

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 12, 2020

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) 72-394-2377

n/a

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Units, each consisting of one share of Common Stock, \$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 November 12, 2020, BiomX Inc. (the “Company”) issued a press release announcing its financial results for the third quarter ended September 30, 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 November 12, 2020, the Company posted an updated corporate slide presentation in the “Investors” portion of its website at www.biomx.com. A copy of the slide presentation is furnished pursuant to Item 7.01 as Exhibit 99.2 hereto. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release dated November 12, 2020
99.2	Investor Presentation dated November 12, 2020

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.

November 12, 2020

BIOMX INC.

By: /s/ Jonathan Solomon

Name: Jonathan Solomon

Title: Chief Executive Officer



BiomX Reports Third Quarter 2020 Financial Results and Announces Expanded Portfolio of Phage Therapy Candidates

Company unveils BOLT (Bacteriophage Lead to Treatment) platform designed for more rapid and efficient development of phage therapy

BOLT enables the Company to expand portfolio with two additional phage therapy programs in cystic fibrosis and atopic dermatitis and allows consolidation of two programs into one product candidate, BX003, for the treatment of both inflammatory bowel disease (IBD) and primary sclerosing cholangitis (PSC)

Company to host conference call today at 8:00 a.m. Eastern Time

Ness Ziona, Israel – November 12, 2020 – BiomX Inc. (NYSE American: PHGE), a clinical stage company developing natural and engineered phage therapies targeting specific pathogenic bacteria, today reported financial results and a business update for the third quarter ended September 30, 2020.

“BiomX continues to lead in the field of phage therapy by implementing proprietary processes for accelerated development,” commented Jonathan Solomon, Chief Executive Officer of BiomX. “Our novel BOLT platform, which is the result of an accumulated five years of technological development, significantly reduces the time required to reach clinical proof-of-concept. The improved efficiency of this platform allows us to expand our portfolio with two significant new programs without affecting our projected cash runway.”

Continued Mr. Solomon, “This expansion includes near term opportunities with phage therapy candidates. We expect clinical proof of concept results in patients for cystic fibrosis and atopic dermatitis by the end of 2021 and mid-2022, respectively. Improvements in R&D also allow for the consolidation of our inflammatory bowel disease (IBD) and primary sclerosing cholangitis (PSC) programs. We now have one improved, broad host range product candidate, BX003, targeting *Klebsiella pneumoniae*, a potential pathogen implicated in both diseases to be developed for both indications. The consolidation of these programs results in an updated timeline for Phase 1b/2a results with BX003 expected in mid-2022. In addition, we expect data from a planned Phase 2 cosmetic clinical study in acne-prone skin in the second quarter of 2021.”

About the BOLT Platform

The newly unveiled BOLT (“Bacteriophage Lead to Treatment”) R&D platform enables BiomX to rapidly develop, manufacture and formulate a phage treatment targeting a given pathogenic bacteria. The platform allows BiomX to conduct an initial clinical proof of concept study in patients (Phase 2 results) within approximately 12-18 months of project initiation¹. The ability to move quickly into clinical development is also driven by the strong safety profile of naturally-occurring phage, as corroborated by regulatory guidance provided to BiomX by the FDA as relating to its IBD program, allowing the Company to bypass safety studies and studies in healthy volunteers and to proceed directly to patient studies.

¹ In certain indications the length of clinical proof of concept may be longer depending on indication, identity of target bacteria, recruitment rate, cohort size and other factors.

Recent Highlights and Key Upcoming Milestones

Acne-Prone Skin

- The Company expects to initiate a Phase 2 cosmetic clinical study of phage therapy BX001 in the first quarter of 2021, with results expected in the second quarter of 2021.

Cystic Fibrosis

- A new program for development of a phage therapy targeting chronic respiratory infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with cystic fibrosis. Phase 2 results of a proof of concept clinical study evaluating safety and efficacy in patients are expected in the fourth quarter of 2021.

Atopic Dermatitis

- A new program for development of a topically administered phage therapy targeting *Staphylococcus aureus*, a bacterium linked to the development and exacerbation of inflammation in atopic dermatitis. Phase 2 results of a proof of concept clinical study evaluating safety and efficacy in patients are expected in the first half of 2022.

IBD and PSC

- Results of a Phase 1a study are expected in the first quarter of 2021. The study is designed to provide safety and pharmacokinetic data, including an assessment of delivery of viable phage to the gastrointestinal system as a key exploratory endpoint.
- Results of the Phase 1b/2a study aimed at evaluating the efficacy of BX003, improved broad host range phage therapy, in reduction of the target bacteria *Klebsiella pneumoniae* are expected by mid-2022.

Tumor-Targeted Delivery in Cancer

- BiomX is exploring phage mediated delivery of therapeutic payloads to *Fusobacterium nucleatum* bacteria residing in the tumors of patients with colorectal cancer. Preclinical results from animal studies evaluating use of phage therapy in combination with checkpoint inhibitors are expected in the second quarter of 2021.

Biomarker Discovery Collaboration with Boehringer Ingelheim

- In September 2020, BiomX entered into a collaboration with Boehringer Ingelheim to utilize the BiomX XMarker microbiome-based biomarker discovery platform to potentially identify biomarkers associated with patient phenotypes in IBD.

Third Quarter 2020 Financial Results

- **Cash balance and short-term deposits as of September 30, 2020**, were \$64.5 million, compared to \$82.4 million as of December 31, 2019. The decrease was primarily due to net cash used in operating activities.
- **Research and development expenses** were \$6.4 million in the third quarter of 2020, compared to \$2.9 million in the same period of 2019. The increase was primarily due to growth in the number of employees which resulted in an increase of salaries and related expenses and due to an increase in depreciation and amortization expenses.
- **General and administrative expenses** were \$2.4 million in the third quarter of 2020, compared to \$1.8 million in the same period in 2019. The 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** was \$8.8 million in the third quarter of 2020, compared to \$4.3 million in the same period of 2019.
- **Net cash used in operating activities** was \$17.3 million for the nine months ended September 30, 2020, compared to \$10.5 million in the same period of 2019.

Financial Expectations

- Existing cash, cash equivalents and short-term deposits are expected to be sufficient to fund the Company's current operating plan through mid-2022.

Conference Call Details

BiomX management will host a conference call and webcast today at 8:00 a.m. ET to report financial results for the third quarter of 2020 and provide business updates. To participate in the conference call, 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 in the Investors section of the company's website at www.biomx.com.

About BiomX

BiomX is a clinical-stage biotechnology 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 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 Language

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 the potential opportunities for and benefits of the BOLT platform, the expected timing of initiation and receipt of results from its various pre-clinical and clinical studies as well as the acceptance of regulatory agencies of the design thereof, its collaboration with Boehringer Ingelheim and the potential thereof and the sufficiency of its funding through mid-2022, 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 most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q 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. 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.

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The background of the slide features a glowing blue and purple DNA double helix structure. The BiomX logo is positioned in the upper left, with 'Biom' in white and 'X' in a vibrant teal. Below the logo, the text 'Company Introduction' and 'November 2020' is displayed in white. On the right side, there are three teal-colored geometric shapes: a large semi-circle and two smaller triangles, one of which is partially overlapping the semi-circle. The slogan 'ADVANCING MEDICINE. PRECISELY.' is written in white capital letters, with 'PRECISELY.' in a larger font size, positioned near the teal shapes.

BiomX

Company Introduction
November 2020

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 pipeline, 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, 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.

BiomX

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

- 6 programs* – acne, IBD, PSC, colorectal cancer, CF and atopic dermatitis
- Reported positive phase 1 data for BX001 in subjects with acne prone skin in 1Q 2020



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

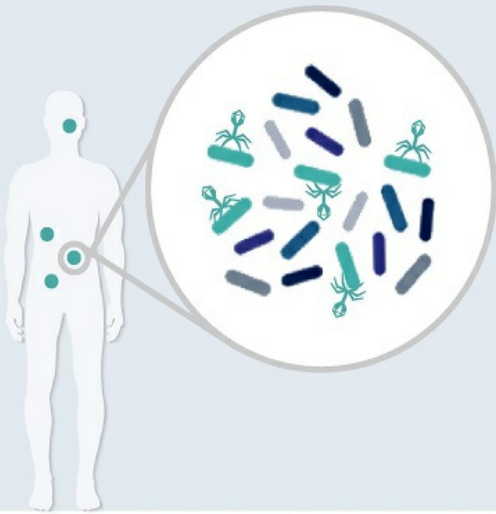


* Inflammatory Bowel Disease (IBD) , Primary Sclerosing Cholangitis (PSC), Cystic Fibrosis (CF)



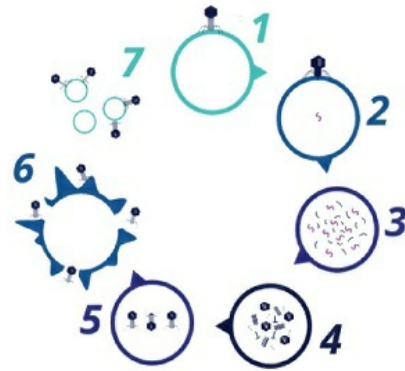
Phage: Nature's precision tool to target bacteria

Each phage binds only to specific bacterial strains



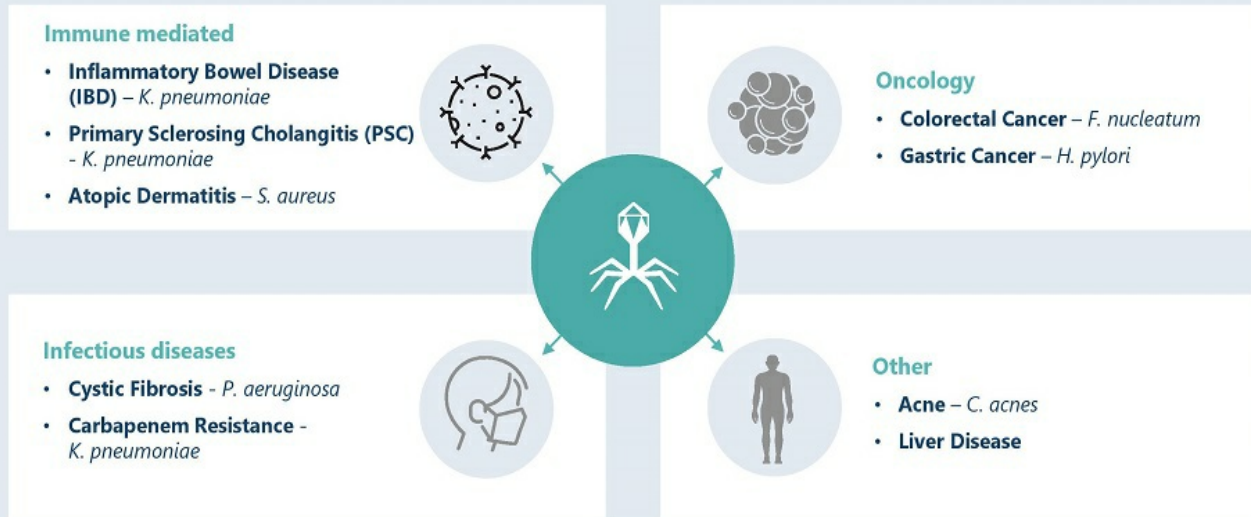
Phage have an amplifying lifecycle

- 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



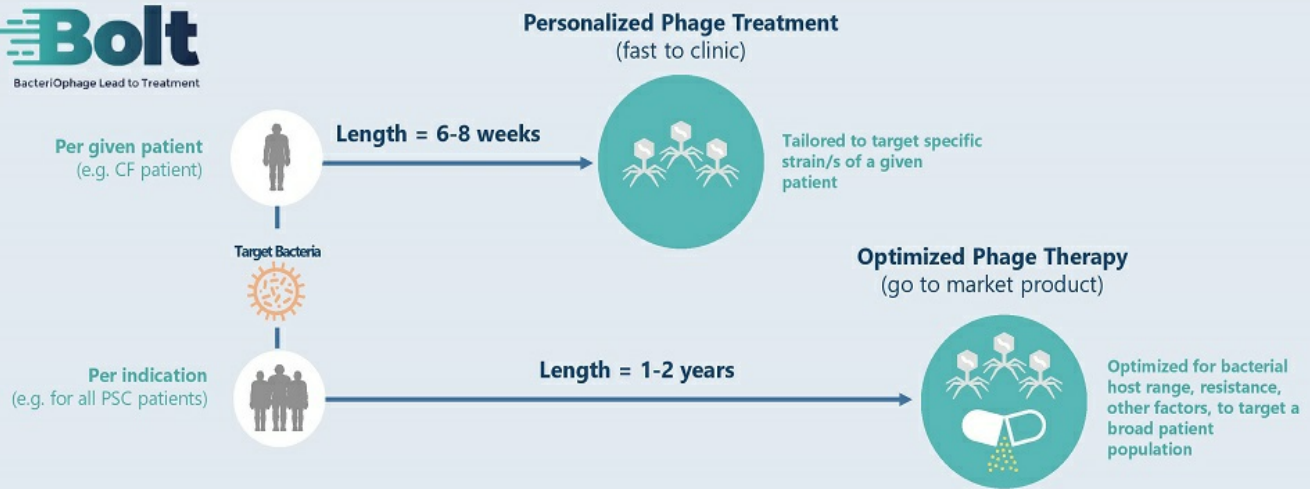
Pipeline

	Phage discovery	Preclinical	Phase I	Phase II
Product Candidates				
Acne • BX001¹ (Cosmetic route)				<ul style="list-style-type: none"> • Positive Phase 1 results • Phase 2 results expected 2Q 2021
IBD/PSC • BX003²				<ul style="list-style-type: none"> • Phase 1a results expected 1Q 2021
NEW: Cystic fibrosis				<ul style="list-style-type: none"> • Phase 2 results expected 4Q 2021
NEW: Atopic dermatitis				<ul style="list-style-type: none"> • Phase 2 results expected in 1H 2022
Colorectal cancer				<ul style="list-style-type: none"> • Animal model results expected 2Q 2021

(1) BX001 is intended to be developed and commercialized as a cosmetic

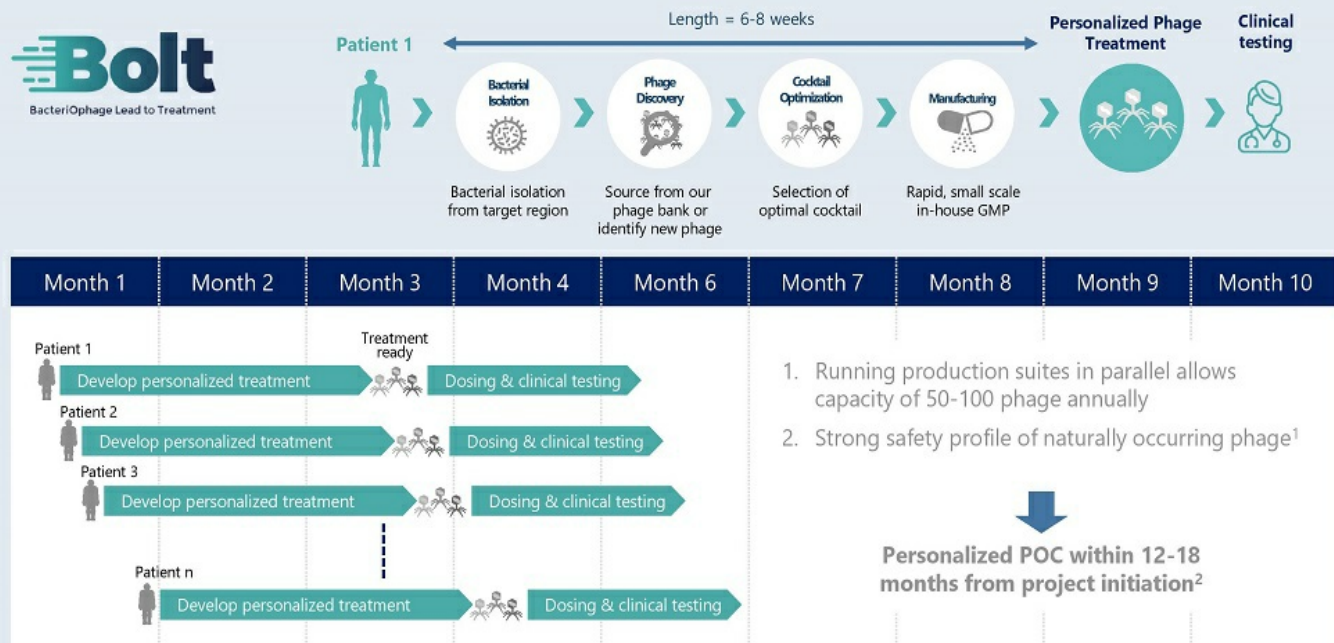
(2) As the IBD and PSC programs share the same bacterial target, *Klebsiella pneumoniae*, we currently anticipate that the BX003 phage cocktail will be developed for both indications. Accordingly, the Phase 1 study is expected to support progress of both indications.

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

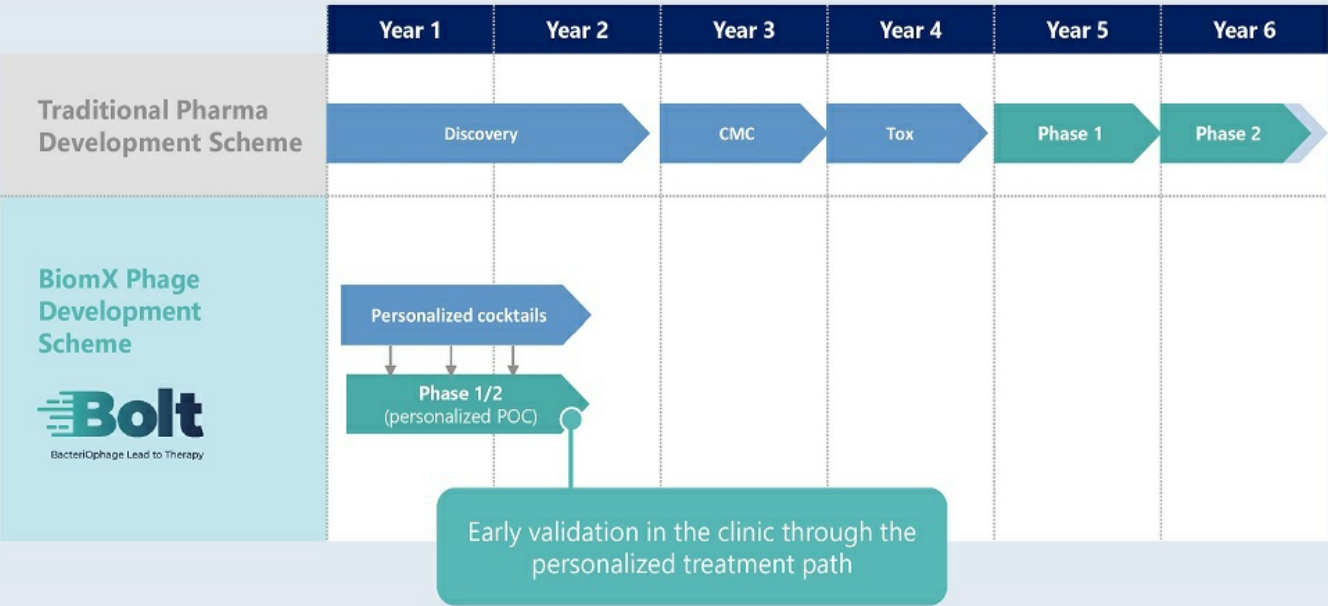
The personalized phage treatment enables a rapid clinical POC



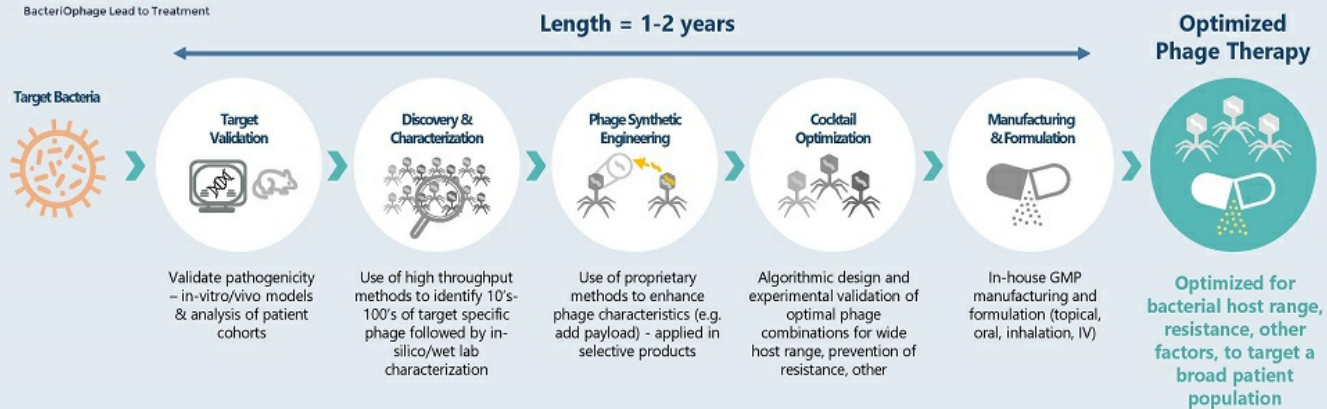
1). Strong safety profile of naturally occurring phage, as evident by the regulatory feedback provided to us in our IBD program allowing us to skip preclinical safety studies and healthy volunteers and go straight to patients.
2). In certain indications the length of clinical validation may be longer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

BiomX

Personalized POC enabled within 12-18 months



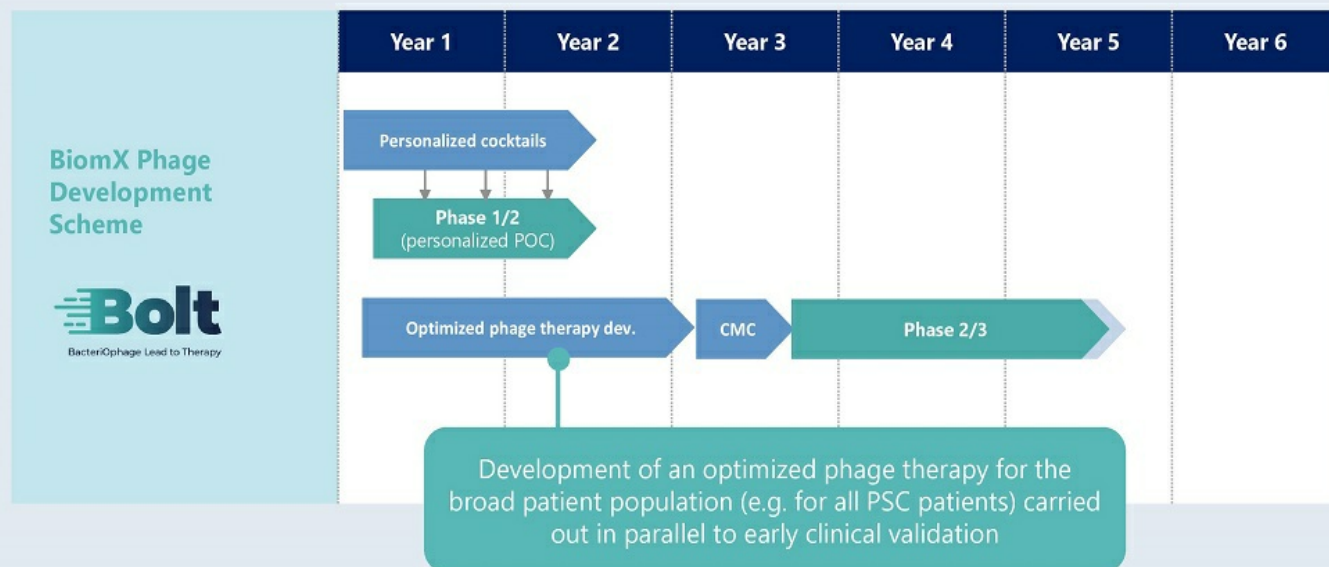
Proprietary methods and capabilities to optimize phage therapy



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 2Q 2021 (cosmetic study)

BiomX

BX001: Phage cocktail attributes

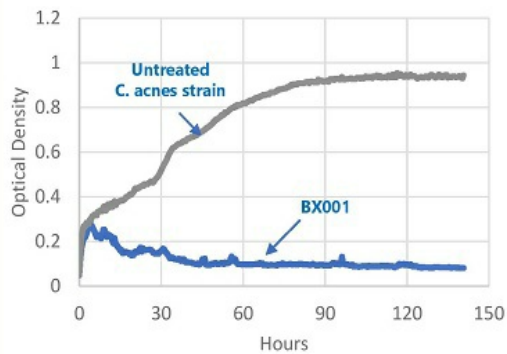
- Active against 96% of tested *C. acnes* clinical strains (*in-vitro*)
- Active against antibiotic-resistant strains (*in-vitro*)
- Self-amplifying: 50-100 phage per bacteria killed
- Penetrates biofilm
(in contrast to antibiotic erythromycin)
- Highly specific: Does not affect other skin microbiome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



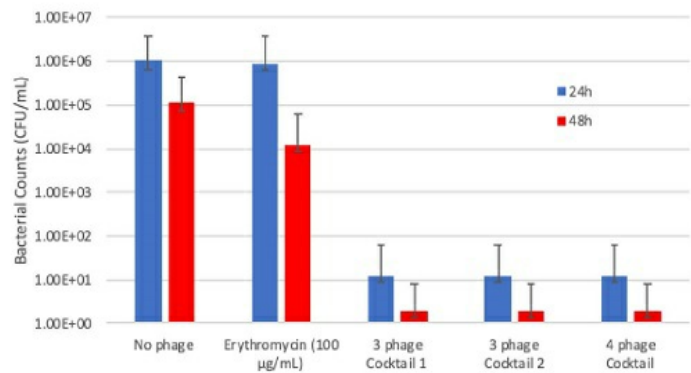
Source: Internal data

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

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



Phage cocktails penetrate biofilm (*in-vitro*)



Source: Internal data

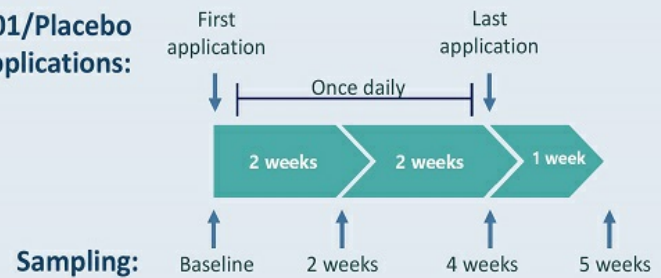
BX001: Phase 1 clinical trial design

Phase 1 – Completed

4-week study (placebo-controlled)

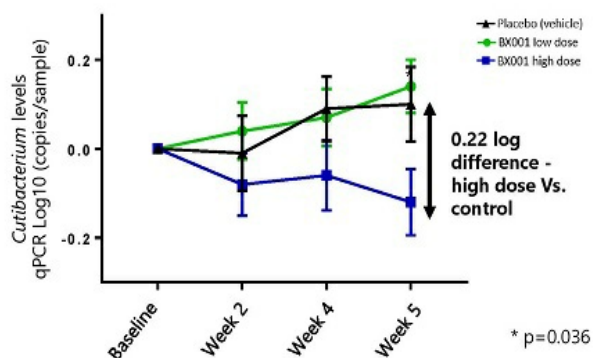
- **Primary endpoint**
 - Safety & Tolerability
- **Exploratory endpoints**
 - Reduction of *C. acnes* (efficacy)
 - Skin microbiome evaluation
- **75 female subjects**
 - 2 doses (high and low dose) + placebo (vehicle)
 - 25 subjects per cohort

BX001/Placebo Applications:

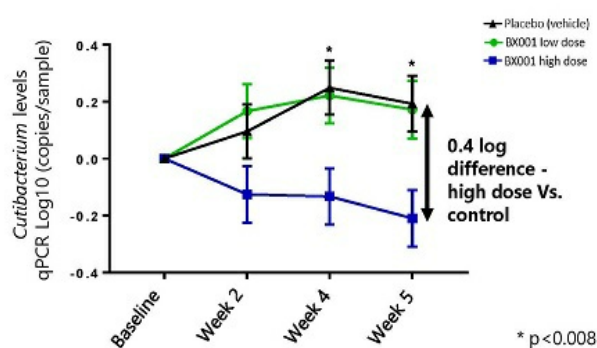


BX001: Phase 1 results demonstrate statistically significant reduction in *C. acnes* levels

Change in level of *Cutibacterium*¹
– All subjects



Change in level of *Cutibacterium*¹
– High sebum subgroup²



- 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

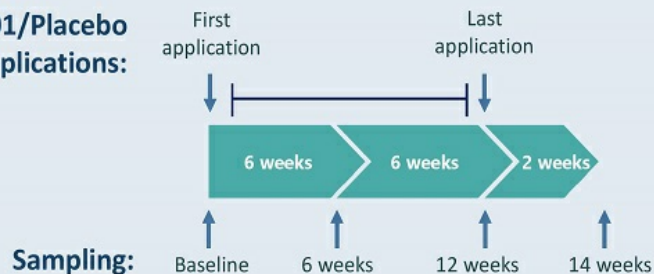
BX001 phase 2 study results expected in 2Q 2021

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)
- **100 female subjects**
 - Phage or placebo (vehicle)
 - 50 subjects per cohort

BX001/Placebo Applications:





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

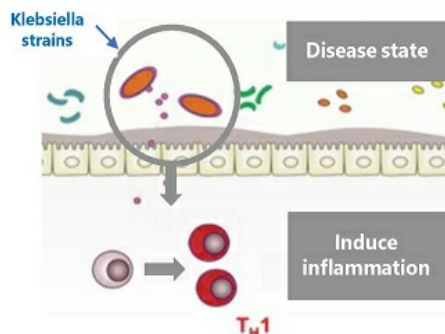
Upcoming milestone: Phase 1 pharmacokinetic data expected in 1Q 2021

BiomX

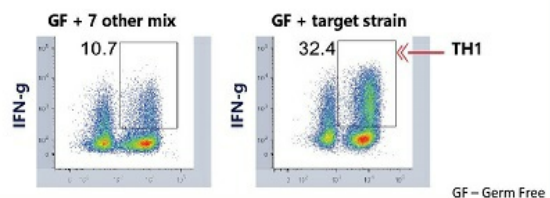
IBD • Identifying potential disease causing pro-inflammatory *Klebsiella* strains



Pro-inflammatory *Klebsiella* strains affect IBD pathology

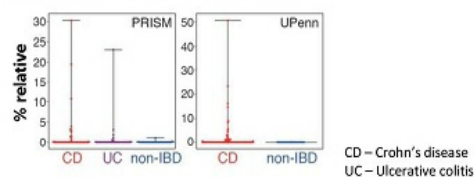


Inflammatory induction is seen in GF mice*



Higher abundance of *Klebsiella* strains in IBD patients

Abundance of *Klebsiella* strains



Activity of bacterial target confirmed by BiomX

Source: Atarashi et al. (2017), Science

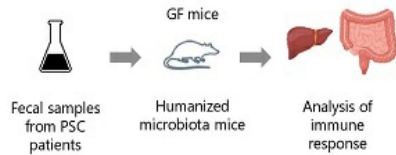
* TH1 – A lineage of CD4+ effector T cell secreting IFNγ and TNF. In IBD, TH1 cells accumulate in the intestinal tract of IBD patients and are directly associated with disease



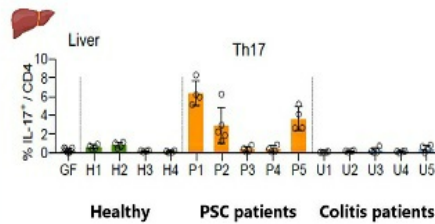
PSC • *Klebsiella* identified as possible driver of "leaky gut"

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	ND
HC-gnotobiot	ND	ND	ND
PSC/UC-gnotobiot	ND	ND	ND

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

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

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

BiomX

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

PSC • Bacterial pathogens contribute to orphan liver disease



PSC (primary sclerosing cholangitis)

Stricture of bile ducts impedes bile flow to intestines and gradually leads to cirrhosis of liver and liver failure

- **~30,000 US patients**
- **10–15 years** until liver transplant is required
- **No existing therapy** to avoid eventual liver transplant

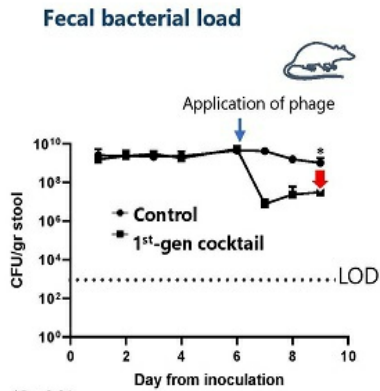
- Evidence that manipulation of microbiome impacts the disease
- Abnormal high abundance of bacteria found in bile fluid of patients
- Most PSC patients suffer from ulcerative colitis

Hepatology. (2013) Dec;58(6):2045-55, UpToDate, MedScape

Source: NEJM 2016, PSC Review, LaRusso and Lazaridis

Phage cocktail composition drives activity

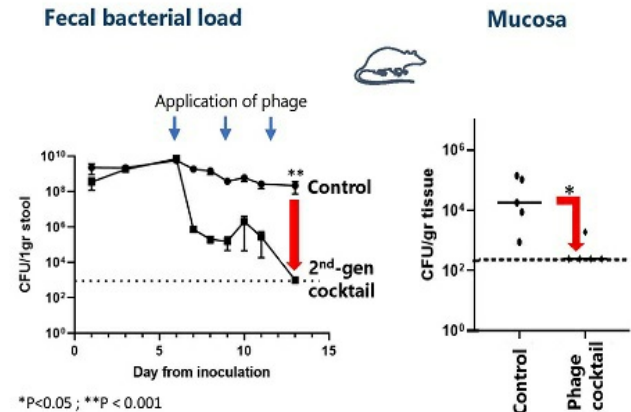
1st-generation phage cocktail (in-vivo)



Adding 2 phages 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

Planned phase 1/2 clinical development

Phase 1a
First-In-Human Pharmacokinetic Study

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**
 - 14 phage treatment + 4 placebo

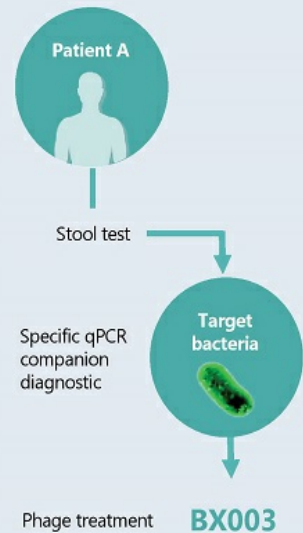
Data expected 1Q 2021

Phase 1b/2a
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**
 - BX003 or placebo
 - 30 subjects per cohort

Data expected 1H 2022



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.

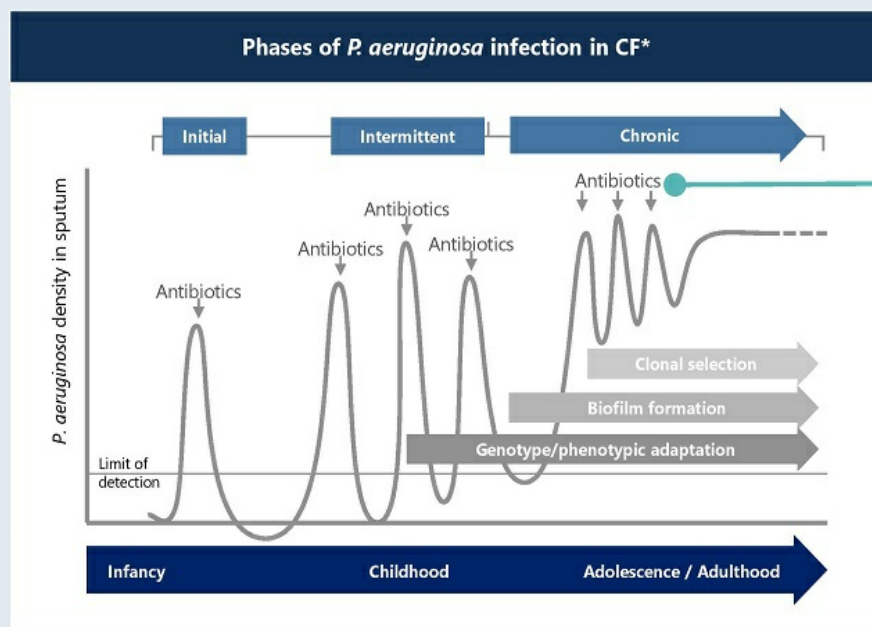


New: Cystic Fibrosis

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

CF phase 2 targeting *P. aeruginosa*

Phase 2 personalized proof of concept

Objectives

- Safety and efficacy

Endpoints

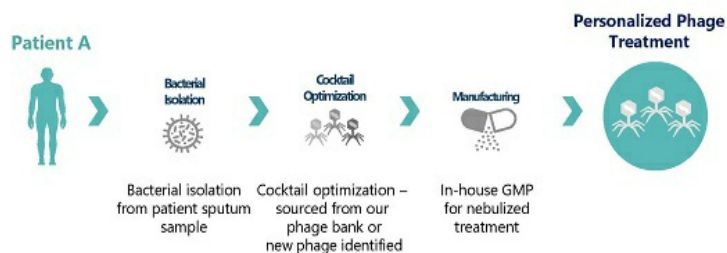
- Safety and tolerability
- Decrease in target bacteria
- Improvement in FEV1 (forced expiratory volume)
- CFQ-R (CF Questionnaire-Revised)

Study Population

- CF patients with chronic *P. aeruginosa* pulmonary infection

20 subjects

- Phage therapy
- 10 days duration of treatment



Data expected 4Q 2021



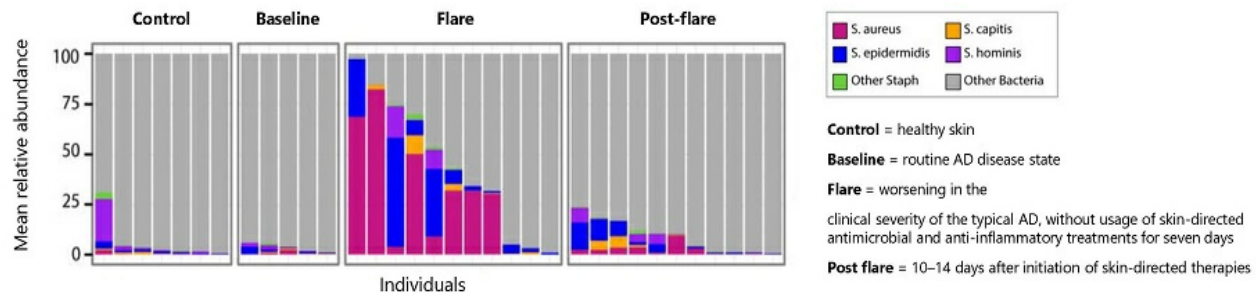
New: Atopic Dermatitis

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 specie during AD flares and was also correlated with SCORAD

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

Atopic Dermatitis phase 2 targeting *S. aureus*

Phase 2 personalized proof of concept

- **Objectives**

- Safety and efficacy

- **Endpoints**

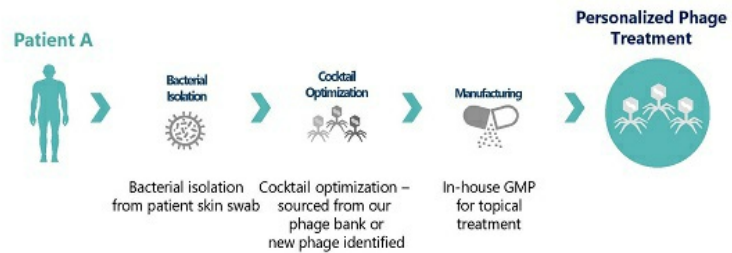
- Safety and tolerability
- Decrease in target bacteria
- Improvement in EASI scores
- Reduction in itch intensity
- Improvement in IGA scores

- **Study Population**

- AD patients
- *S. aureus* colonized

- **50 subjects**

- Topical phage or placebo
- 12-week duration of treatment
- 25 subjects per cohort



Data expected 1H 2022



Colorectal Cancer

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

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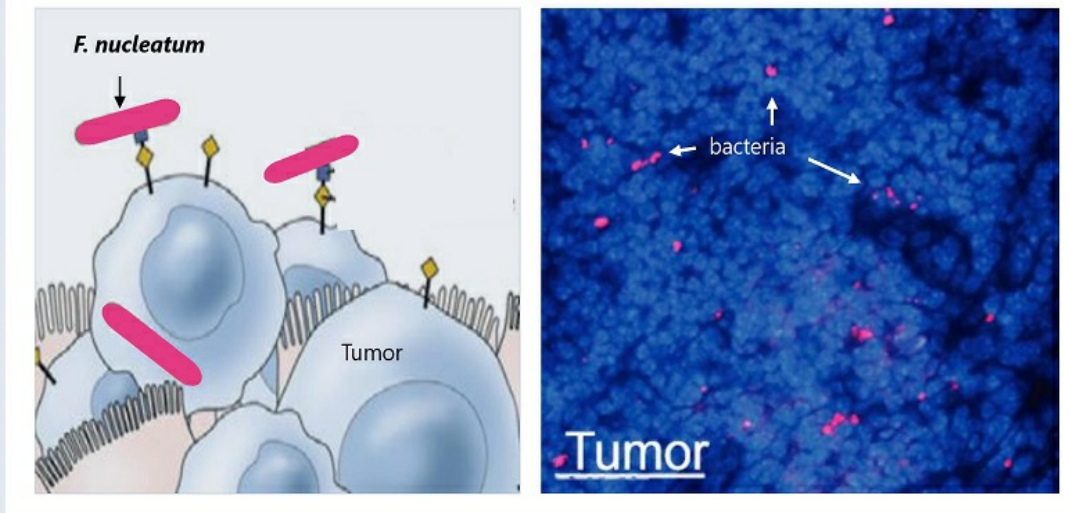
Most colorectal cancer (CRC) patients do not respond to immunotherapy



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”

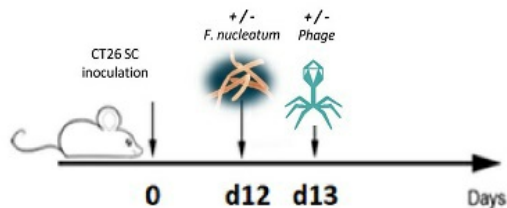
Numerous observations of bacteria residing inside tumors



Bachrach et al. (2016), *Cell Host & Microbe*
Kostic et al. (2013), *Cell Host & Microbe*

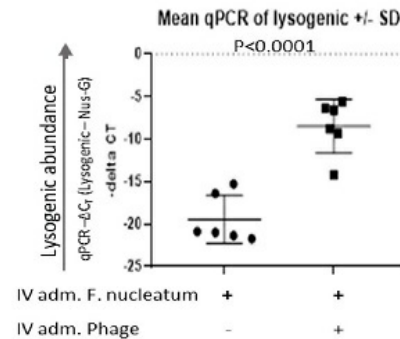
IV delivery of phage to intra-tumor bacteria has been demonstrated

Experimental outline



Termination: 24h after IV administration of phage, followed by qPCR analysis of the tumor for presence of phage and *F. nucleatum*

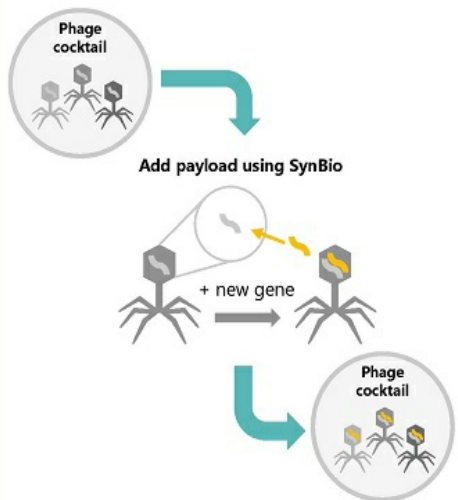
Results – Mice tumor qPCR analysis



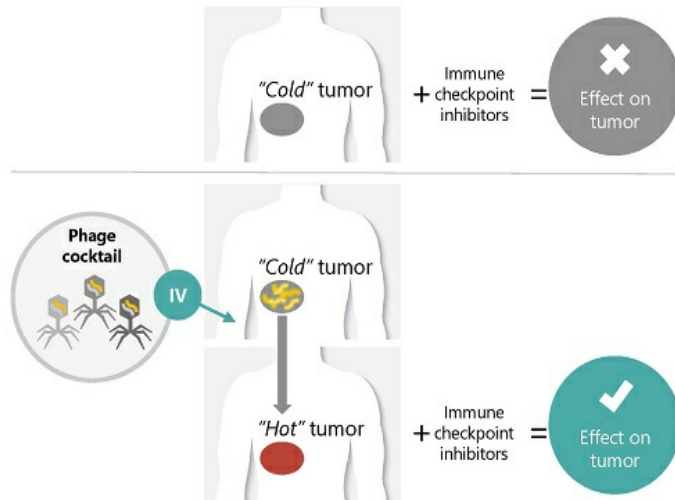
Detection of lysogenized intra-tumor *F. nucleatum* demonstrates that phage administered intravenously reached bacteria within the tumor microenvironment and integrated stably into the host bacteria genome

Engineered phage are designed to bring immune-stimulating payload to bacteria in tumors

Phage are designed to carry payloads to intra-tumor bacteria



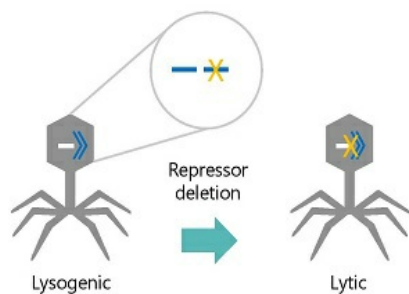
Phage cocktail with a payload turns cold tumors into hot



Multiple payloads added to phage using proprietary synthetic engineering approaches

Clinical F. nucleatum strain converted from lysogenic to lytic

Lysogenic to lytic



The engineered lytic phage was isolated and verified through NGS

Addition of payload to a clinical F. nucleatum strain underway

Examples of payloads



Immuno-stimulatory



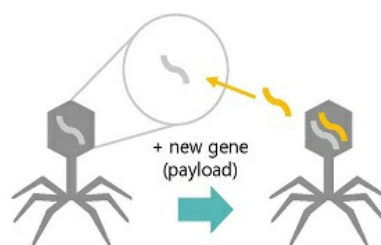
Immunogenic cell death



Prodrug converting

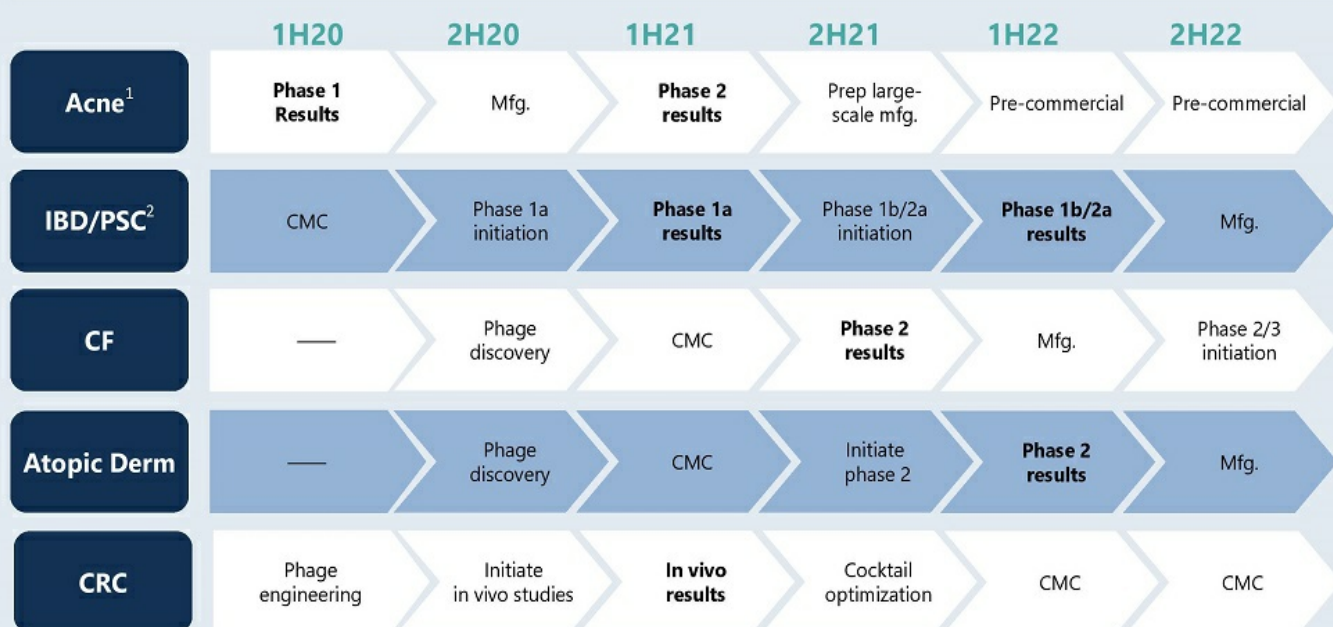


Angiogenesis inhibition



Source: Internal data

Key catalysts



Cash, cash equivalents and short-term deposits as of September 30, 2020: approximately \$64 million

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(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, Gbola Amusa, MD



Director, Jonas Grossman



Director, Alan Moses, MD



Director, Paul Sekhri



Director, Lynne Sullivan



Director, Jonathan Solomon





THANK YOU

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