

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): **March 31, 2021**

**BiomX Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**0001-38762**

(Commission File Number)

**82-3364020**

(I.R.S. Employer  
Identification No.)

**7 Pinhas Sapir St., Floor 2  
Ness Ziona, Israel**

(Address of Principal Executive Offices)

**7414002**

(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 March 31, 2021, BiomX Inc., or the Company, issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2020. 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 March 31, 2021, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at [www.biomx.com](http://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 March 31, 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.

March 31, 2021

**BIOMX INC.**By: /s/ Jonathan Solomon

Name: Jonathan Solomon

Title: Chief Executive Officer

---

## BiomX Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update

- Initiated Phase 2 cosmetic clinical study for BX001 in subjects with acne-prone skin; results expected from 8-week treatment period in Q3 2021
- Results from Phase 2 proof-of-concept clinical study of newly selected phage cocktail candidate, BX004, in cystic fibrosis expected to readout in Q4 2021
- Phase 2 proof-of-concept clinical study of newly selected phage cocktail candidate, BX005, in atopic dermatitis expected to initiate in second half of 2021
- Company will host a conference call and webcast today at 8:00 am ET

**Ness Ziona, Israel -- March 31, 2021** -- BiomX Inc. (NYSE American: PHGE) (“BiomX” or the “Company”), acinical-stage microbiome company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the fourth quarter and full year ended December 31, 2020.

“2020 was a tremendous year of growth for BiomX, as we expanded our pipeline with programs in cystic fibrosis and atopic dermatitis, both designed to address unmet medical needs,” said Jonathan Solomon, Chief Executive Officer of BiomX. “Fueled by the rapid development capabilities of our novel BOLT platform, we are excited to announce today that we have selected two new phage cocktail candidates, BX004 and BX005, for cystic fibrosis and atopic dermatitis, respectively.”

Mr. Solomon added, “2021 is poised to be a year of multiple potential value inflection points for BiomX, due to anticipated efficacy data readouts from two Phase 2 clinical studies, BX001 in subjects with mild-to-moderate acne and BX004 in subjects with cystic fibrosis. Due to the historic safety of phage therapies and the cutting-edge capabilities of our BOLT platform, we are accelerating toward additional efficacy readouts by mid-2022 for our inflammatory bowel disease and atopic dermatitis programs, which are large market opportunities. We believe phage could play a substantial role in the growing field of microbiome therapies.”

### RECENT HIGHLIGHTS AND KEY UPCOMING MILESTONES

#### Acne-Prone Skin

- Earlier this month, BiomX announced the dosing of the first subject in a Phase 2 cosmetic clinical study of BX001 in subjects with mild-to-moderate acne over the course of 12 weeks, a longer duration than the Phase 1 study. Results from 8-week and 12-week timepoints are expected in the third and fourth quarter of 2021, respectively.
- In March 2020, BiomX reported positive data from the Phase 1 cosmetic clinical study of BX001 in subjects with acne-prone skin, where BX001 was shown to be safe and tolerable, as well as demonstrated a statistically significant reduction of *Cutibacterium acnes* levels with the high dose compared to placebo.

#### Inflammatory Bowel Disease (“IBD”) and Primary Sclerosing Cholangitis (“PSC”)

- In February 2021, BiomX announced positive results from a first-in-human Phase 1a pharmacokinetic study of BX002 in the IBD/PSC program, the first ever clinical study detailing pharmacokinetics of an oral phage therapy under a U.S. Food and Drug Administration (“FDA”) IND approved protocol. BX002 demonstrated safety and tolerability with successful delivery of a high concentration of viable phage to the lower gastrointestinal tract, specifically at levels approximately 1,000 times the bacterial burden of the target bacteria, *Klebsiella pneumoniae*, in IBD and PSC patients as measured in stool.
- Based on the Phase 1a study results, BiomX plans to initiate a Phase 1b/2a study with results expected by mid-2022. The Phase 1b/2a study will evaluate the efficacy of BX003 in reducing the intestinal bacterial burden of *Klebsiella pneumoniae* in target bacteria carriers. In November 2020, the Company consolidated its IBD and PSC programs into one product candidate, BX003, with a broad host range for both indications.

#### Cystic Fibrosis (“CF”)

- The Company today announced the selection of the phage cocktail candidate, BX004, for subjects with CF, specifically for the treatment of chronic lung infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with this and other underlying conditions. In preclinical *in vitro* studies, BX004 was shown to be active against antibiotic resistant strains of *Pseudomonas aeruginosa* and demonstrated the ability to penetrate biofilm, an assemblage of surface-associated microbial cells enclosed in an extracellular polymeric substance and one of the leading causes for antibiotic resistance.
- Phase 2 results of a proof-of-concept clinical study evaluating the safety and efficacy of BX004 in CF patients are expected in the fourth quarter of 2021.

#### Atopic Dermatitis

- The Company today announced the selection of the phage cocktail candidate, BX005, for subjects with atopic dermatitis, specifically to target *Staphylococcus aureus*, a bacterium linked to the development and exacerbation of inflammation in atopic dermatitis. In preclinical *in vitro* studies, BX005 was shown to be active against over 90% of strains from a panel of *Staphylococcus aureus*, including antibiotic resistant strains, isolated from the skin of subjects in the U.S. and Europe.
- BiomX expects to initiate a Phase 2 proof-of-concept clinical study evaluating the safety and efficacy of BX005 in atopic dermatitis patients in the second half of 2021, with results 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 is present within colorectal tumors. In December 2020, BiomX presented preclinical results confirming the presence of *Fusobacterium nucleatum* in 80% of tumor samples collected from patients with colorectal cancer, at the European Society of Medical Oncology (“ESMO”) Immunology Virtual Congress. The Company has also successfully engineered an IL-15 gene payload into *Fusobacterium nucleatum* phage.

- BiomX previously disclosed data from preclinical models demonstrating that intravenously administered phage has the ability to target bacteria inside colorectal cancer tumors.

- Preclinical results from animal studies evaluating use of phage therapy in combination with checkpoint inhibitors are expected in the second and third quarters of 2021.

#### Corporate and Business Highlights

- In September 2020, BiomX entered into a collaboration with Boehringer Ingelheim to utilize BiomX's XMarker, a microbiome-based discovery platform to potentially identify biomarkers associated with patient phenotypes in IBD.
- In October 2020, BiomX announced the appointment of Paul Sekhri and Alan Moses, M.D., to its Board of Directors.

#### Fourth Quarter and Full Year 2020 Financial Results

- **Cash balance and short-term deposits** as of December 31, 2020, were \$57.1 million, compared to \$82.4 million as of December 31, 2019. 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 through mid-2022.
- **Research and development (R&D) expenses, net** were \$6.5 million for the three months ended December 31, 2020, compared to \$5 million for the same period in 2019. R&D expenses, net were \$21 million for the year ended December 31, 2020, compared to \$13.5 million for the prior year. The full year increase was primarily due to the growth in number of employees, resulting in additional stock-based compensation, salaries and related expenses, and due to manufacturing of candidate products for clinical trials in acne-prone skin and IBD/PSC.
- **General and administrative (G&A) expenses** were \$2.6 million for the three months ended December 31, 2020, compared to \$4.7 million for the same period in 2019. G&A expenses were \$9.3 million for the year ended December 31, 2020, compared to \$8.7 million for the prior year. In the fourth quarter of 2019 the expenses included merger-related costs. The full year increase was primarily due to expenses associated with operating as a public company, such as directors' and officers' insurance, filing and legal and accounting expenses.
- **Net loss** for the fourth quarter of 2020 was \$9.1 million, compared to \$9.3 million for the same period in 2019. For the full year 2020 net loss was \$30.1 million, compared to \$20.6 million for the prior year.
- **Net cash used in operating activities** for the full year 2020 was \$24.4 million, compared to \$17.6 million in 2019.

3

#### 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 corporate updates for the fourth quarter and year ended December 31, 2020. 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](http://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](http://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 Current Report on Form 8-K filed with the Securities and Exchange Commission (the "SEC") on December 4, 2020 and additional disclosures BiomX makes in its filings with the Securities and Exchange Commission (the "SEC"), which are available on the SEC's website at [www.sec.gov](http://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.

#### Media Contact:

Courtney Solberg, Solebury Trout  
(917) 698-8253  
[csolberg@soleburytrout.com](mailto:csolberg@soleburytrout.com)

Source: BiomX Inc.

The logo for BiomX, with 'Biom' in white and 'X' in a vibrant blue.

Company Introduction

A detailed 3D rendering of a bacteriophage, showing its hexagonal head, tail sheath, and tail fibers. The phage is positioned on a textured, spherical surface. The background is a gradient of blue and purple, with other faint phage structures visible. Two large, semi-transparent blue shapes are overlaid on the right side of the image.

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 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](http://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 – Currently can support annually over 50 different phage at a clinical grade



## Pipeline

- Programs\* – acne, IBD/PSC, CF, atopic dermatitis, colorectal cancer
- 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 evaluating oral delivery



## Partnerships

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



## Financing and investors

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



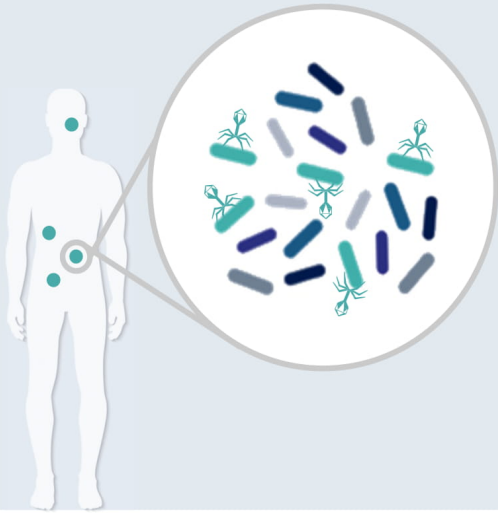
\* Inflammatory Bowel Disease (IBD) , Primary Sclerosing Cholangitis (PSC), Cystic Fibrosis (CF)





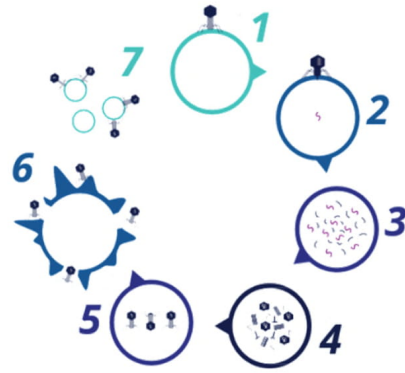
# Phage: Nature's precision tool to target bacteria

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

# Multiple potential applications of phage therapy

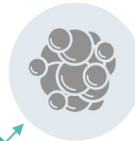
## Immune mediated

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



## Oncology

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



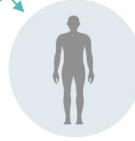
## Infectious diseases

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



## Other

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



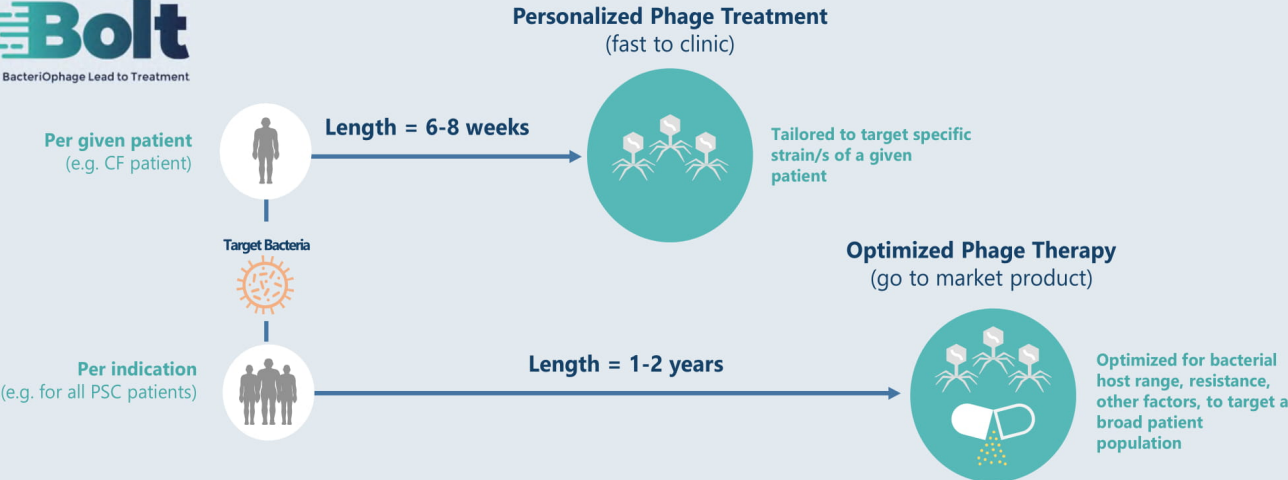
# Pipeline

	Phage discovery	Preclinical	Phase I	Phase II	Phase III
<b>Product Candidates</b>					
<b>Acne • BX001<sup>1</sup></b> (Cosmetic route)				<ul style="list-style-type: none"> <li>• Positive Phase 1 results (1Q 2020)</li> <li>• Phase 2 results exp. 3Q and 4Q 2021</li> </ul>	
<b>IBD/PSC • BX003<sup>2</sup></b>				<ul style="list-style-type: none"> <li>• Positive Phase 1a results (1Q 2021)</li> <li>• Phase 1b/2a results expected 2Q 2022</li> </ul>	
<b>Cystic fibrosis • BX004</b>				<ul style="list-style-type: none"> <li>• Phase 2 results expected 4Q 2021</li> </ul>	
<b>Atopic dermatitis • BX005</b>				<ul style="list-style-type: none"> <li>• Phase 2 results expected in 1H 2022</li> </ul>	
<b>Colorectal cancer</b>				<ul style="list-style-type: none"> <li>• Animal model results expected 2Q-3Q 2021</li> </ul>	

(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)



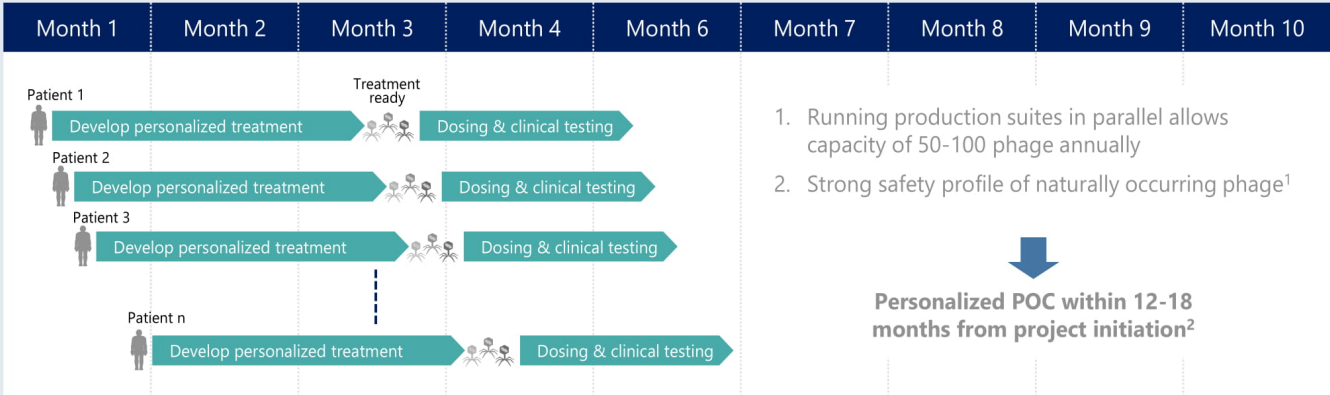
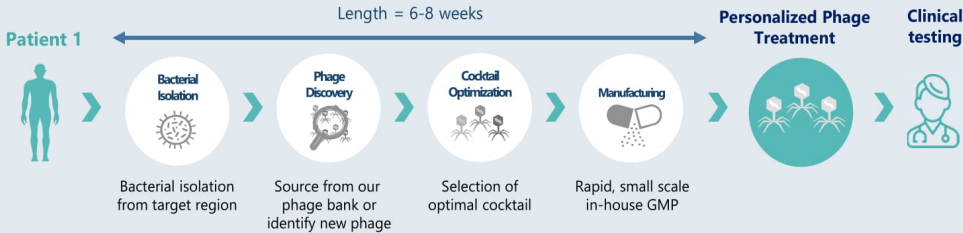
# Two development paths enabled by the Bolt phage discovery platform



The personalized path enables rapid launch of a clinical POC, while the longer path delivers a final go to market product



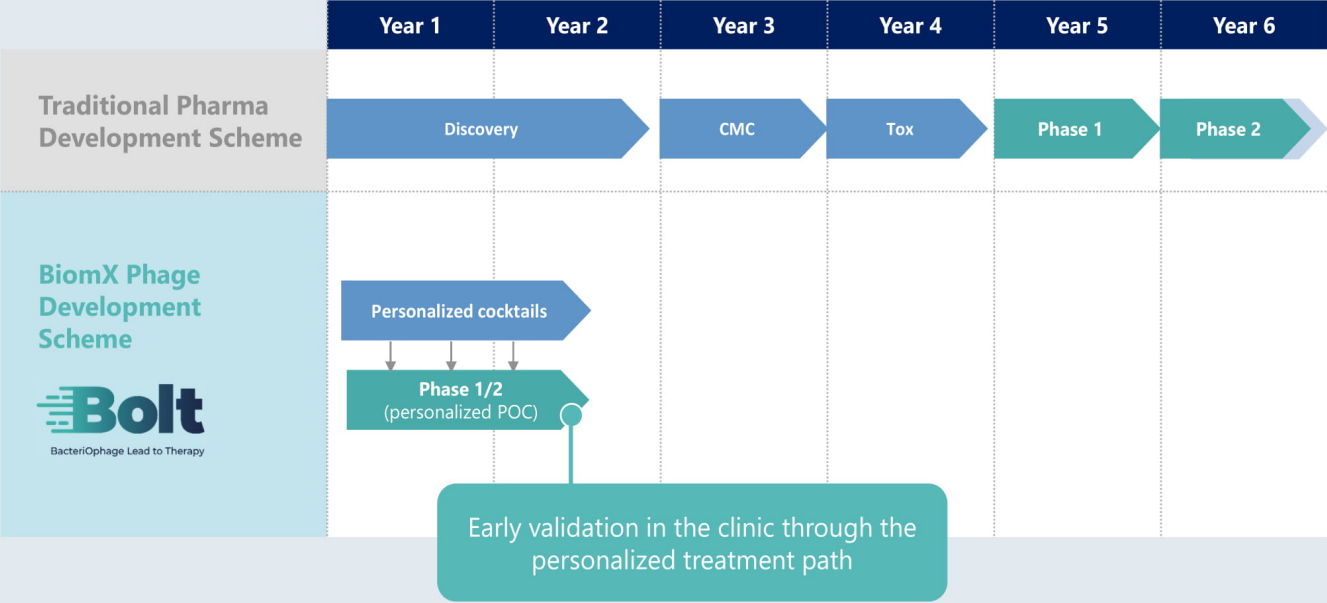
# The personalized phage treatment enables a rapid clinical POC



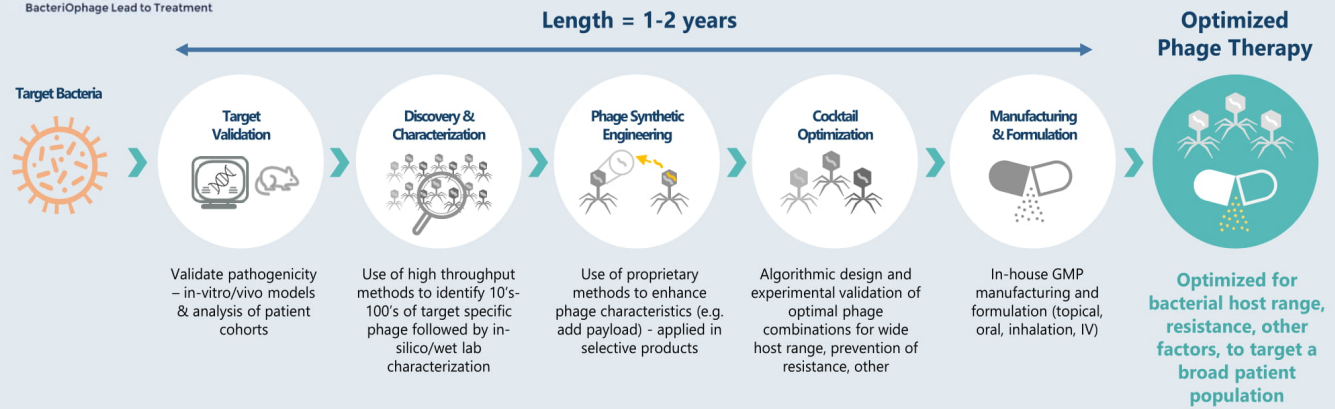
1). Strong safety profile of naturally occurring phage, as evident by the regulatory feedback provided to us in our IBD program allowing us to skip preclinical safety studies and healthy volunteers and go straight to patients.  
 2). In certain indications the length of clinical validation may be longer depending on indication, identity of target bacteria, recruitment rate, cohort size and other factors.



# Personalized POC enabled within 12-18 months



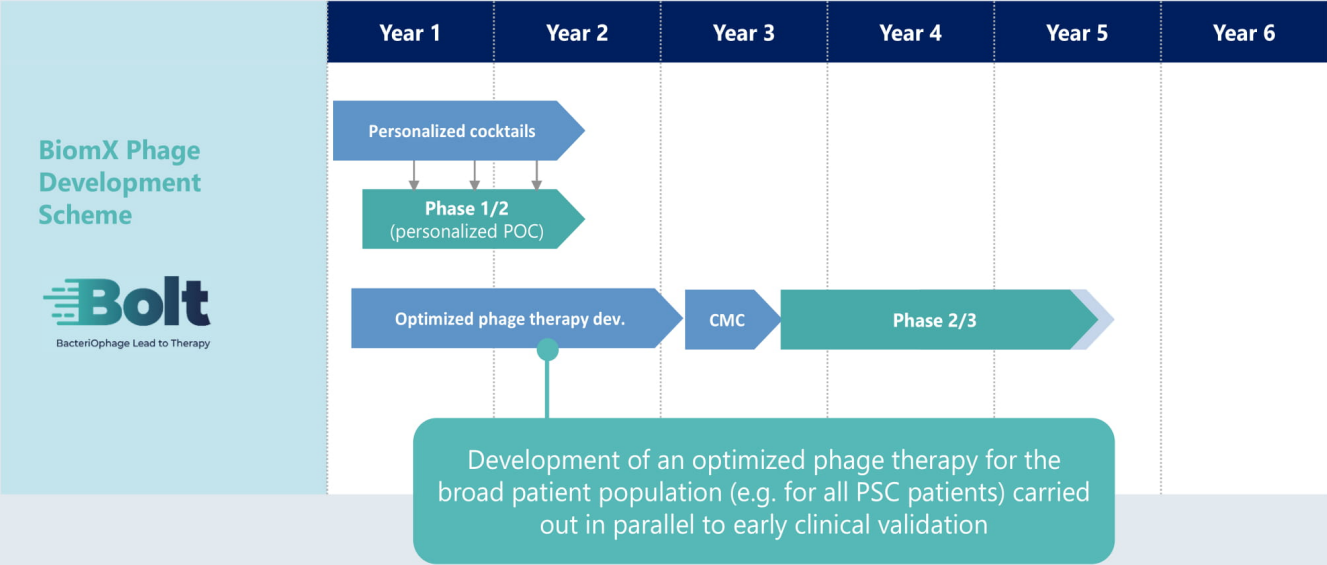
# Proprietary methods and capabilities to optimize phage therapy



Our clinically validated platform deploys high resolution computational tools, novel synthetic biology methods and flexible manufacturing and formulation capabilities



# Seamless transition from personalized POC to a phase 2/3





# Acne

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

**BiomX**

## BX001: Phage cocktail attributes

---

- Active against 96% of tested *C. acnes* clinical strains (*in-vitro*)
- Active against antibiotic-resistant strains (*in-vitro*)
- Self-amplifying: 50-100 phage per bacteria killed
- Penetrates biofilm (in contrast to antibiotic erythromycin)
- Highly specific: Does not affect other skin microbiome bacteria
- Proprietary gel formulation

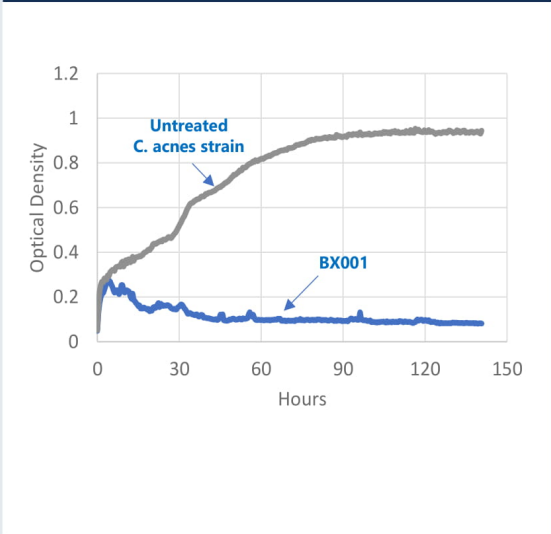


Source: Internal data

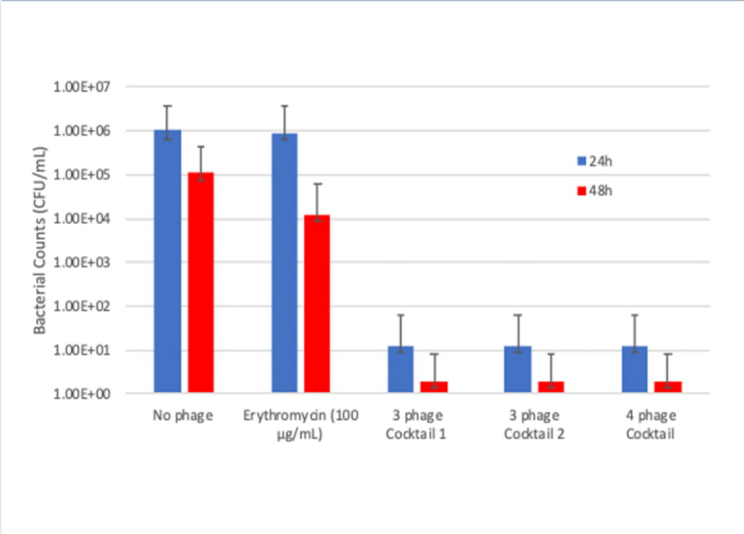
**BiomX**

# BX001 targets *C. acnes*, penetrates biofilm *in vitro*

**BX001 eradicates *C. acnes* (*in-vitro*)**



**Phage cocktails penetrate biofilm (*in-vitro*)**



Source: Internal data



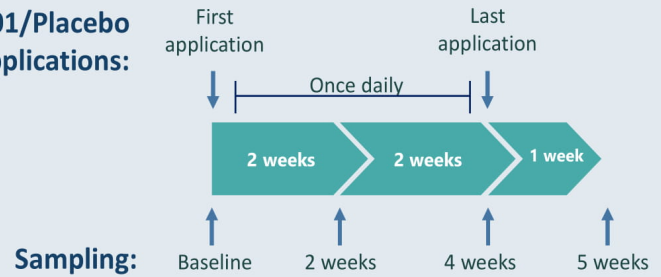
# BX001: Phase 1 clinical trial design

## Phase 1 – Completed

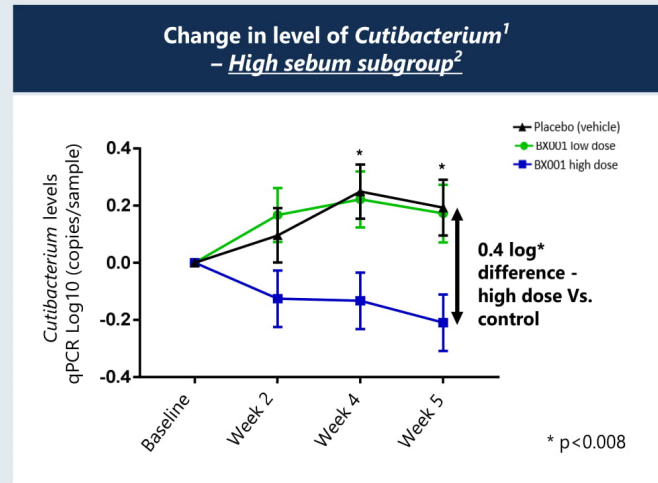
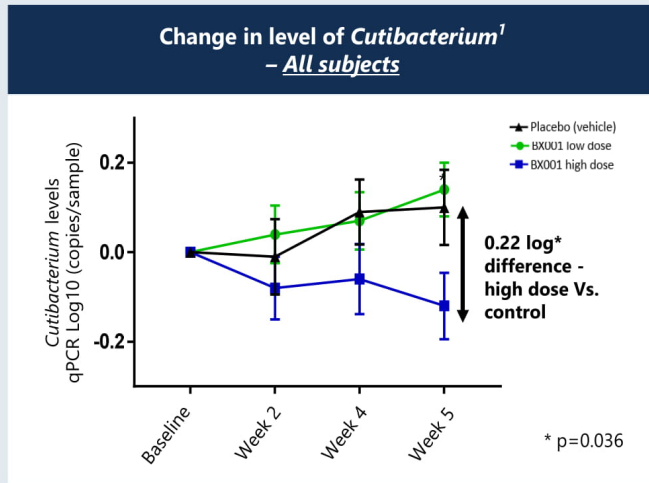
### 4-week study (placebo-controlled)

- **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

### BX001/Placebo Applications:



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



- 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/cm<sup>2</sup>)



# BX001 phase 2 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

### BX001/Placebo Applications:



# Inflammatory Bowel Disease (IBD), Primary Sclerosing Cholangitis (PSC)

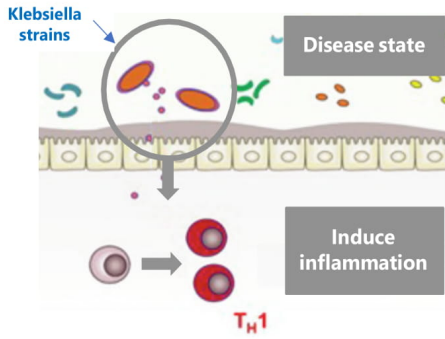
Upcoming milestone: Phase 1b/2a data expected in 2Q 2022

**BiomX**

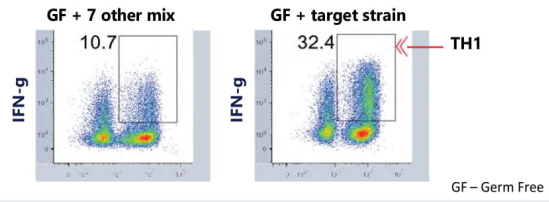
# IBD • Identifying potential disease causing pro-inflammatory *Klebsiella* strains



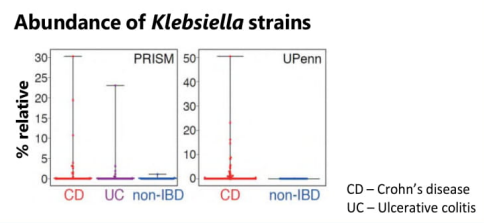
## Pro-inflammatory *Klebsiella* strains affect IBD pathology



## Inflammatory induction is seen in GF mice\*



## Higher abundance of *Klebsiella* strains in IBD patients



Activity of bacterial target confirmed by BiomX



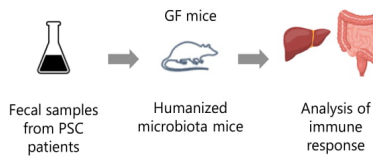
Source: Atarashi et al. (2017), Science  
 \* TH1 – A lineage of CD4+ effector T cell secreting IFN $\gamma$  and TNF. In IBD, TH1 cells accumulate in the intestinal tract of IBD patients and are directly associated with disease



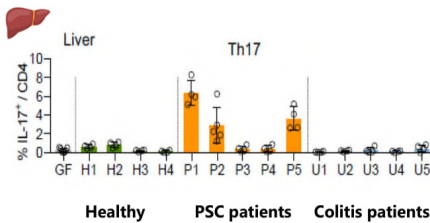
# PSC • *Klebsiella* identified as possible driver of "leaky gut"

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-gnotobiotite	ND		ND
PSC/UC-gnotobiotite	ND		ND

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

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

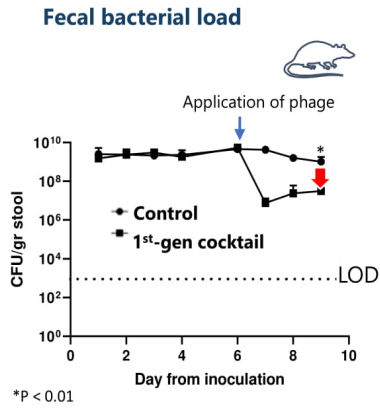
*Klebsiella pneumoniae* (KP) is a specific gut pathobiont of PSC that is an intestinal barrier disrupter and is pro-inflammatory ("leaky gut")

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

**BiomX**

# Phage cocktail composition drives activity

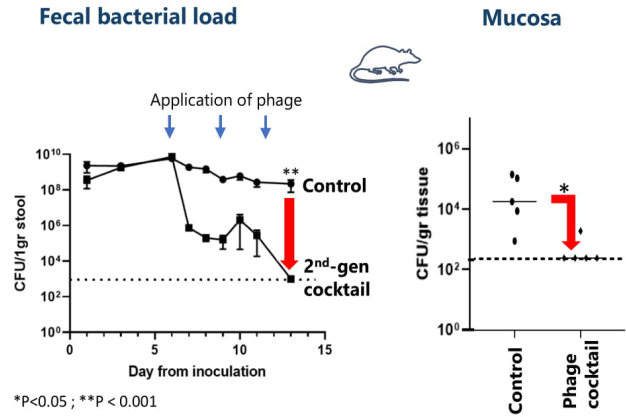
## 1<sup>st</sup>-generation phage cocktail (in-vivo)



Adding 2 phage with new MOA



## 2<sup>nd</sup>-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

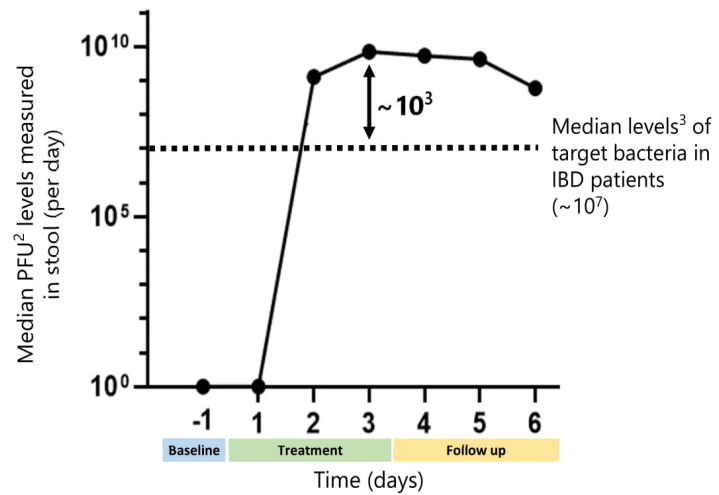
# BX002: Phase 1a pharmacokinetic results demonstrate delivery of high levels of viable phage to the gut<sup>1</sup>

## 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.

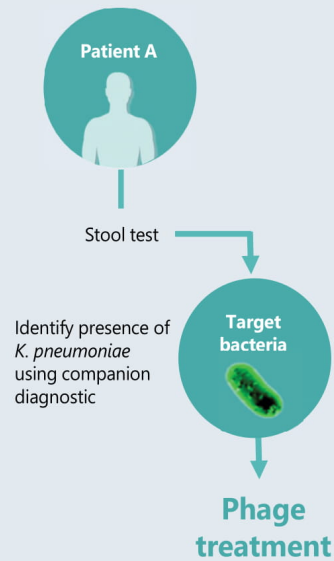
# Phase 1b/2a study results expected in 2Q 2022

## 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.

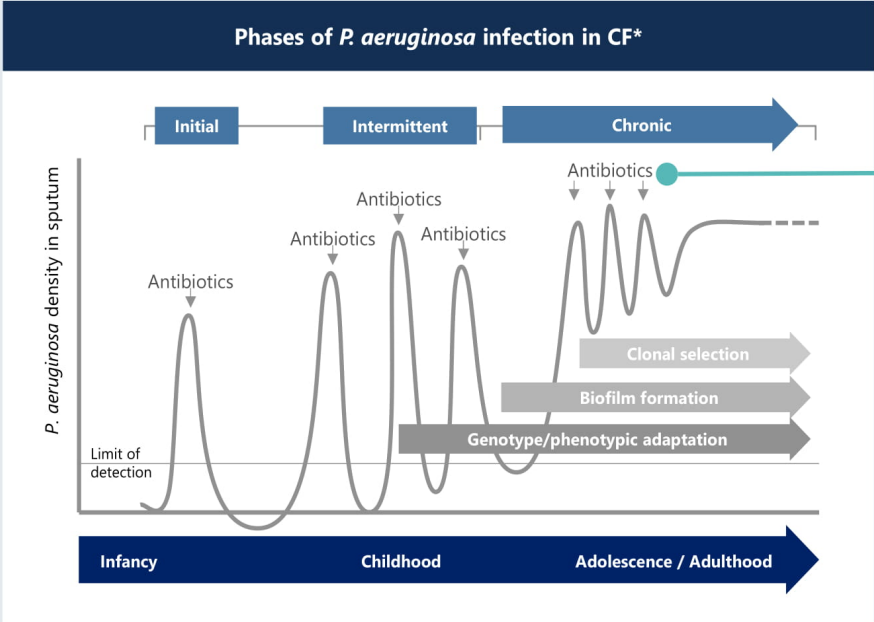
whitley A35 anaerobic workstation

# Cystic Fibrosis

Upcoming milestone: Phase 2 data expected in 4Q 2021

**BiomX**

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

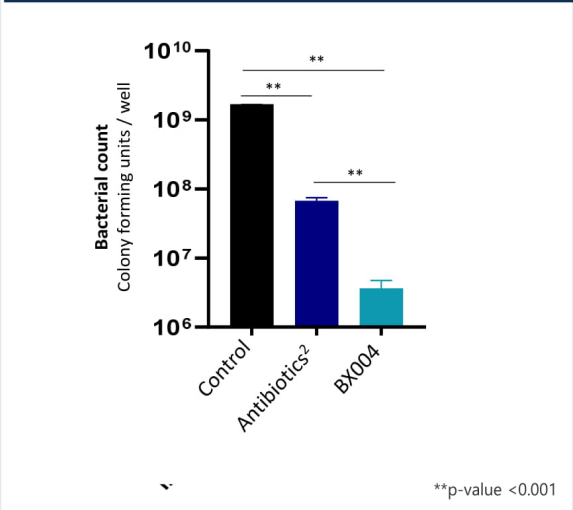


Repeated antibiotic courses lead to nonmucoid and mucoid multidrug-resistance (MDR) of *P. aeruginosa* strains

\* CF Foundation, Bomberg et al., 2008

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

## BX004 penetrates biofilm in-vitro<sup>1</sup>



## *P. aeruginosa* engulfed in biofilm (electron microscope)<sup>3</sup>



BX004 displays better biofilm penetration compared to antibiotics

1. Internal data. A *P. aeruginosa* strain sensitive to the antibiotics and BX004 was grown to form biofilm  
2. Imipenem 200 micrograms/ml, which is a  $\beta$ -lactam antibiotic active on *P. aeruginosa*  
3. Future Med. Chem. (2015) 7(4), 493-512

# CF phase 2 study targeting *P. aeruginosa*

## Phase 2 personalized proof of concept

### Objectives

- Safety and efficacy

### Endpoints

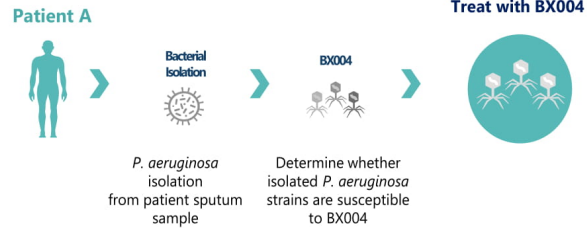
- Safety and tolerability
- Decrease in target bacteria
- Improvement in FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised)

### Study Population

- CF patients with chronic PsA pulmonary infection

### ~40 subjects

- BX004 nebulized phage therapy or placebo
- 7-10 days duration of treatment



Data expected 4Q 2021





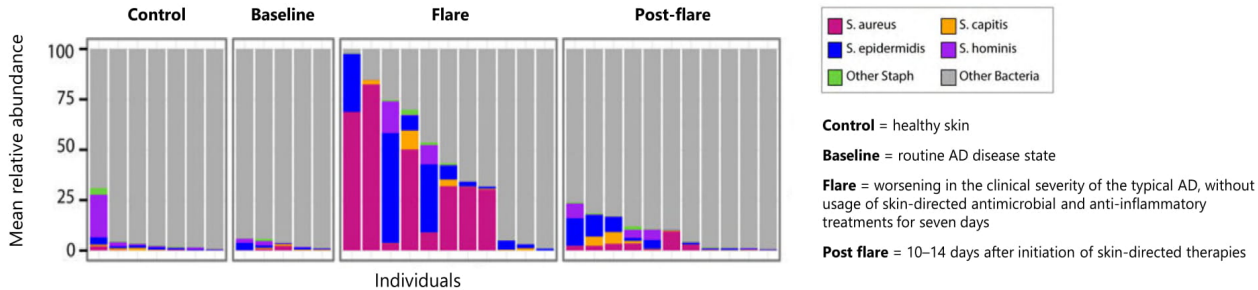
# Atopic Dermatitis

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)



*S. aureus* becomes the dominant bacterial species during AD flares and was also correlated with SCORAD

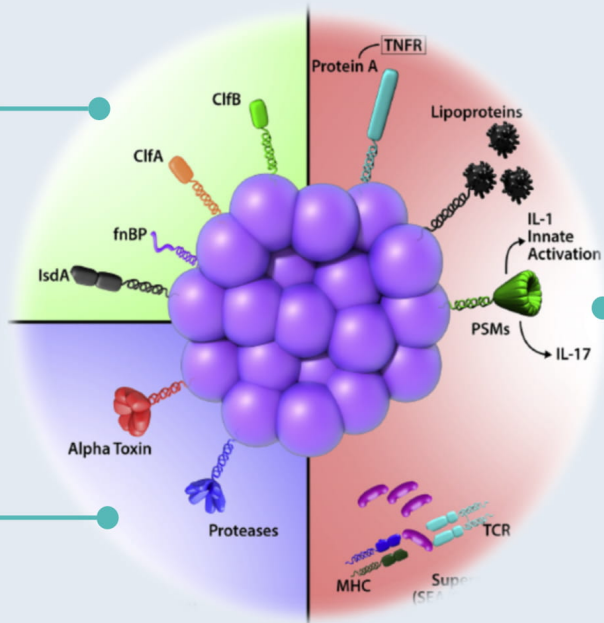
Byrd and Kong (2017) Sci Transl Med. 05 9(397)



# *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.



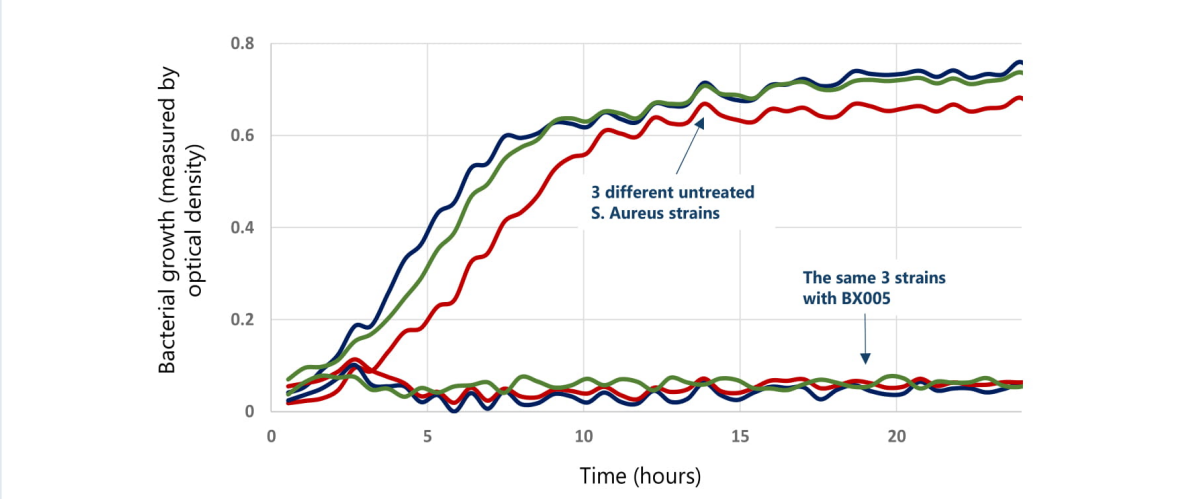
**Proinflammatory mechanisms**  
Such as, protein A and superantigens (enterotoxins) which trigger inflammatory responses and cytokine release

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



# BX005 phage cocktail shows broad host range targeting of *S. aureus* in vitro

**BX005 eradicates *S. aureus* (in vitro, 3 experiments with 3 different strains)**



*In vitro*, BX005 was shown to eradicate **over 90%** of strains from a panel of *S. aureus* strains<sup>1</sup>

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



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

## Study design in atopic dermatitis patients

### • Objectives

- Safety, efficacy and pharmacodynamics

### • Endpoints

- Safety and tolerability
- Decrease in target bacteria
- Reduction in active disease (e.g. change in EASI/IGA scores)

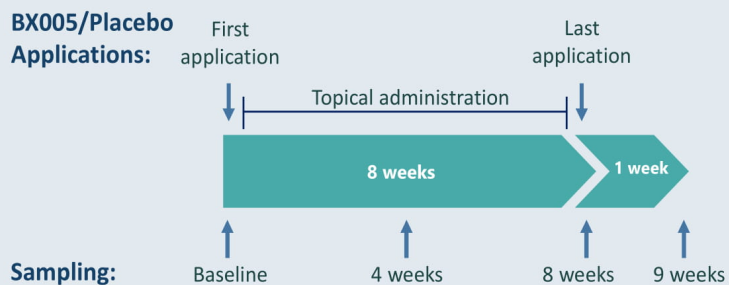
### • Study Population

- Atopic dermatitis patients
- *S. aureus* colonized

### • 80 subjects

- BX005 or placebo (vehicle)
- 8-week duration of treatment

Data expected 1H 2022

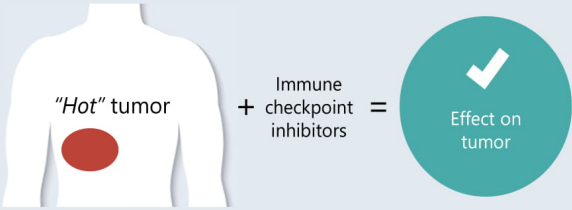
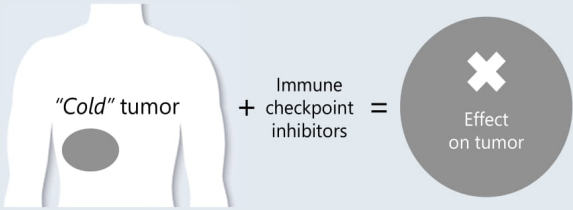


# Colorectal Cancer

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

**BiomX**

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

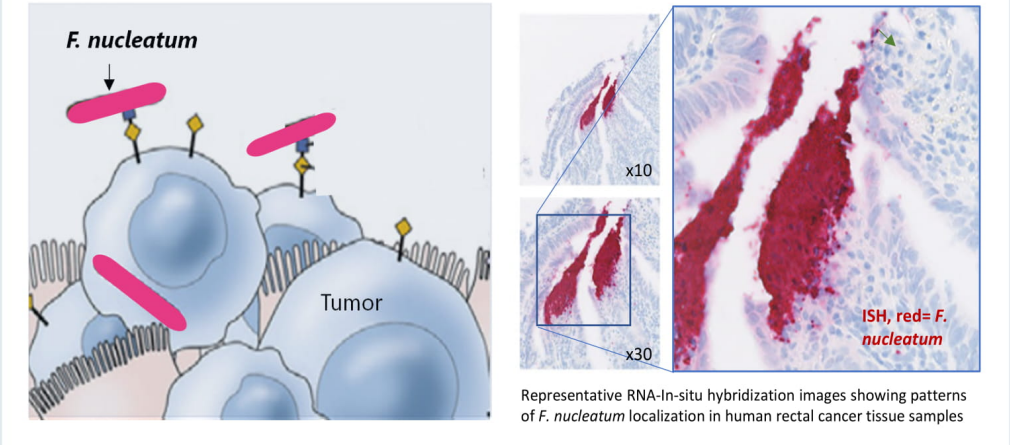


Sources: Vareki (2018), Journal for immunotherapy of Cancer; Galon et al. (2019), Nature Reviews/Drug Discovery



# Bacteria residing inside tumors offer a novel targeted intervention to “uncloak” tumors to “hot”

## Numerous observations of bacteria residing inside tumors



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

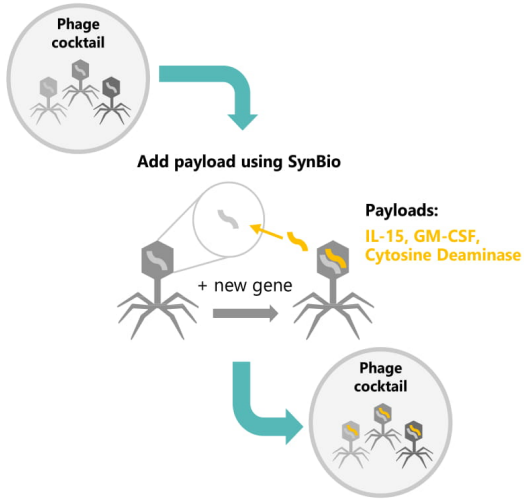


BiomX internal data  
Li YY, Ge QX, Cao J, et al. (2016) *World J Gastroenterol.*  
Bachrach et al. (2016), *Cell Host & Microbe*  
Serna et al. (2020) *Annals of Oncology*  
Kostic et al. (2013), *Cell Host & Microbe*

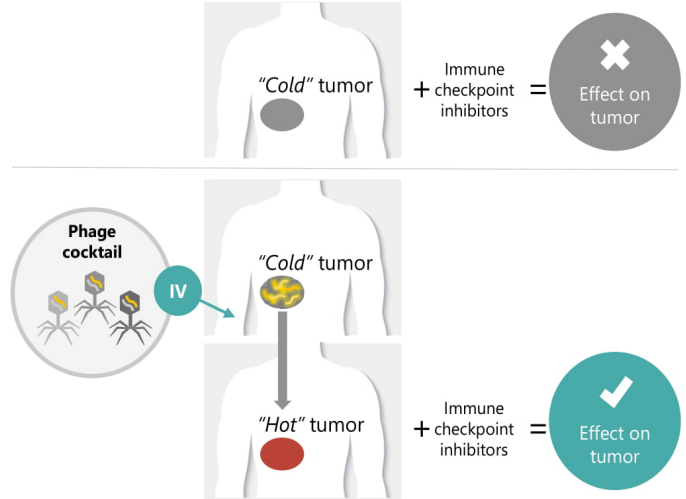


# Engineered phage are designed to deliver payloads to bacteria in tumors

Phage are designed to carry payloads to intra-tumor bacteria



Phage cocktail with a payload turns cold tumors into hot

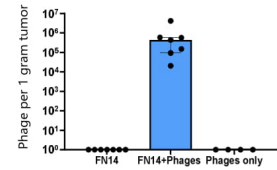
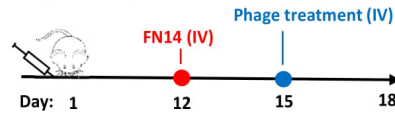


# Key development milestones



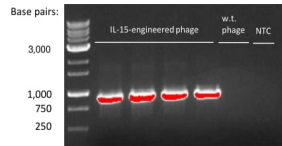
**IV delivery of phage to intra-tumor bacteria (*in-vivo*)**

CT-26  $2 \times 10^5$ /mouse (SC)

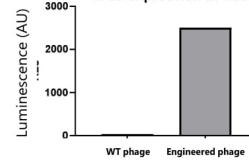


**IL-15 payload engineered into *F. nucleatum* phage (*in-vitro*)**

**IL15 insertion into phage**



**IL-15 expression in bacteria**

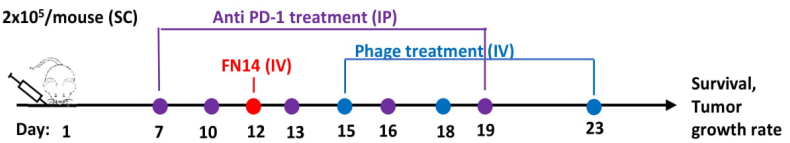


Planned  
2Q-3Q  
2021

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

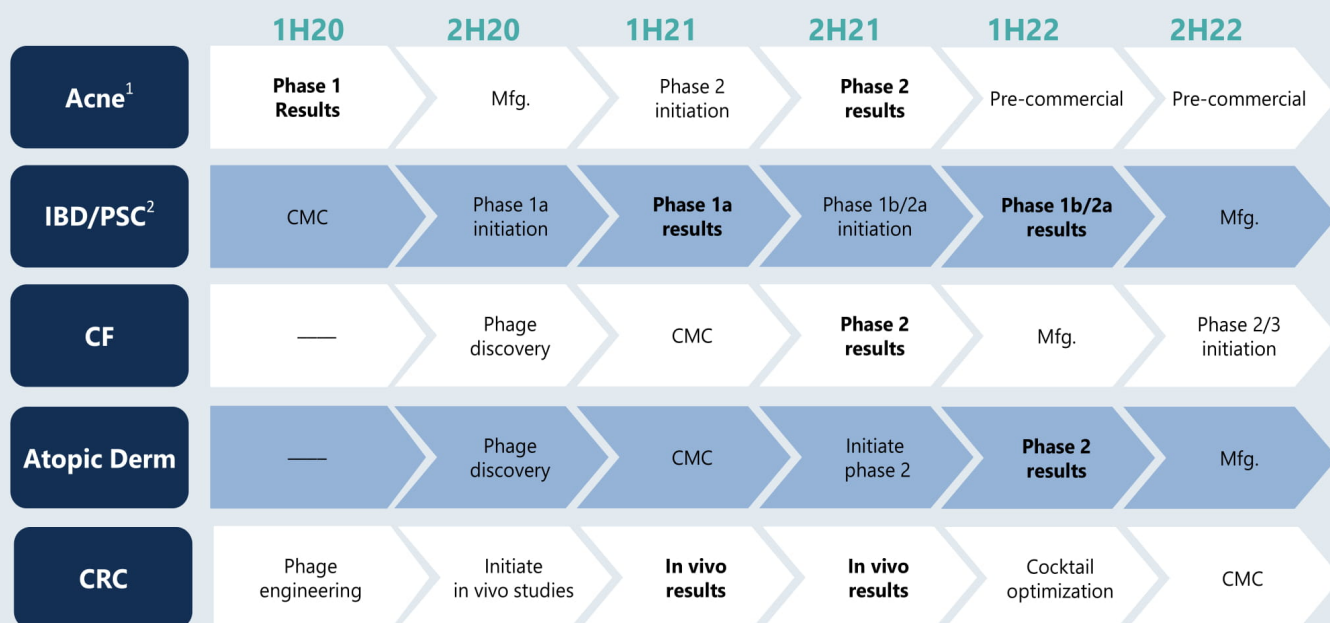
**Engineered Payloads:**  
IL-15, GM-CSF, Cytosine Deaminase

CT-26  $2 \times 10^5$ /mouse (SC)



Source: Internal data

# Key catalysts



Cash, cash equivalents and short-term deposits as of December 31<sup>st</sup>, 2020 were \$57.1M million

(1) 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.  
 (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.



# 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**



**Prof. Eran Elinav**



**Prof. Timothy K. Lu**



# Experienced leadership team

## Board of Directors



Chairman, Russell Greig, PhD



Director, Paul Sekhri



Director, Gbola Amusa, MD



Director, Lynne Sullivan



Director, Jonas Grossman



Director, Jonathan Solomon



Director, Alan Moses, MD





THANK YOU

**BiomX**

---