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): **May 24, 2021**

BiomX Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**0001-38762**	**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	**7414002**
(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, included as part of the Units	PHGE	NYSE American
Warrants included as part of the Units	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 May 24, 2021, BiomX Inc., or the Company, issued a press release announcing its financial results for the first quarter ended March 31, 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 May 24, 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 May 24, 2021

99.2 Investor Presentation dated May 24, 2021

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.

May 24, 2021

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

BiomX Reports First Quarter 2021 Financial Results and Provides Business Updates

- *Company announces completion of enrollment for Phase 2 cosmetic clinical study of BX001 for acne-prone skin with results from 8-week treatment period expected in Q3 2021*
- *BiomX continues to anticipate clinical trial readouts in up to 4 different therapeutic indications by mid-2022*
- *Company will host a conference call and webcast today at 8:00 am ET*

NESS ZIONA, Israel -- May 24, 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, today reported financial results and provided business updates for the first quarter ended March 31, 2021.

"We are off to a strong start in 2021 and are well-positioned to continue making solid progress throughout our entire pipeline of novel phage therapies with the potential to make a significant impact in the microbiome space. Within the next 14 months, we will have clinical readouts in four distinct indications and remain committed to advancing our phage therapies that have the potential to restore health to the microbiome and in turn, provide safe and effective treatments to patients in need," said Jonathon Solomon, Chief Executive Officer of BiomX. "In March, we initiated a Phase 2 cosmetic clinical study of BX001 for acne-prone skin and today we are announcing completion of enrollment for 140 patients with results at the 8- and 12-week treatment periods expected in the third and fourth quarters of 2021, respectively. Importantly, in the first quarter we also announced positive safety and tolerability results from the Phase 1a study of BX002 for Inflammatory Bowel Disease, which met its objective of delivering high concentrations of viable phage to the gastrointestinal tract. With these promising results in hand, we are advancing to a Phase 1b/2a study of BX003 for Inflammatory Bowel Disease and Primary Sclerosing Cholangitis to evaluate the reduction of target bacteria, *Klebsiella pneumoniae,* with data expected in the second quarter of 2022."

Mr. Solomon added, "Based on ongoing conversations and recommendations from the cystic fibrosis Therapeutic Development Network, we are modifying our Phase 2 trial design in cystic fibrosis to a Phase 1b/2a trial design comprised of two parts. Results from Part 1 and Part 2 are expected in the first and second quarters of 2022, respectively. We are pleased that Dr. David Nichols, M.D., an experienced cystic fibrosis clinical investigator and clinician, will be assisting us with this trial as the academic principal investigator through the Therapeutic Development Network."

RECENT HIGHLIGHTS AND KEY UPCOMING MILESTONES

Acne-Prone Skin (BX001)

- In March 2021, BiomX dosed the first subject in a Phase 2 cosmetic clinical study of BX001 and today announced completion of enrollment for this study. BX001 is a topical gel that includes a combination of naturally occurring phage that specifically target *Cutibacterium acnes*. The study will evaluate reduction in *Cutibacterium acnes* burden as well as improvement in the appearance of acne-prone skin in 140 subjects with mild-to-moderate acne vulgaris. The trial is a 12-week randomized, single center, double-blind, placebo-controlled study, and is on track for results to be reported following the 8- and 12-week treatment periods in the third and fourth quarters of 2021, respectively.

Inflammatory Bowel Disease ("IBD") and Primary Sclerosing Cholangitis ("PSC") (BX003)

- In February 2021, BiomX announced positive Phase 1a pharmacokinetic data of BX002 designed to target *Klebsiella pneumoniae*, a bacteria linked to the pathogenesis of IBD and PSC. The results showed that orally administered BX002 was safe, well-tolerated and met its key objective of delivering viable phage at high concentrations of approximately 10^{10} plaque forming units to the gastrointestinal tract as measured in all stool samples of treated subjects.
- Based on the promising results from the Phase 1a trial of BX002, BiomX plans to initiate a Phase 1b/2a study to evaluate the safety, tolerability, and efficacy of BX003 amongst 60 subjects. Results are expected in the second quarter of 2022. The goal of this study is to demonstrate reduction of target bacteria *Klebsiella pneumoniae,* as measured in stool of target bacteria carriers. BiomX previously consolidated its IBD and PSC programs to develop one product candidate, BX003, with a broad host range for both indications.
- BiomX is hosting a Key Opinion Leader ("KOL") webinar on May 26th at 8:00 am ET with a focus on BX003, the Company's microbiome-based therapeutic, for IBD. The event will feature KOL, Ryan Balfour Sartor, M.D., who will discuss the IBD treatment landscape as well as the unmet medical need for these patients. Dr. Sartor will be joined by BiomX management, who will provide updates on the BX003 program for IBD and PSC.

Cystic Fibrosis ("CF") (BX004)

- In March 2021, BiomX announced the selection of phage cocktail candidate, BX004, for chronic respiratory infections caused by *Pseudomonas aeruginosa,* a main contributor to morbidity and mortality in patients with CF.
- BiomX is updating its Phase 2 proof-of-concept study design and timelines to a Phase 1b/2a trial comprised of two parts in CF patients with chronic respiratory infections caused by *Pseudomonas aeruginosa.* Part 1 results are expected in the first quarter of 2022 and will evaluate the safety, pharmacokinetics and microbiologic/clinical activity of BX004 in eight CF patients in a single ascending dose and multiple ascending dose design. Part 2 of the Phase 1b/2a trial will evaluate the safety and efficacy of BX004 in 21 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 are expected by the second quarter of 2022.

Atopic Dermatitis (BX005)

- In March 2021, BiomX announced the selection of a phage cocktail candidate, BX005, aimed to target *Staphylococcus aureus*, a bacterium associated with the development and exacerbation of inflammation in patients with atopic dermatitis. When patients experience flares, this bacterium increases in abundance and becomes the dominant bacteria. By reducing *Staphylococcus aureus* burden, BX005 is designed to shift the skin microbiome composition to its "pre-flare" state to potentially result in clinical improvement.
- Results from a Phase 2 proof-of-concept trial evaluating the safety and efficacy of BX005 in atopic dermatitis patients are expected in the first half of 2022.

Colorectal Cancer

- BiomX is exploring phage-mediated delivery of therapeutic payloads for the treatment of colorectal cancer, such as immune-stimulating proteins, GM-CSF and IL-15, to target *Fusobacterium nucleatum* bacteria, which are present within a majority of colorectal tumors.

- BiomX is on track to report results from preclinical *in vivo* studies evaluating the use of phage therapy for colorectal cancer in combination with checkpoint inhibitors in the second and third quarters of 2021.

First Quarter 2021 Financial Results

- **Cash balance and short-term deposits** as of March 31, 2021, were $53.6 million, compared to $57.1 million as of December 31, 2020. The decrease was primarily due to net cash used in operating activities. Existing cash, cash equivalents and short-term deposits are expected to be sufficient to fund the Company's current operating plan and capital expenditure requirements until at least mid-2022.

- **Research and development (R&D) expenses, net** were $5.8 million for the three months ended March 31, 2021, compared to $3.5 million for the same period in 2020. The increase was primarily due to the growth in the number of employees, resulting in additional stock-based compensation, salaries and related expenses, and due to clinical activities and expenses related to conducting pre-clinical and clinical trials of our product candidates.

- **General and administrative expenses** were $2.5 million for the three months ended March 31, 2021, compared to $2.1 million for the same period in 2020. The increase was primarily due to an increase in stock-based compensation, salaries and related expenses and an increase in expenses associated with operating as a public company, such as directors' and officers' insurance.

- **Net loss** for the first quarter of 2021 was $8.4 million, compared to $5.9 million for the same period in 2020.

- **Net cash used in operating activities** for the first quarter of 2021 was $6.4 million, compared to $6.9 million 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 first quarter 2021 ended March 31, 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 Phage Therapy

Bacteriophage, or phage, are viruses that target bacteria and are considered inert to mammalian cells. Phage are designed to target and kill specific bacterial species or strains without disrupting other bacteria or the healthy microbiota. BiomX's phage-based product candidates derive from its proprietary BOLT ("BacteriOphage Lead to Treatment") R&D platform that enables the company to rapidly develop, manufacture and formulate rationally-designed phage combinations ("cocktails") of naturally-occurring or synthetic phage to target pathogenic bacteria. The phage cocktails contain multiple phage with complementary functions optimized through in vitro and in vivo testing.

About BiomX

BiomX is a clinical-stage microbiome company developing both natural and engineered phage cocktails designed to target and destroy bacteria that affect the appearance of skin, as well as target bacteria in the treatment of chronic diseases, such as inflammatory bowel disease, primary sclerosing cholangitis, cystic fibrosis, atopic dermatitis 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 potential markets opportunities, the capabilities of the BOLT platform, the design, aim, expected timing, and interim and final results of its preclinical and clinical trials and studies, the sufficiency of its existing cash, cash equivalents and short-term deposits, 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 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

	Three months ended March 31,	
	2021	**2020**
Research and development expenses, net	5,794	3,529

Amortization of intangible assets	379	379
General and administrative expenses	2,497	2,058
Operating loss	8,670	5,966
Finance income, net	(271)	(65)
Loss before taxes	8,399	5,901
Tax expenses	3	-
Net loss	8,402	5,901
Basic and diluted loss per share of Common Stock	0.35	0.26
Weighted average number of shares of Common Stock outstanding, basic and diluted	23,944,573	22,897,723

BIOMX INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

USD in thousands

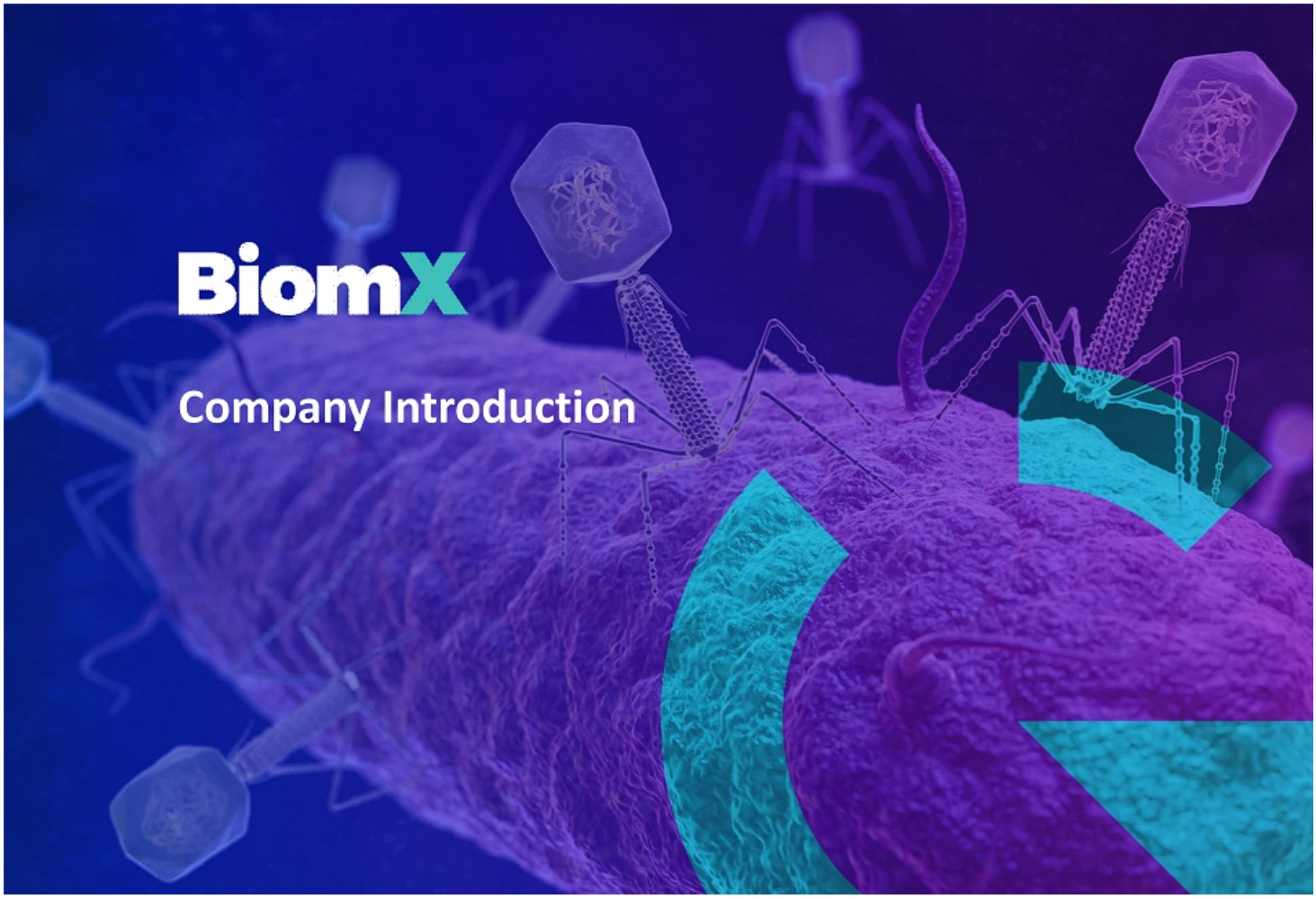
	As of March 31, 2021	As of December 31, 2020
Current assets		
Cash and cash equivalents	39,411	36,477
Restricted cash	976	763
Short-term deposits	13,205	19,851
Other current assets	2,943	3,576
Total current assets	56,535	60,667
Property and equipment, net	3,531	2,228
Intangible assets, net	2,658	3,038
Operating lease right-of-use assets	4,338	4,430
Total non-current assets	10,527	9,696
	67,062	70,363

	As of March 31, 2021	As of December 31, 2020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade account payables	2,685	2,320
Other account payables	4,350	3,978
Current portion of operating lease liabilities	763	863
Total current liabilities	7,798	7,161
Non-current liabilities		
Operating lease liabilities, net of current portion	4,738	5,032
Contingent considerations	572	701
Total non-current liabilities	5,310	5,733
Stockholders' equity		
Preferred stock, $0.0001 par value; Authorized – 1,000,000 shares as of March 31, 2021 and December 31, 2020. No shares issued and outstanding as of March 31, 2021 and December 31, 2020	-	-
Common stock, $0.0001 par value; Authorized -60,000,000 shares as of March 31, 2021 and December 31, 2020. Issued - 24,247,040 shares as of March 31, 2021 and 23,270,337 shares as of December 31, 2020. Outstanding - 24,241,340 shares as of March 31, 2021 and 23,264,637 shares as of December 31, 2020.	2	2
Additional paid in capital	134,612	129,725
Accumulated deficit	(80,660)	(72,258)
Total stockholders' equity	53,954	57,469
	67,062	70,363

Media:
Courtney Solberg, Solebury Trout
(917) 698-9253
csolberg@soleburytrout.com

Source: BiomX Inc.

Exhibit 99.2



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 ability to quickly generate clinical proof of concept in patients and the advantages of our BOLT platform, our leadership position in phage technology and timing of, among other things, clinical trials initiations, conclusion and receipt of results and meeting milestones relating to our development plan as well as commercialization plans, 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*

* 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

- Positive Phase 1 data for topical delivery of BX001 in subjects with acne prone skin
- Positive Phase 1a data of pharmacokinetic study for IBD/PSC[1] evaluating oral delivery
- **4 Phase 2 readouts expected by mid 2022[2]**

Partnerships

- Acne collaboration with leading global cosmetic company
- Biomarker discovery collaborations in IBD
  - Janssen (J&J)
  - Boehringer Ingelheim

janssen

Boehringer Ingelheim

Financing and investors

- Approximately $60M raised in 2 private rounds
- October 2019 public listing (**NYSE:PHGE**) and raising an additional $60M

OrbiMed

Takeda

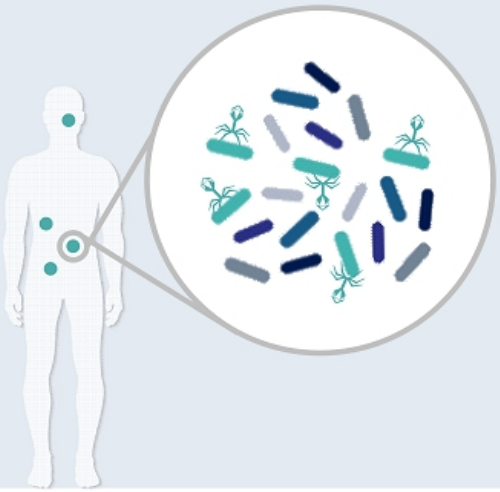
Johnson & Johnson

1. Inflammatory Bowel Disease (IBD), Primary Sclerosing Cholangitis (PSC)
2. Phase 2 results in acne, Phase 1b/2a results in cystic fibrosis, Phase 2 results in atopic dermatitis, Phase 1b/2a results in IBD/PSC

BiomX

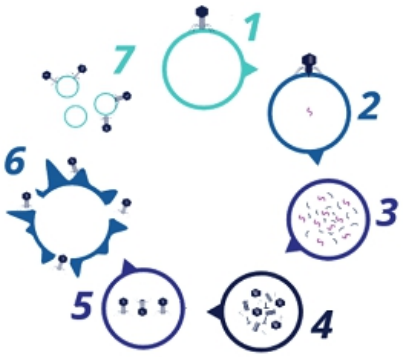
Phage: Nature's precision tool to target bacteria

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



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

BiomX

Multiple potential applications of phage therapy

Immune mediated

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

Infectious diseases

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

Oncology

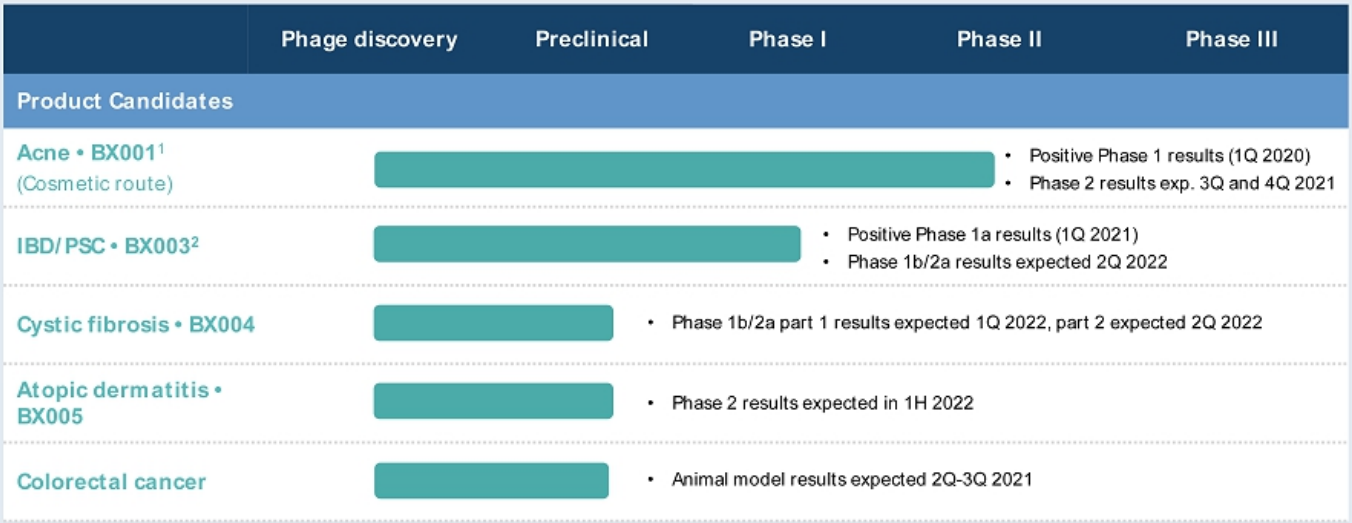
- **Colorectal Cancer** – *F. nucleatum*
- **Gastric Cancer** – *H. pylori*

Other

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

BiomX

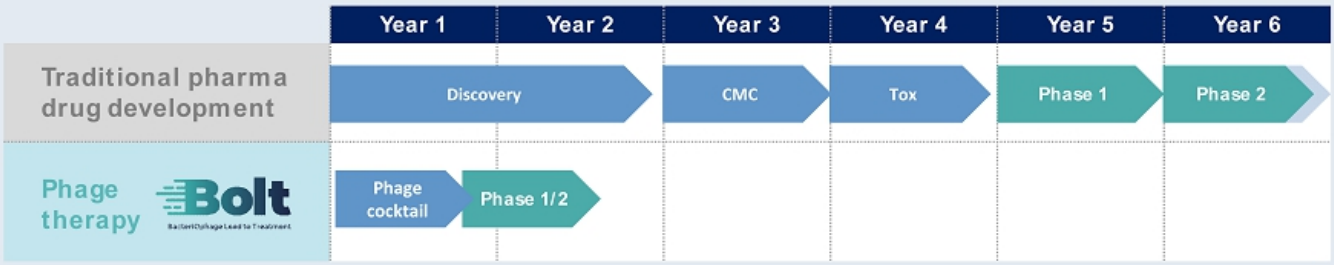
Pipeline

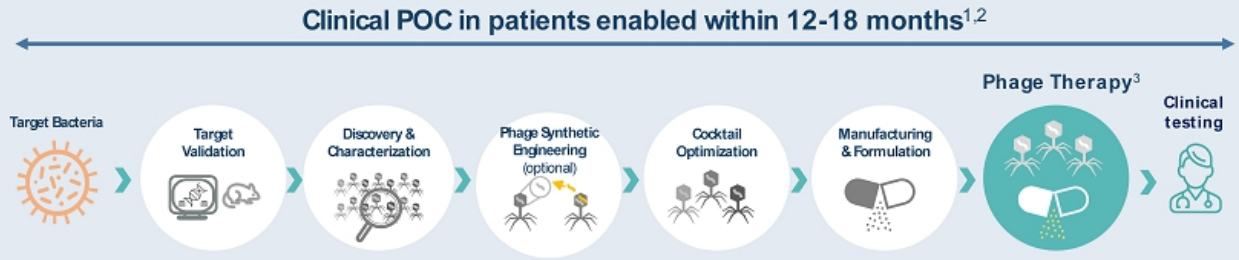


(1) *BX001 is intended to be developed and commercialized as a cosmetic*
(2) In November 2020, BiomX announced the consolidation of its IBD and PSC programs to develop one broad host range product candidate for both IBD and PSC, designated BX003 (replacing a previous phage product candidate for IBD named BX002)

BiomX

Our Bolt platform allows clinical POC within 12-18 months





BiomX

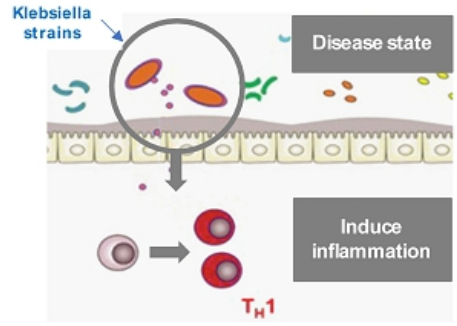
1). Strong safety profile of naturally occurring phage supported by regulatory feedback allows proceeding to Phase 2 studies without preclinical safety studies or Phase 1 studies in healthy volunteers.
2). In certain indications the length of clinical validation may be longer depending on indication, 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


Inflammatory Bowel Disease (IBD), Primary Sclerosing Cholangitis (PSC)
Upcoming milestone: Phase 1b/2a data expected in 2Q 2022
BiomX

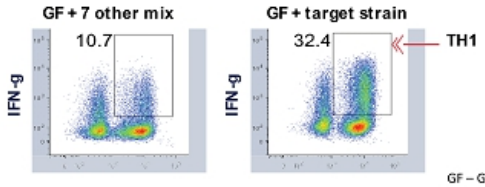
IBD • Identifying potential disease causing pro-inflammatory *Klebsiella* strains

Science

Pro-inflammatory *Klebsiella* strains affect IBD pathology

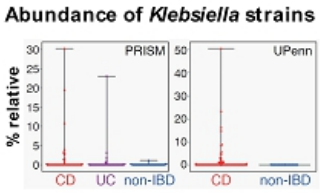


Inflammatory induction is seen in GF mice*



GF – Germ Free

Higher abundance of *Klebsiella* strains in IBD patients



CD – Crohn's disease
UC – Ulcerative colitis

Activity of bacterial target confirmed by 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*

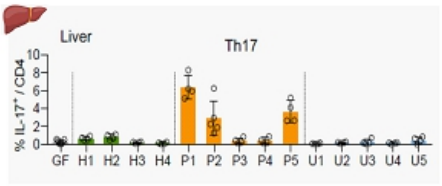
BiomX

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

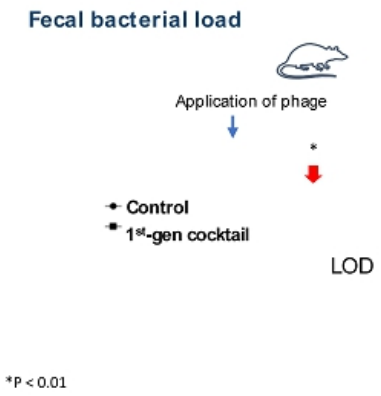
Klebsiella pneumoniae (KP) is a specific gut pathobiont of PSC that is an intestinal barrier disrupter and is pro-inflammatory ("*leaky gut*")

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

BiomX

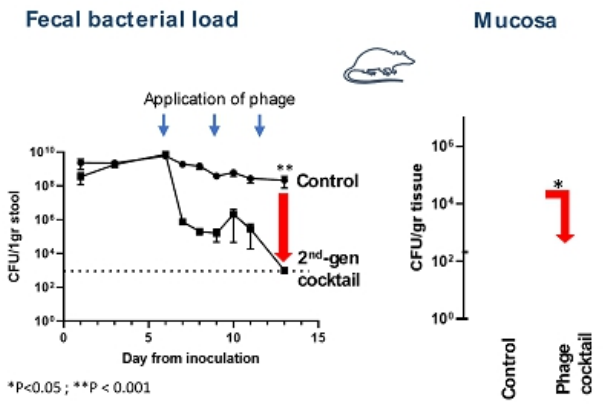
Phage cocktail composition drives activity

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

Source: Internal data

BiomX

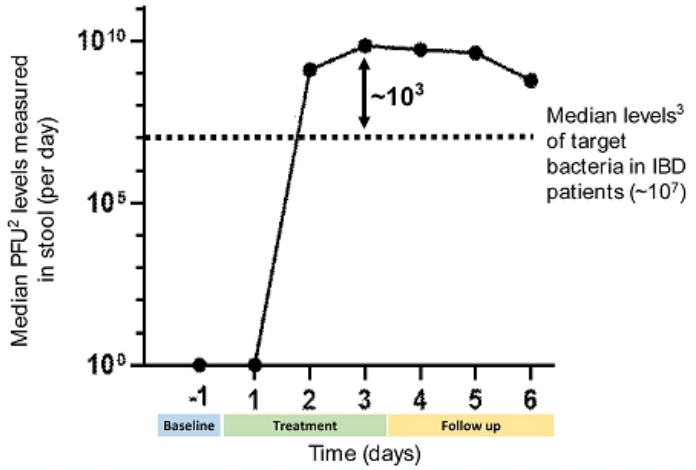
BX002: Phase 1a pharmacokinetic results demonstrate delivery of high levels of viable phage to the gut[1]

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

(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.

BiomX

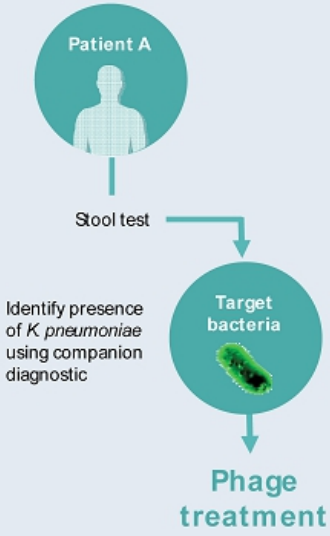
Phase 1b/2a study results expected in 2Q 2022

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 2Q 2022

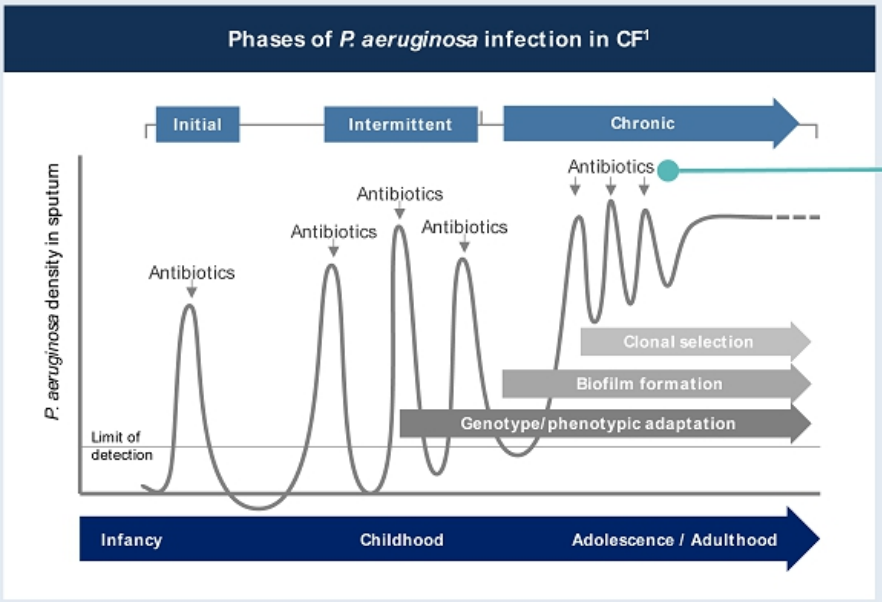


In November 2020, BiomX announced the consolidation of its IBD and PSC programs to develop one broad host range product candidate for both indications, designated BX003.

BiomX


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

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

BiomX

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 noted ($10^7 \rightarrow 10^4$ 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%

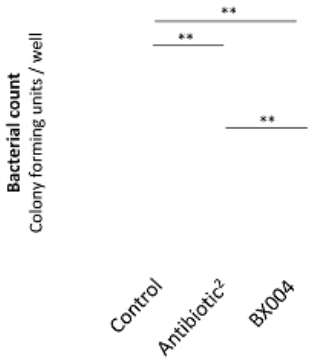
Results demonstrate the potential of phage therapy to decrease bacterial burden and improve FEV1

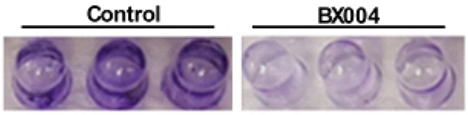
BiomX

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

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 in 1Q 2022

Phase 1b/2a – Part 1

Objectives
- Safety, PK and microbiologic/clinical activity

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

Study Population
- CF patients with chronic *P. aeruginosa* infection

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

Key Design Features
- Single ascending dose followed by multiple doses

Data expected 1Q 2022

Phase 1b/2a – Part 2

Objectives
- Safety and efficacy

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

Study Population
- CF patients with chronic *P. aeruginosa* infection

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

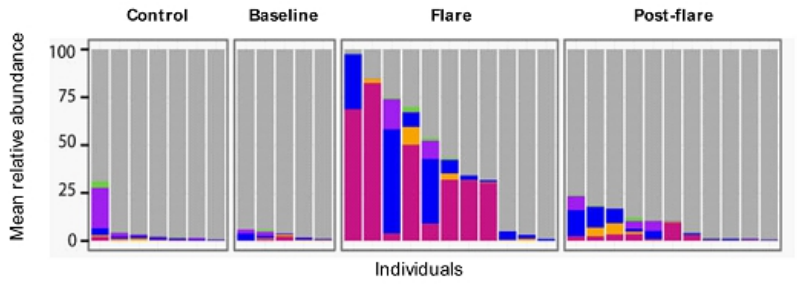
Data expected 2Q 2022

BiomX


Atopic Dermatitis
Upcoming milestone: Phase 2 data expected in 1H 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

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

BiomX

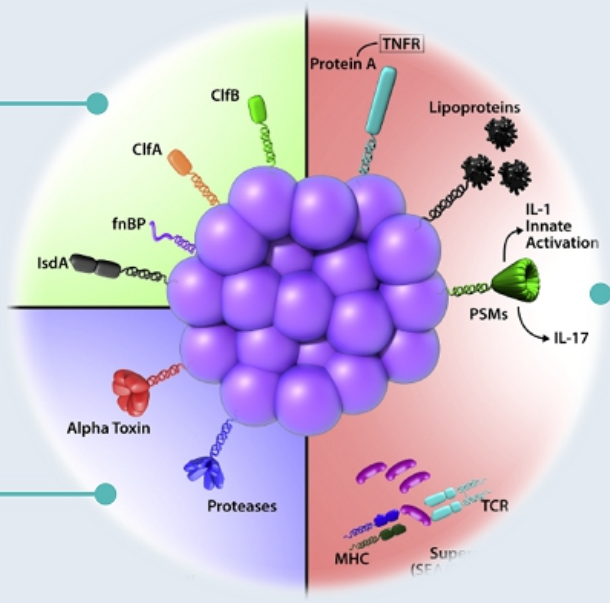
S. aureus contributed to pathogenicity through multiple virulence factors

Adhesion

S. aureus has developed several surface molecules to adhere to the human stratum corneum

Barrier disfunction

Alpha-toxin forms pores in keratinocytes and proteases facilitate dissolution of the stratum corneum.



Proinflammatory mechanisms

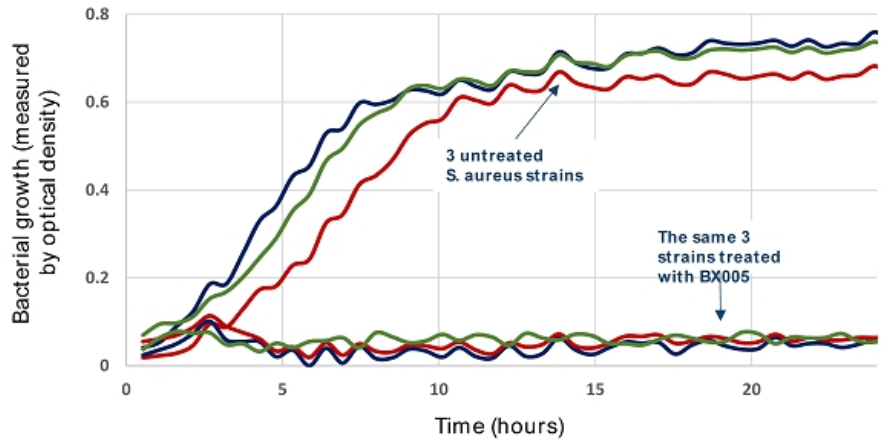
Such as, protein A and superantigens (enterotoxins) which trigger inflammatory responses and cytokine release

Kong, H.H. et al, (2012). Genome research. Byrd, A.L. et al, (2017) Science translational medicine

BiomX

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]

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

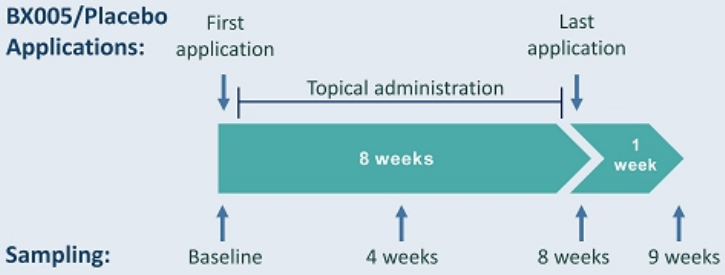
BiomX

Phase 2 study results targeting *S. aureus* expected in 1H 2022

Study design

- **Objectives**
  - Safety, efficacy and pharmacodynamics
- **Endpoints**
  - Safety and tolerability
  - Decrease in target bacteria
  - Clinical improvement (e.g. change in EASI/IGA scores)
- **Study Population**
  - Atopic dermatitis patients
  - *S. aureus* colonized
- **80 subjects**
  - BX005 or placebo (vehicle) administered topically
  - 8-week duration of treatment

Data expected 1H 2022



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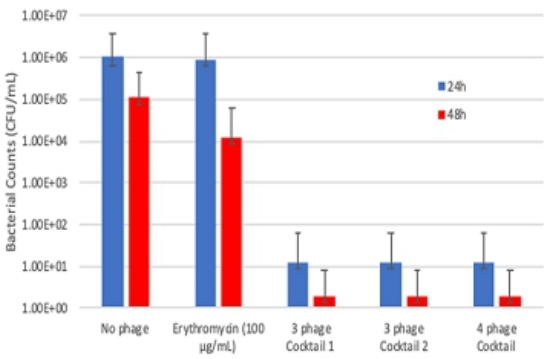
Acne
Upcoming milestone: Phase 2 data expected in 3Q and 4Q 2021
(cosmetic study)
BiomX

BX001: Phage cocktail attributes

BX001
A topical gel containing natural phage against *C. acnes* to modulate skin microbiome

- Active against antibiotic-resistant strains*
- Penetrates biofilm*

Phage cocktails penetrate biofilm (*in vitro*)



* *Source: Internal data, in vitro results*

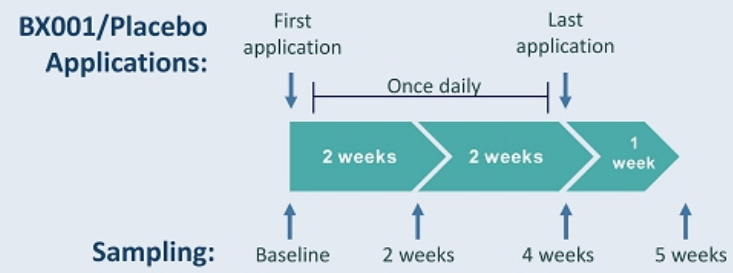
BiomX

BX001: Phase 1 clinical trial design

Phase 1 – Completed

4-week study (placebo-controlled)

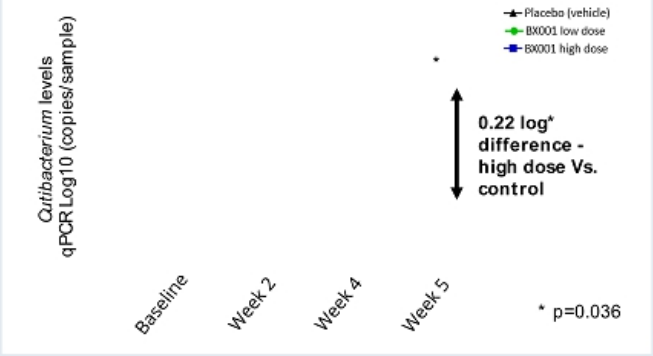
- **Primary endpoint**
  - Safety & Tolerability
- **Exploratory endpoints**
  - Reduction of *C. acnes* (efficacy)
  - Skin microbiome evaluation
- **75 subjects**
  - 2 doses (high and low dose) + placebo (vehicle)
  - 25 subjects per cohort



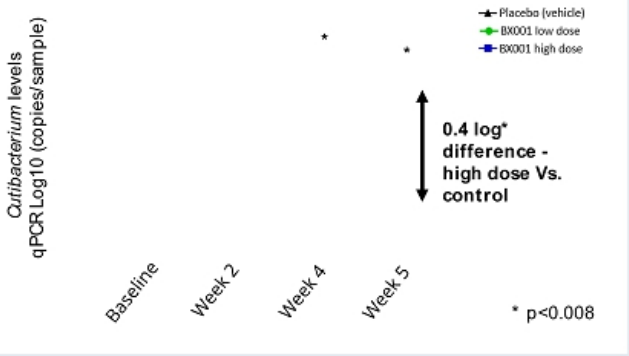
BiomX

BX001: Phase 1 results demonstrate statistically significant reduction in *C. acnes* levels

Change in level of *Cutibacterium*[1] – *All subjects*



Change in level of *Cutibacterium*[1] – *High sebum subgroup*[2]



- Both high and low doses demonstrated excellent safety and tolerability
- Findings on the high sebum subgroup support enrichment of study population in the Phase 2 study

(1) Measured by qPCR Cutibacterium acnes (or C. acnes) comprised over 98% of Cutibacterium spp.
(2) Subjects were divided into high and low sebum level groups based on median level of sebum at baseline (133 µg/cm2)

BiomX

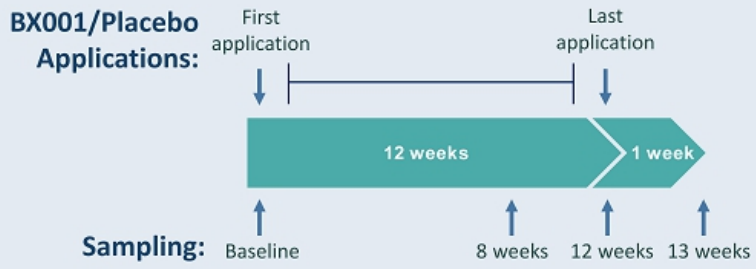
BX001 phase 2 cosmetic study results expected in 2H 2021

Phase 2 Study Design

12-week application, Placebo-controlled

- **Objectives**
  - Safety and efficacy
- **Endpoints**
  - Safety and tolerability
  - Reduction of *C. acnes* (efficacy)
  - Skin microbiome evaluation
  - IGA and lesion numbers (efficacy)
- **140 subjects**
  - Phage or placebo (vehicle)
  - 70 subjects per cohort

- 8-week data expected 3Q 2021
- 12-week data expected 4Q 2021



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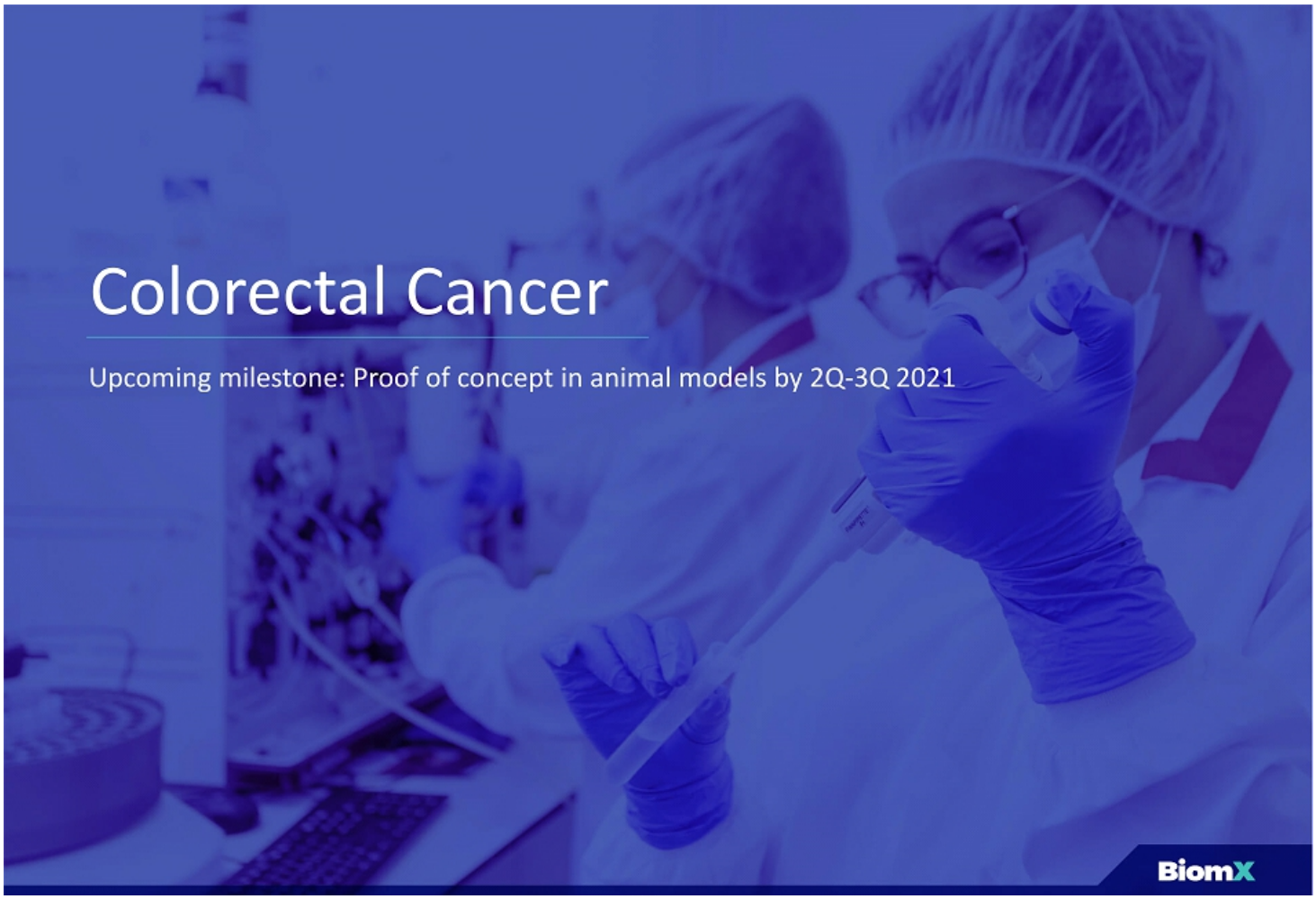
Colorectal Cancer
Upcoming milestone: Proof of concept in animal models by 2Q-3Q 2021
BiomX

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

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

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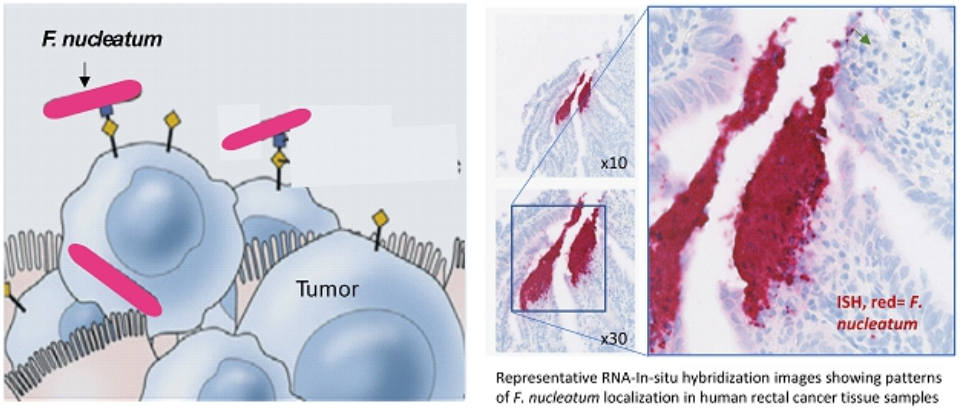
Bacteria residing inside tumors offer a novel targeted intervention to *"uncloak" t*umors to *"hot"*

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

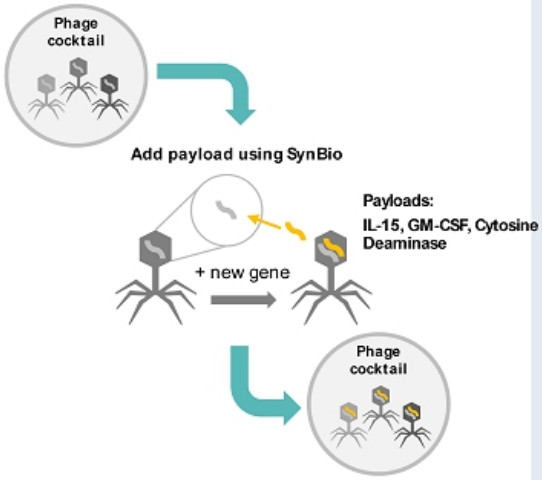
F. nucleatum is found in **over 80%** of colorectal cancer tumors (BiomX internal analysis and public data)

BiomX

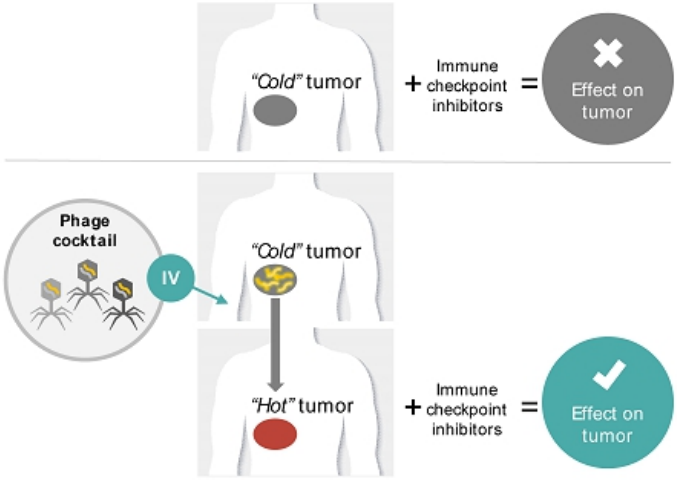
BiomX internal data
Li YY, Ge QX, Cao J et al. (2016) World J Gastroenterol.
Bachrach et al. (2016). Cell Host & Microbe
Serna et al. (2020) Annals of Oncology
Kostic et al. (2013). Cell Host & Microbe

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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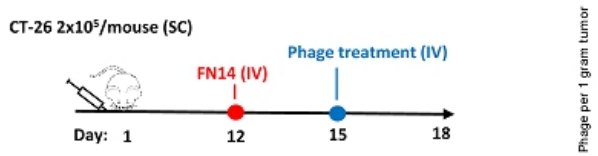
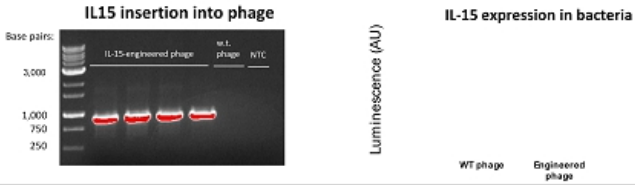
Key development milestones

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



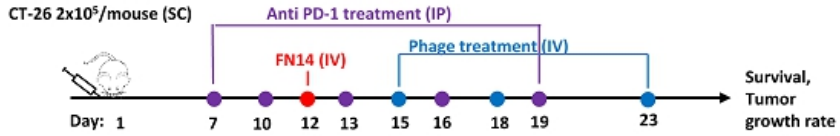
IL-15 payload engineered into F. nucleatum phage (*in-vitro*)



Planned 2Q-3Q 2021

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

Engineered Payloads:
IL-15, GM-CSF, Cytosine Deaminase



Source: Internal data

BiomX

Key Catalysts: 4 Phase 2 readouts by mid 2022[1]

	1H20	2H20	1H21	2H21	1H22	2H22
Acne[2]	**Phase 1 Results**	Mfg.	Phase 2 initiation	**Phase 2 results**	Pre-commercial	Pre-commercial
IBD/PSC[3]	CMC	Phase 1a initiation	**Phase 1a results**	Mfg.	**Phase 1b/2a results**	Mfg.
CF	—	Phage discovery	Cocktail optimization	Phase 1b/2a initiation	**Phase 1b/2a results**	Mfg
Atopic Dermatitis	—	Phage discovery	Cocktail optimization	Mfg	**Phase 2 results**	Mfg.
CRC	Phage engineering	Initiate in vivo studies	**In vivo results**	**In vivo results**	Cocktail optimization	Mfg

Cash, cash equivalents and short-term deposits as of March 31st , 2021 were $53.6M million

BiomX

1. Phase 2 results in acne, Phase 1b/2a results in cystic fibrosis, Phase 2 results in atopic dermatitis, Phase 1b/2a results in IBD/PSC
2. *Our acne product is developed under a cosmetic regulatory path and we currently do not anticipate any additional clinical trials beyond the Phase 2 study.*
3. *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.*

Experienced leadership team

Management Team

Jonathan Solomon
CEO and Board Member

Former co-founder, president, and CEO of ProClara for treating neurodegenerative diseases; raised >$100M. Harvard Business School grad. Service in an elite IDF unit

Sailaja Puttagunta, MD
CMO

Infectious disease physician (Yale graduate), Developed several antibiotics through all clinical development stages under Allergan, Pfizer, Durata and other biotechs

Merav Bassan, PhD
CDO

Over 20 years of early and clinical drug development experience at Teva Pharmaceuticals and small biotechs. Most recently served as VP of translational sciences at Teva

Assaf Oron
CBO

Former CBO of Evogene, an agricultural biotechnology company; raised $85M in NYSE listing. Executed transactions with turnover of >$100M with global seed companies

Marina Wolfson, CPA
SVP Finance & Operations

Most recently principle financial officer of Bioview (TASE:BIOV). Former senior auditor at E&Y working with large pharmaceutical and hi-tech companies, VCs and start-ups

Inbal Benjamini-Elran
VP Human Resource

15 years experience in executive HR roles globally. Former head of HR at Herzog law firm and HR director at Teva Europe (NYSE:TEVA)

Scientific Founders

Prof. Rotem Sorek
מכון ויצמן למדע
WEIZMANN INSTITUTE OF SCIENCE

Prof. Eran Elinav
מכון ויצמן למדע
WEIZMANN INSTITUTE OF SCIENCE

Prof. Timothy K. Lu
MIT BE
BIOLOGICAL ENGINEERING

BiomX

Experienced leadership team

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BiomX · Proclara


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