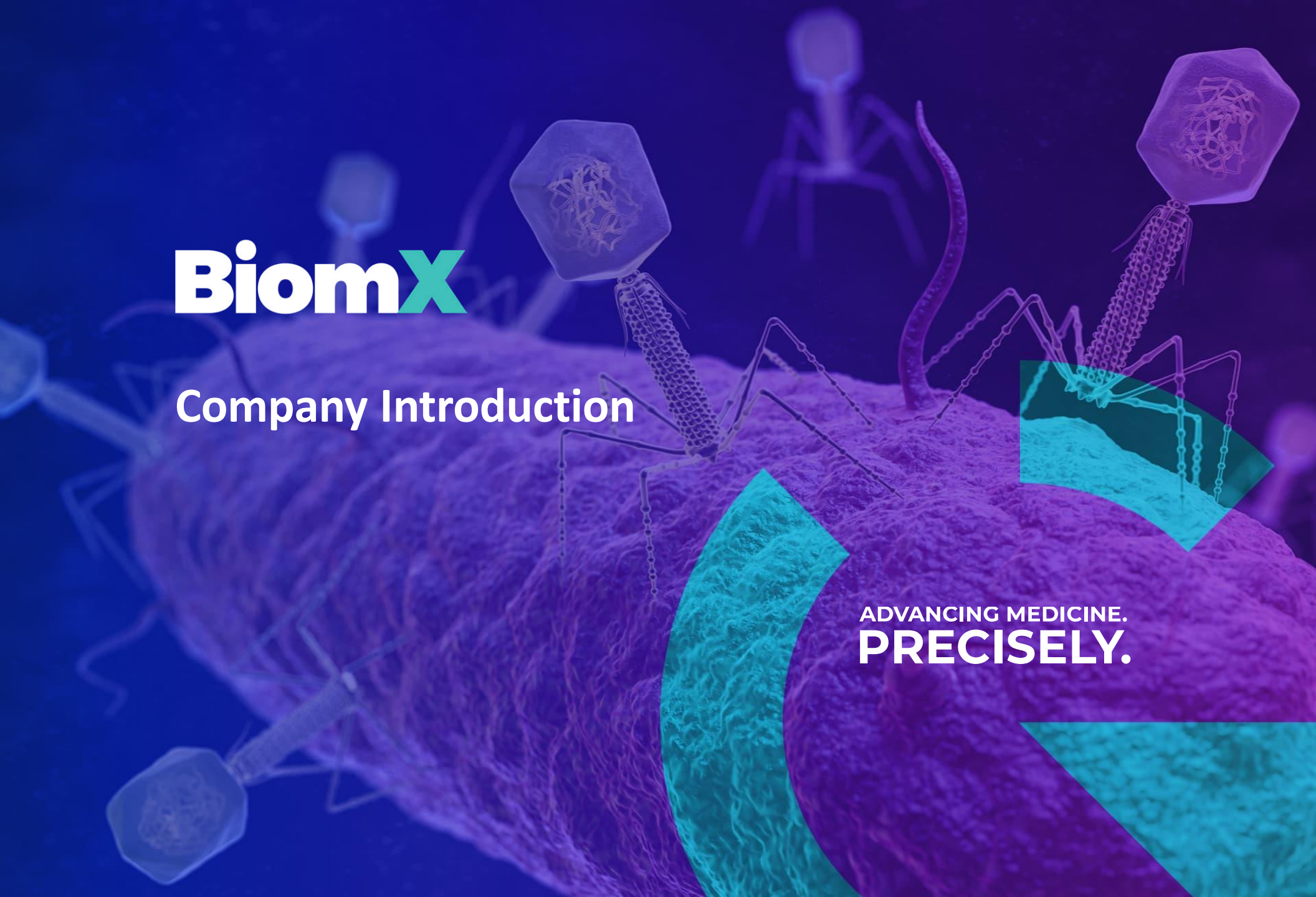

BiomX
Company Introduction
ADVANCING MEDICINE.
PRECISELY.

Safe Harbor Statement

This presentation contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on BiomX management's current beliefs, expectations and assumptions. When we discuss our 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.

BiomX

What we do

We develop disease modifying therapies based on natural or engineered phage cocktails as precision medicines to target and specifically destroy harmful bacteria

Bolt
BacteriOphage Lead to Treatment

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

* 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 – can support annually over 50 different phage at a clinical grade

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

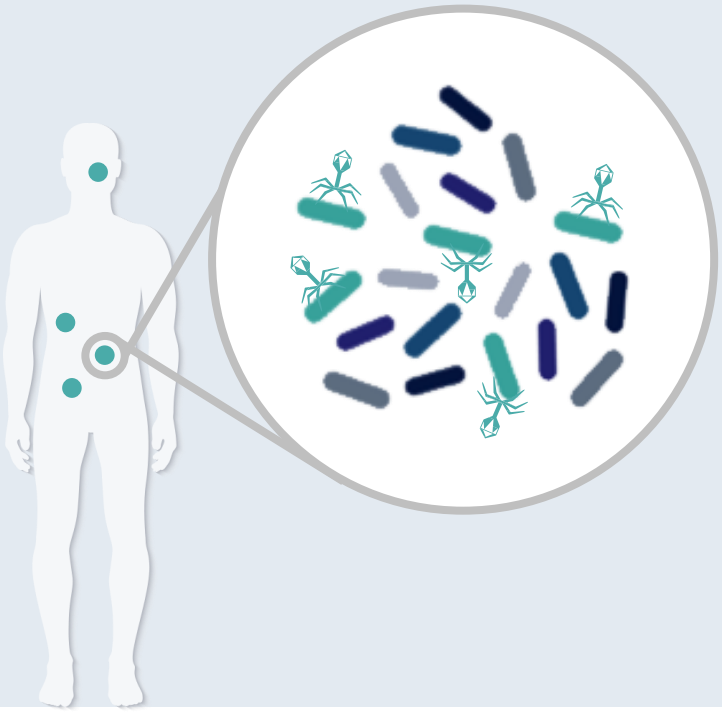
Financing and investors

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

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

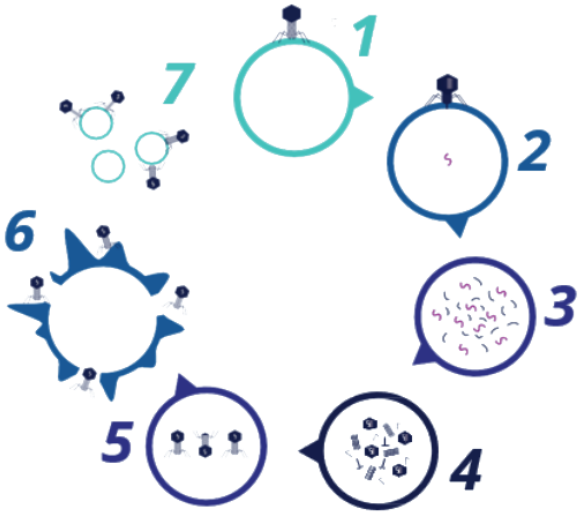
Phage: Nature's precision tool to target bacteria

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

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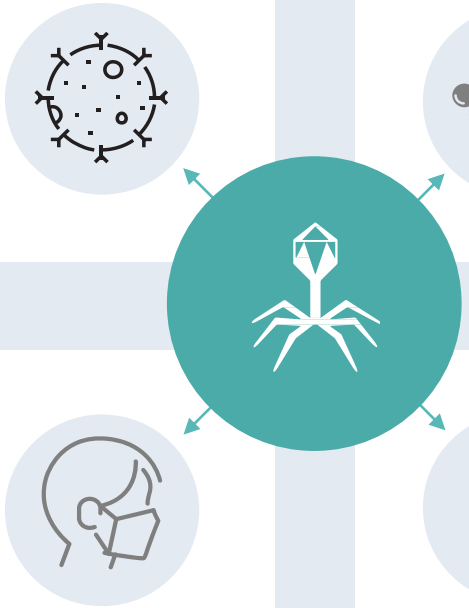
Multiple potential applications of phage therapy

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*

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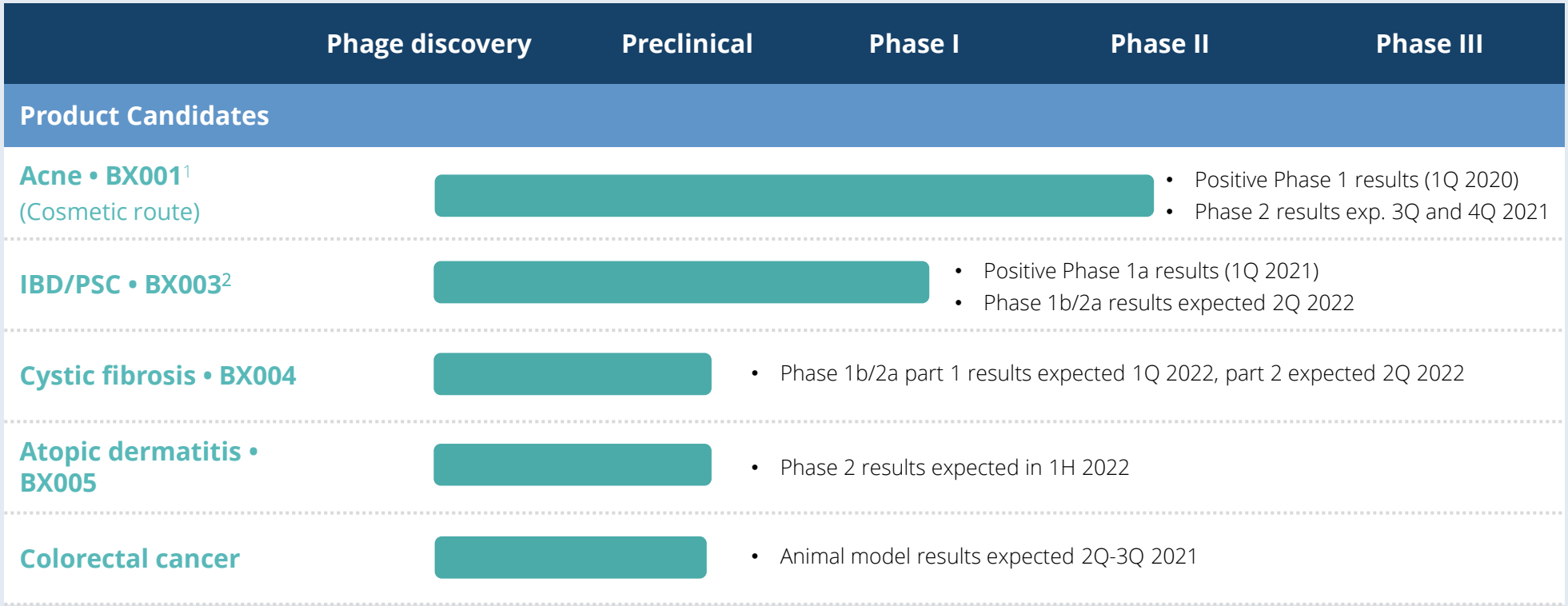
Pipeline



(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)

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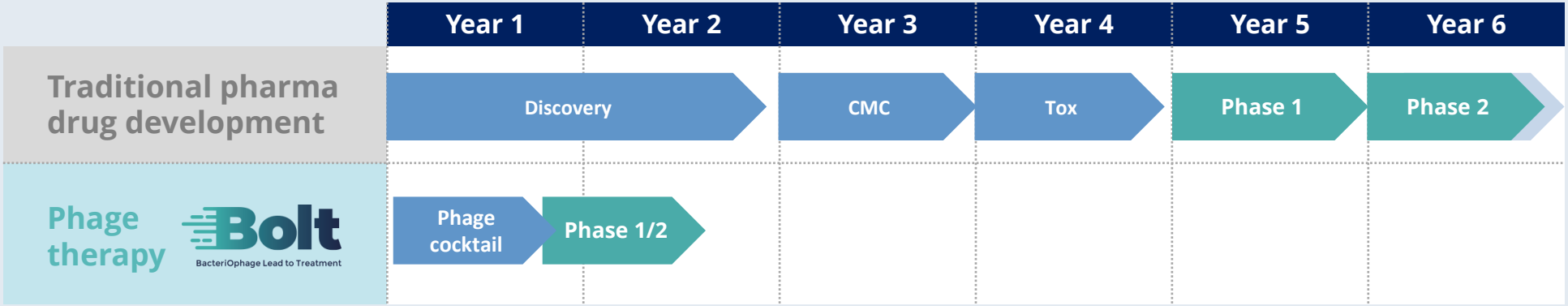
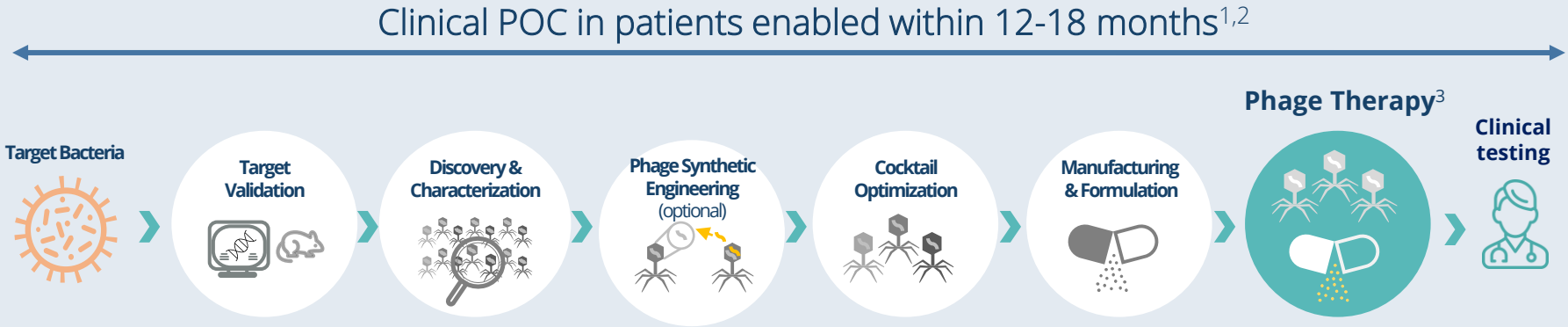
Our Bolt platform allows clinical POC within 12-18 months





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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

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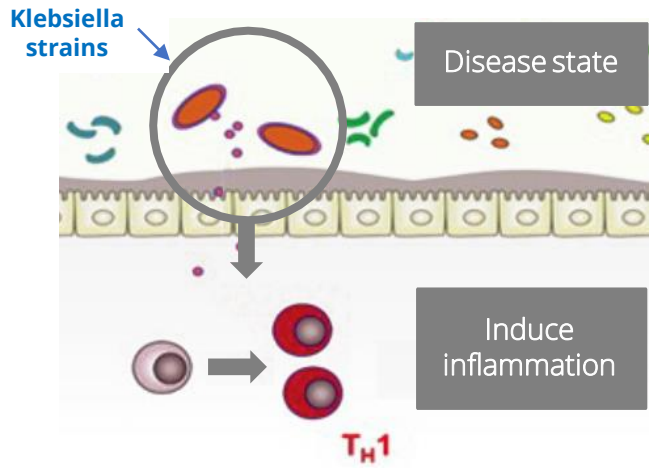
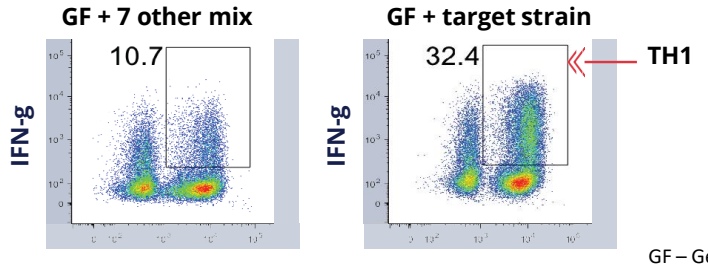
IBD · Identifying potential disease causing pro-inflammatory *Klebsiella* strains

Science AAAS

Pro-inflammatory *Klebsiella* strains affect IBD pathology



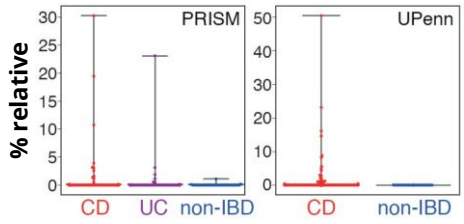
Inflammatory induction is seen in GF mice*



GF – Germ Free

Higher abundance of *Klebsiella* strains in IBD patients

Abundance of *Klebsiella* strains



CD – Crohn's disease
UC – Ulcerative colitis

Activity of bacterial target confirmed by BiomX

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*

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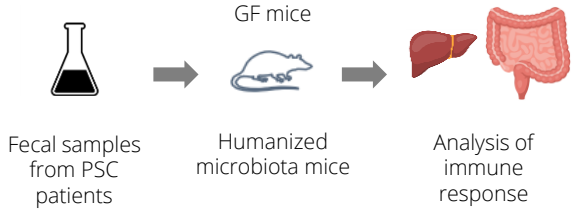
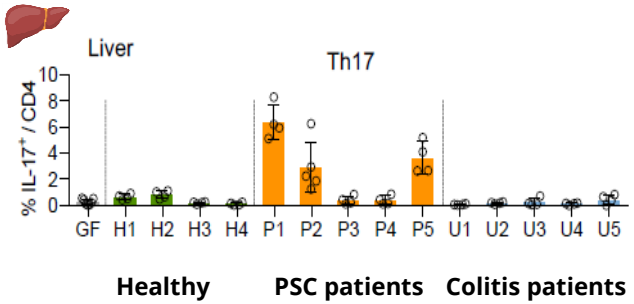
PSC • *Klebsiella* identified as possible driver of "leaky gut"

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*

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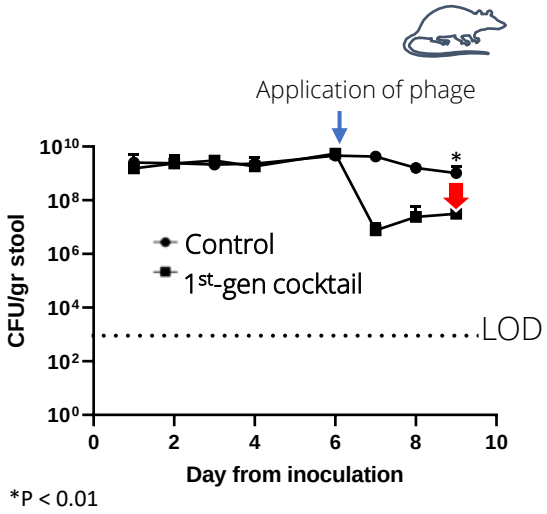
Phage cocktail composition drives activity

1st-generation phage cocktail (in-vivo)

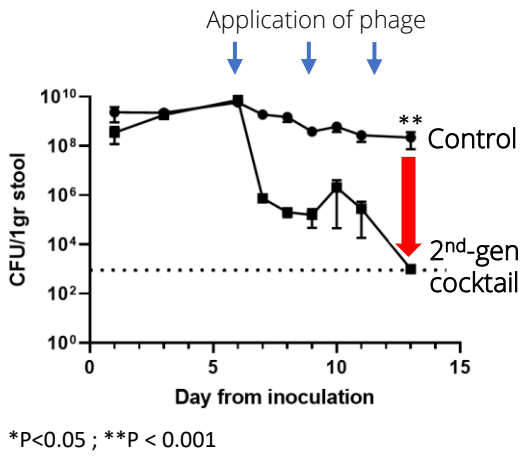
Fecal bacterial load



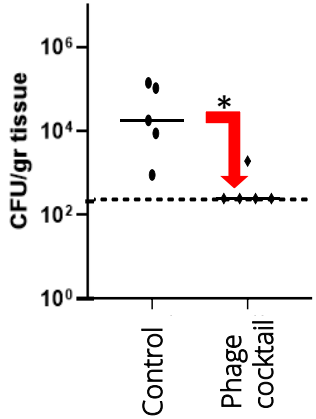
Adding 2 phage with new MOA

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

Fecal bacterial load



Mucosa



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

Source: Internal data

BiomX

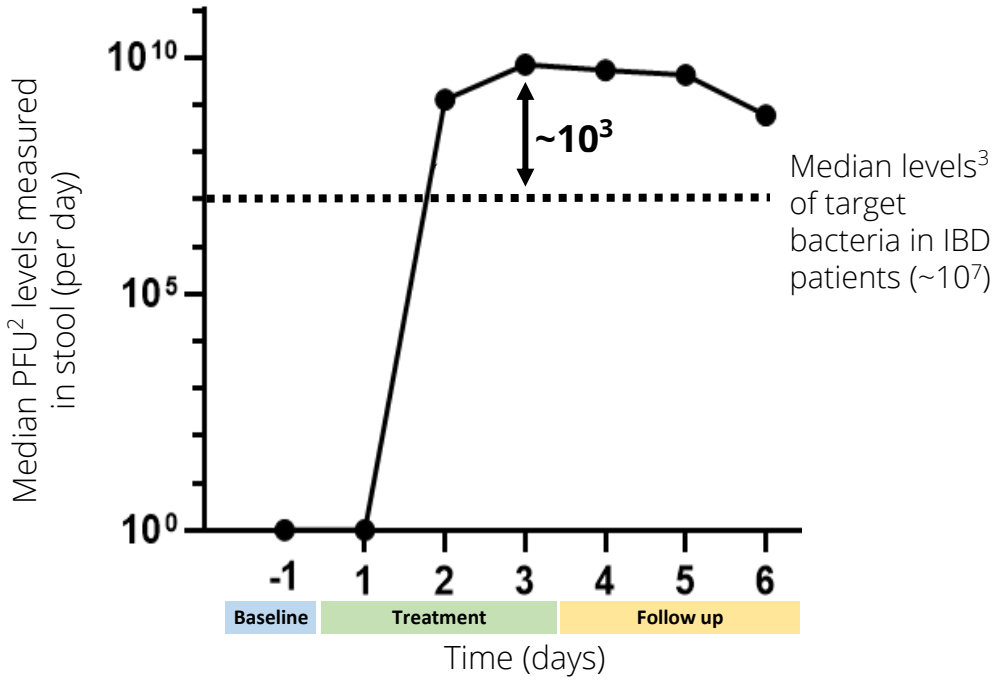
BX002: Phase 1a pharmacokinetic results demonstrate delivery of high levels of viable phage to the gut[1]

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.

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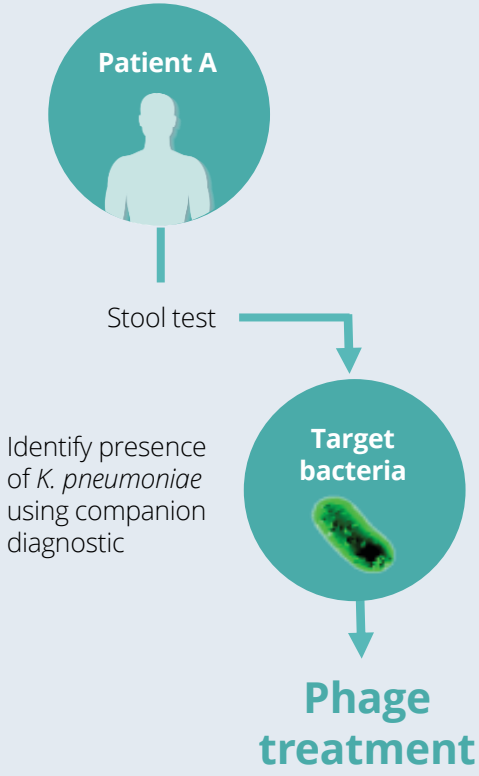
Phase 1b/2a study results expected in 2Q 2022

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.

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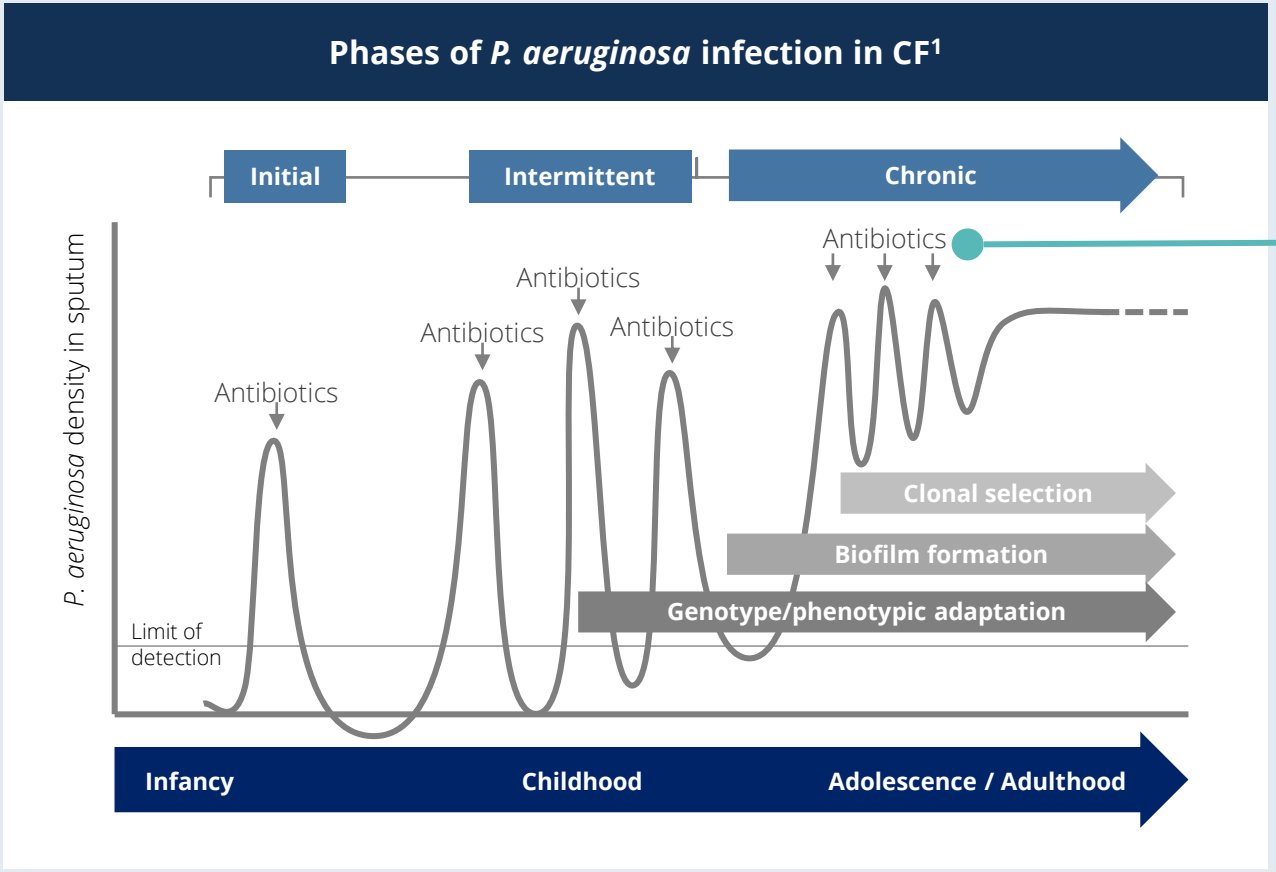
Cystic Fibrosis

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

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

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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

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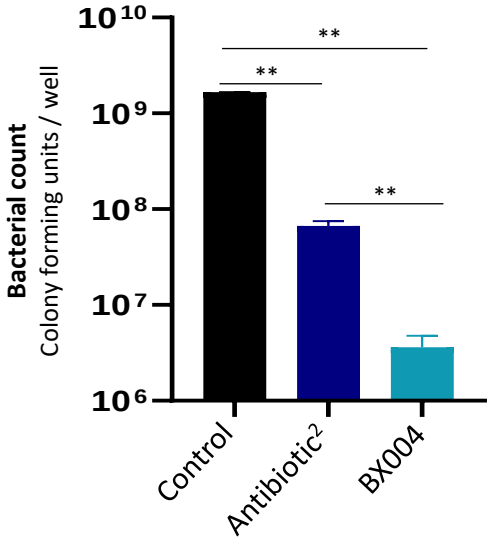
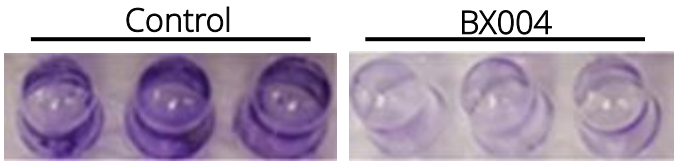
1 Kutateladze et al., 2008
2 Kvachadze et al., 2011
3 Law et al., 2019
4 Stanley et al., 2020

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

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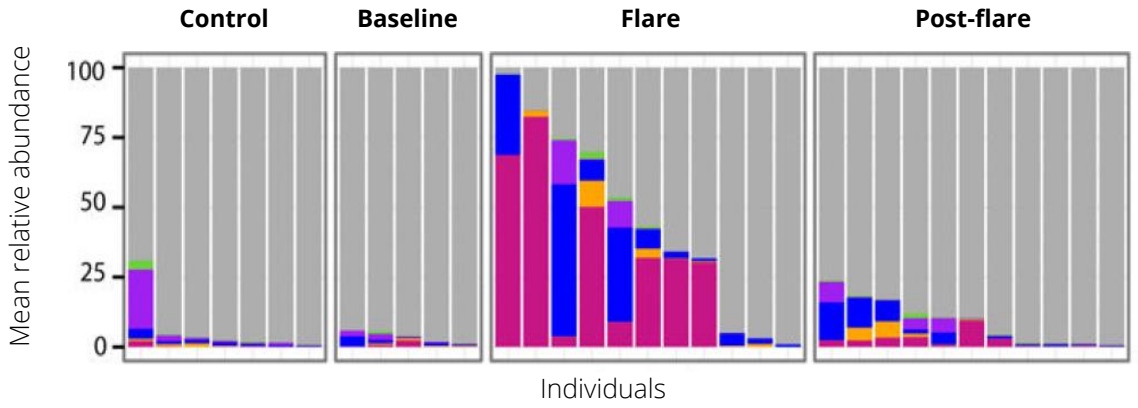
Atopic Dermatitis

Upcoming milestone: Phase 2 data expected in 1H 2022

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)

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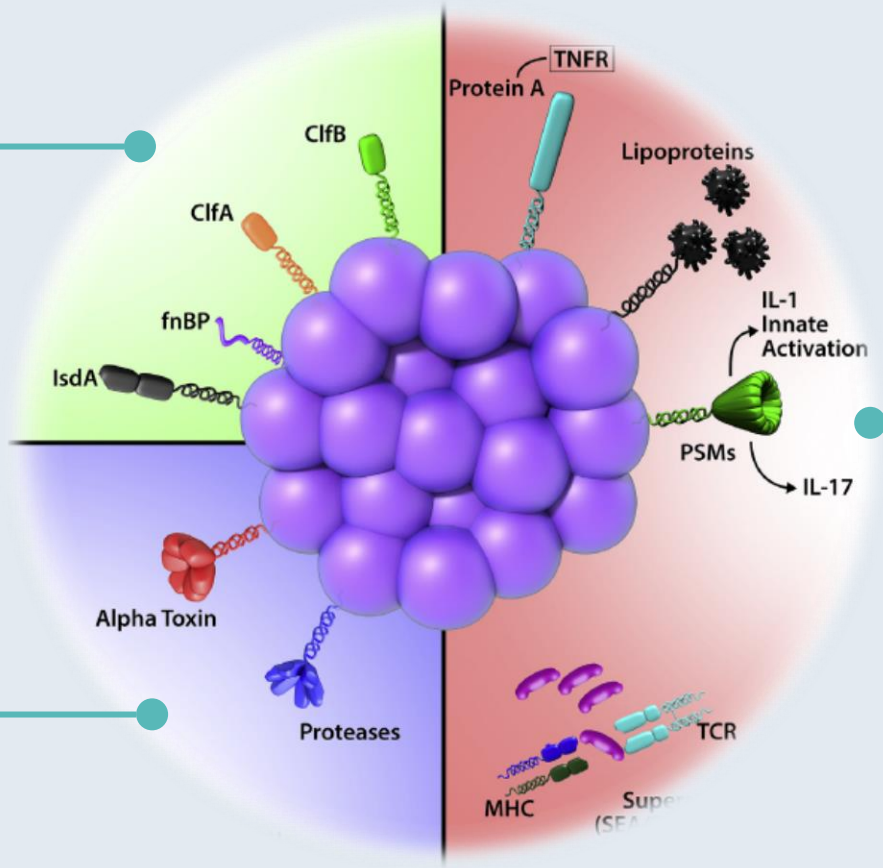
S. aureus contributed to pathogenicity through multiple virulence factors

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

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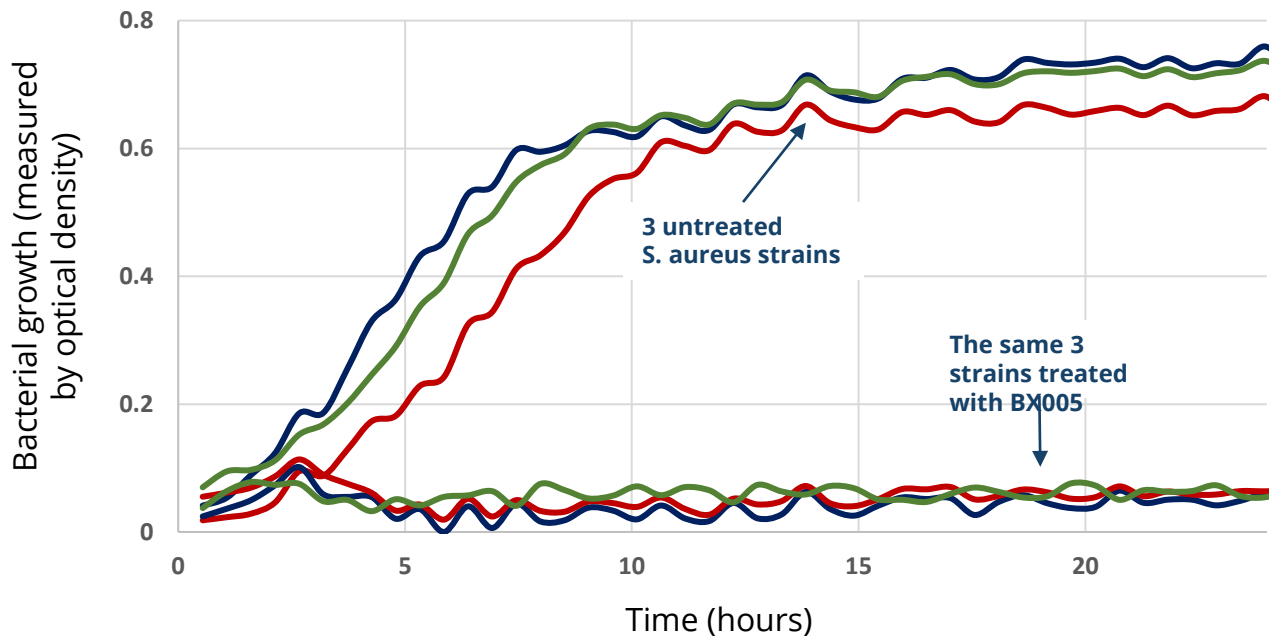
BX005 phage cocktail shows broad host range targeting of *S. aureus in vitro*

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

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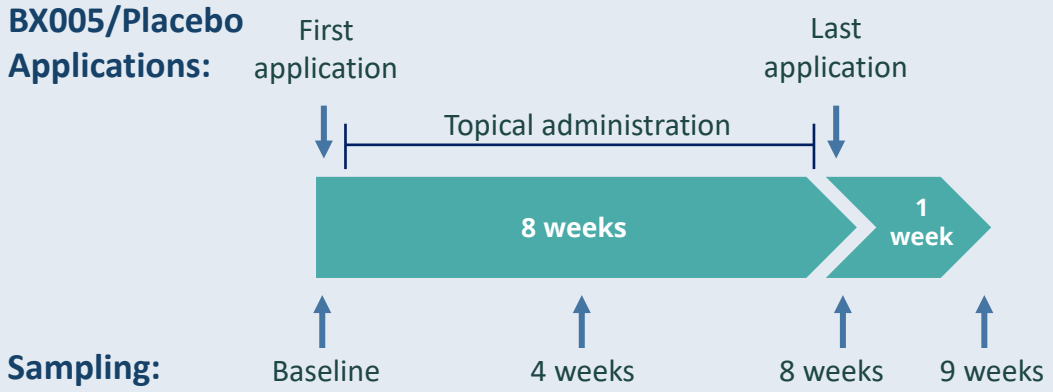
Phase 2 study results targeting *S. aureus* expected in 1H 2022

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)

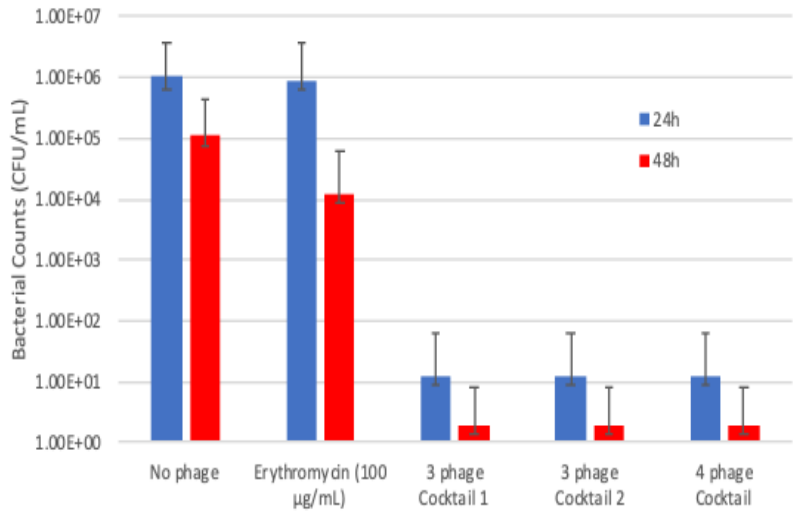
BX001: Phage cocktail attributes

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*

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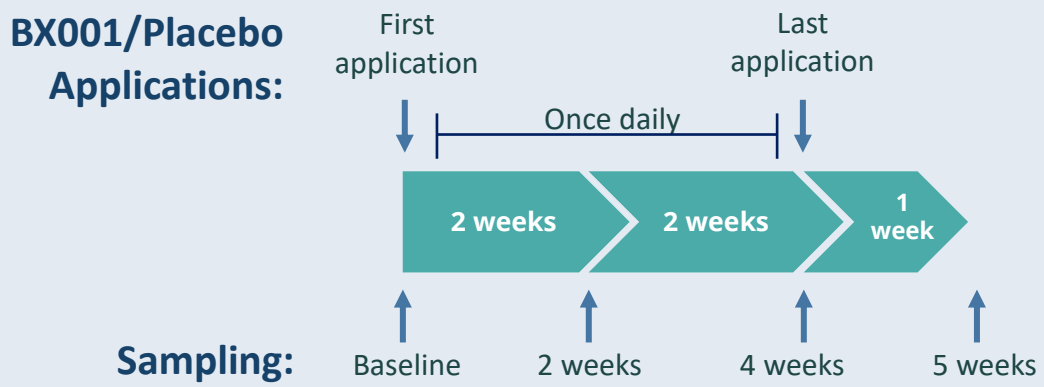
BX001: Phase 1 clinical trial design

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



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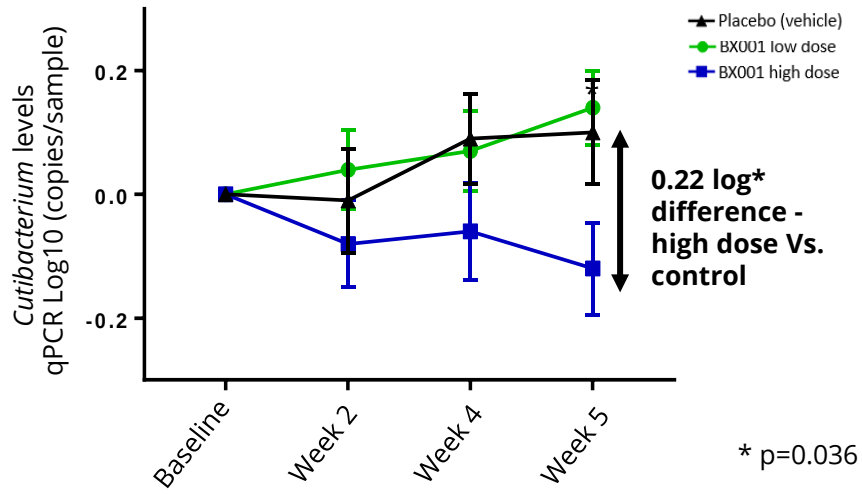
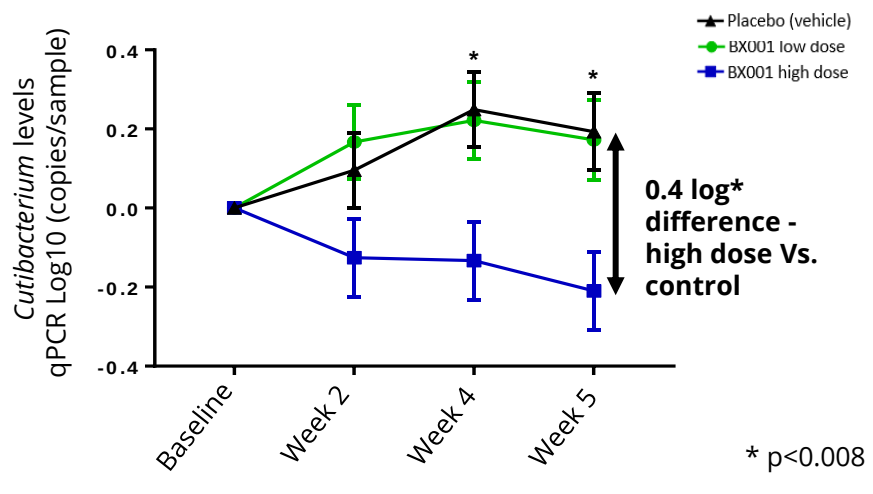
BX001: Phase 1 results demonstrate statistically significant reduction in *C. acnes* levels

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)

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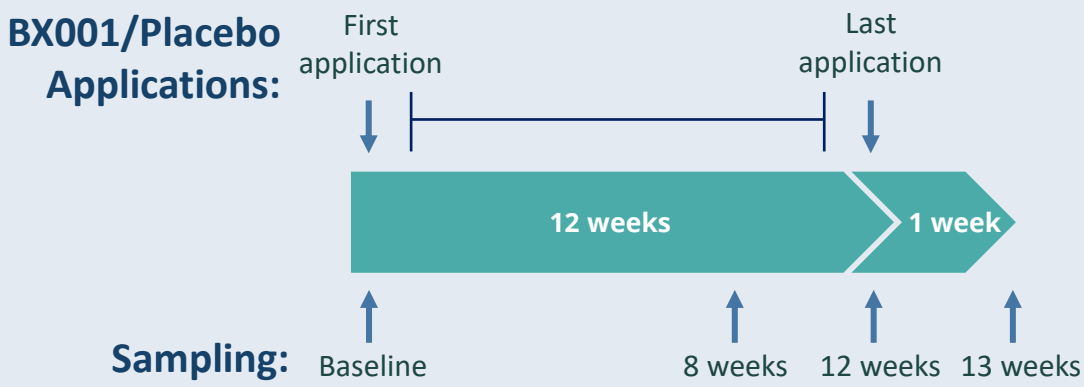
BX001 phase 2 cosmetic study results expected in 2H 2021

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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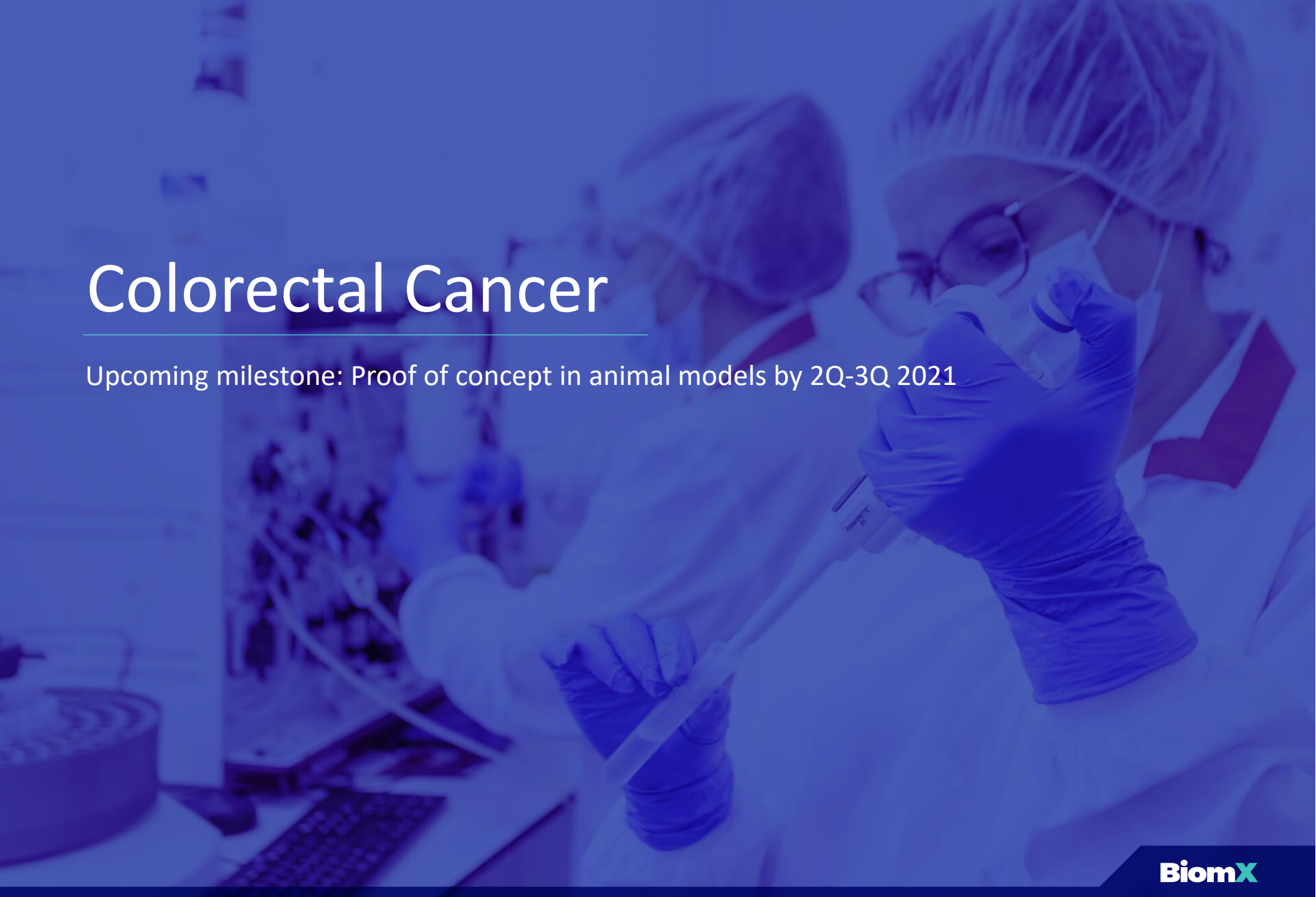
Colorectal Cancer

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



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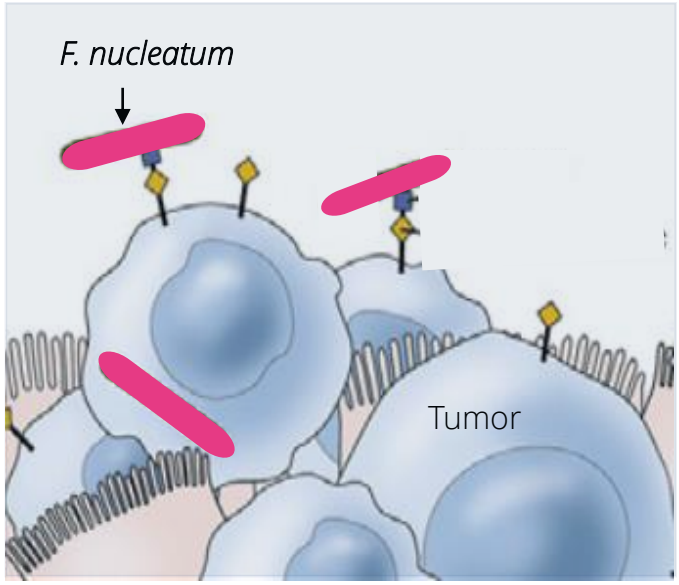
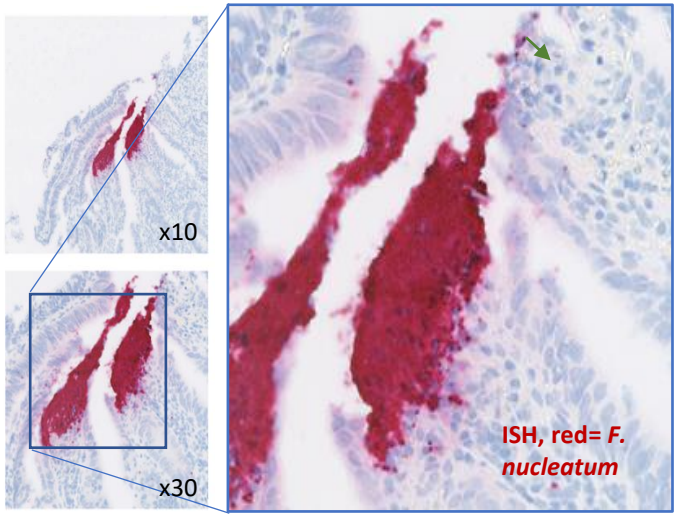
Bacteria residing inside tumors offer a novel targeted intervention to *"uncloak" t*umors to *"hot"*

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)

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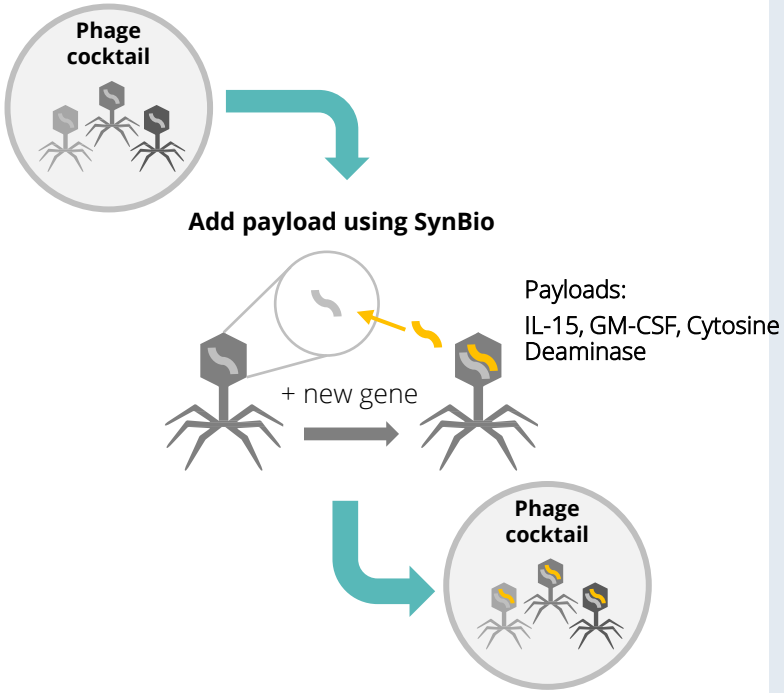
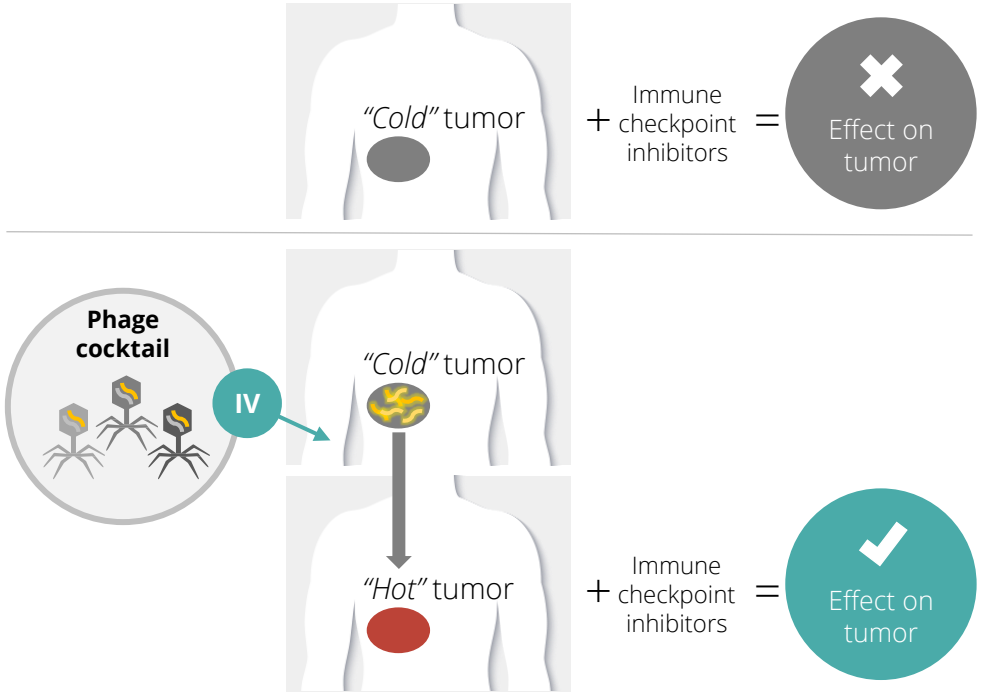
BiomX internal data
Li YY, Ge QX, Cao J, et al. (2016) World J Gastroenterol.
Bachrach et al. (2016), Cell Host & Microbe
Serna et al. (2020) Annals of Oncology
Kostic et al. (2013), Cell Host & Microbe

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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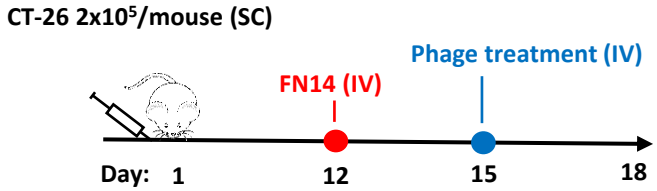
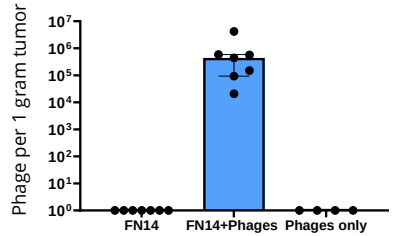
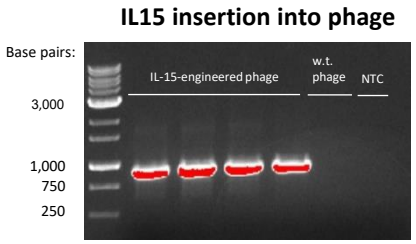
Key development milestones

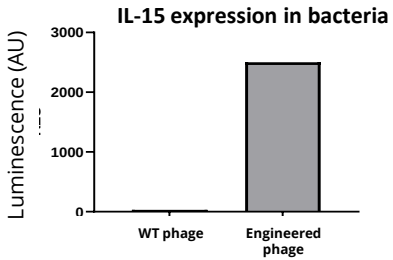
IV delivery of phage to intra-tumor bacteria (*in-vivo*)





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



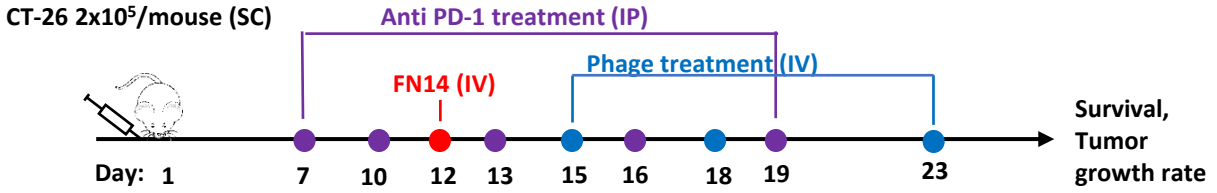


Planned 2Q-3Q 2021

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

Engineered Payloads:

IL-15, GM-CSF, Cytosine Deaminase



Source: Internal data

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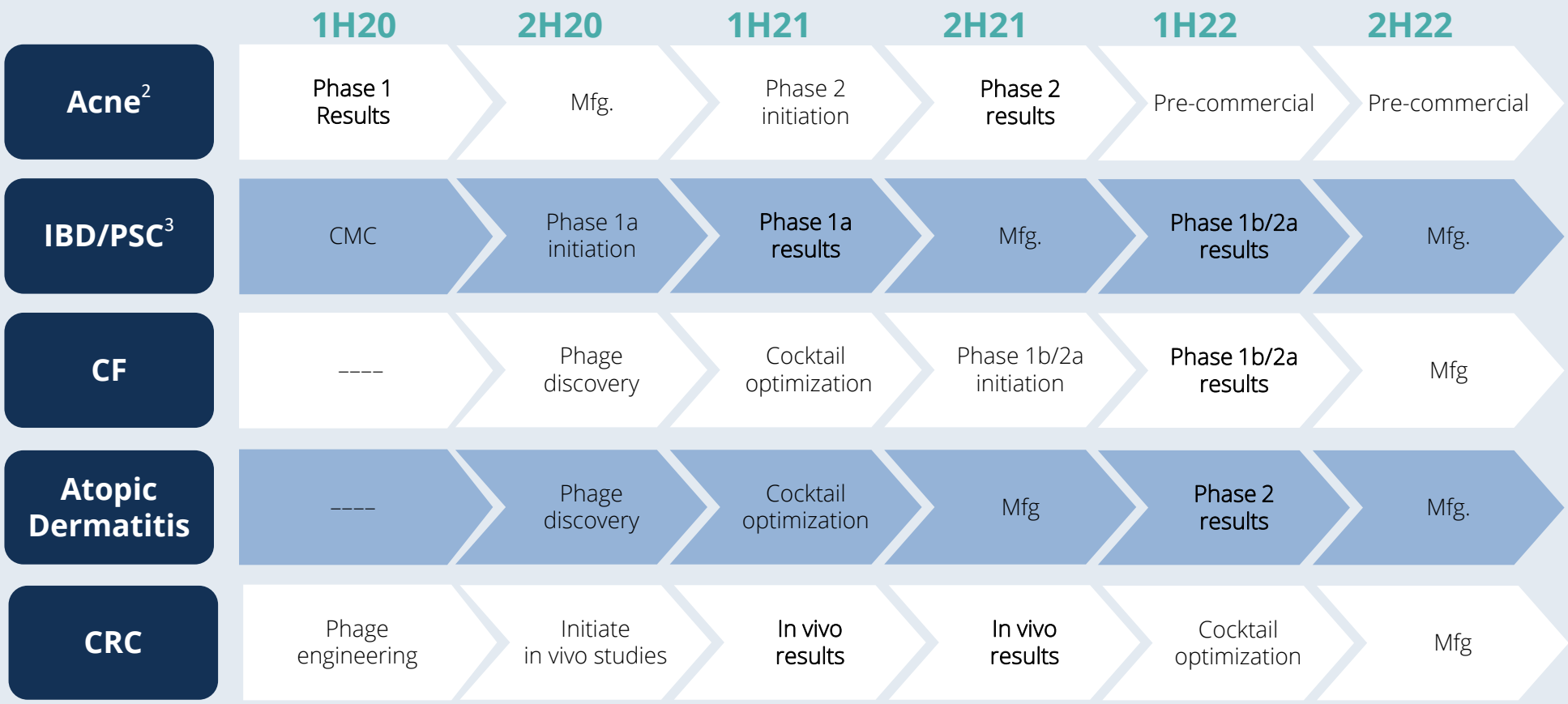
Key Catalysts: 4 Phase 2 readouts by mid 2022[1]



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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gsk SR·one

Director, Gbola Amusa, MD

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Director, Jonas Grossman

CHARDAN CAPITAL MARKETS · RAMIUS A Cowen Group Company

Director, Alan Moses, MD

novo nordisk · HARVARD MEDICAL SCHOOL

Director, Paul Sekhri

egenesis ENGINEERING LIFE · teva · NOVARTIS

Director, Lynne Sullivan

Biogen · ARTHUR ANDERSEN · UNITY BIOTECHNOLOGY

Director, Jonathan Solomon

BiomX · Proclara BIOSCIENCES

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THANK YOU
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