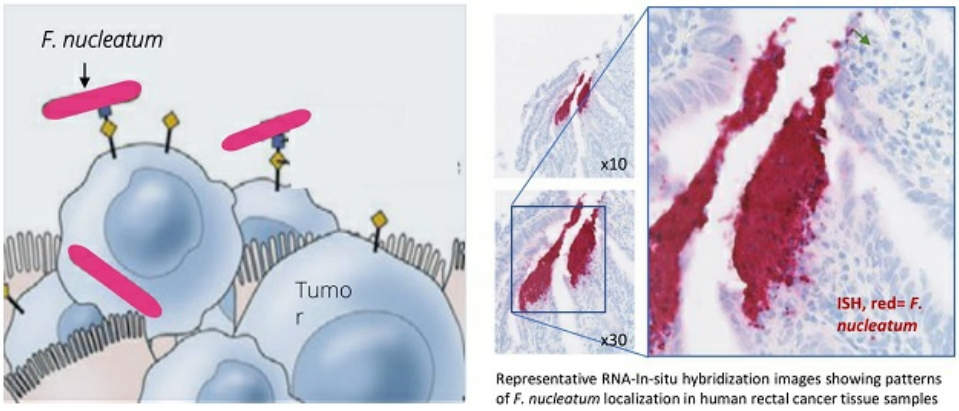
Sources: Vareki (2018), Journal for immunotherapy of Cancer; Galon et al. (2019), Nature Reviews/Drug Discovery

Bacteria residing inside tumors offer a novel targeted intervention to *"uncloak"* tumors to *"hot"*

Numerous observations of bacteria residing inside tumors



Representative RNA-In-situ hybridization images showing patterns of *F. nucleatum* localization in human rectal cancer tissue samples

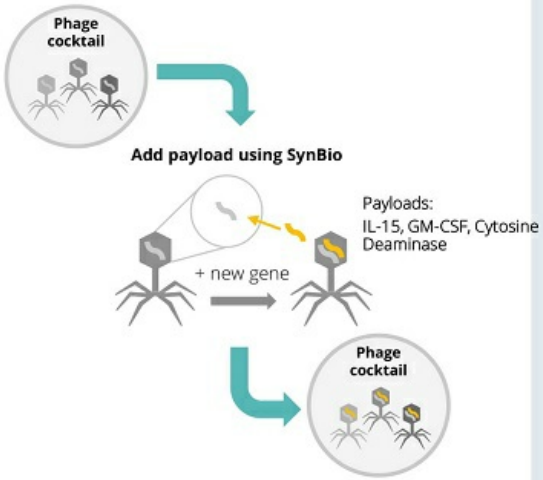
F. nucleatum is found in **over 80%** of colorectal cancer tumors (BiomX internal analysis and public data)

BiomX

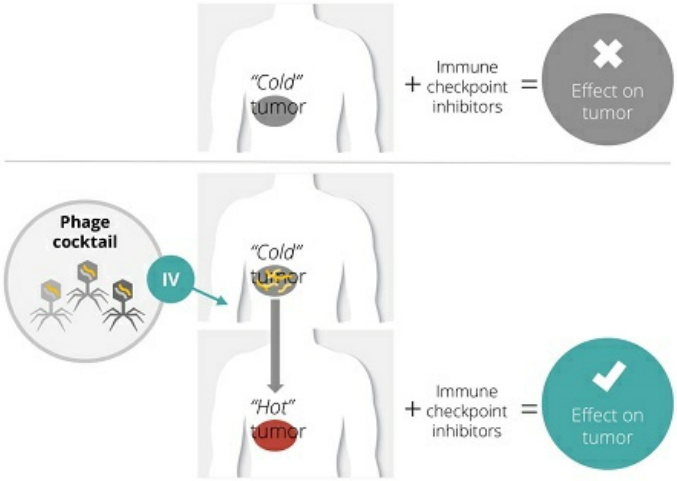
BiomX internal data
Li YY, Ge QX, Cao J, et al. (2016) World J Gastroenterol.
Bachrach et al. (2016), Cell Host & Microbe
Serna et al. (2020) Annals of Oncology
Kostic et al. (2013), Cell Host & Microbe

Engineered phage are designed to deliver payloads to bacteria in tumors

Phage are designed to carry payloads to intra-tumor bacteria



Phage cocktail with a payload turns cold tumors into hot



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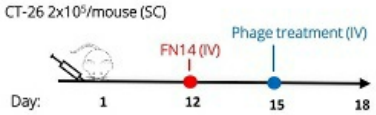
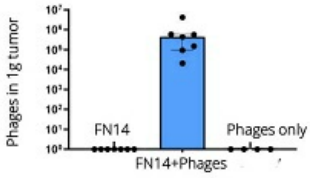
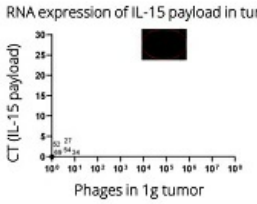
Key development milestones

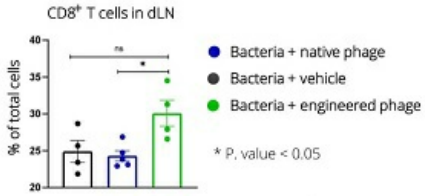
- IV delivery of phage to intra-tumor bacteria (*in-vivo*)





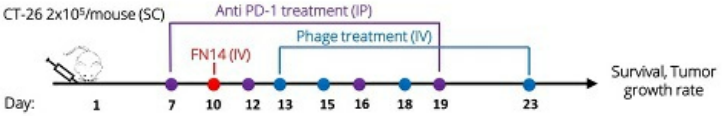
- IL-15–engineered phage treatment resulted in RNA expression of IL-15 payload in tumors and elevation of CD8+ cells in draining lymph nodes





H2 2023 — Impact of engineered phage + anti-PD1 in CRC mouse model

Engineered Payloads:
IL-15



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Source: Internal data


THANK YOU
BiomX