

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): January 9, 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 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 7.01 Regulation FD Disclosure.

On January 9, 2020 after this report is furnished, BiomX Inc. (the “Company”) will post an investor presentation to its website, in connection with upcoming investor meetings. A copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this report is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Items 7.01 and 9.01 of this report will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified as being incorporated therein by reference. The furnishing of the information in this report is not intended to, and does not, constitute a determination or admission by the Company that the information in this report is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company or any of its affiliates.

Forward-Looking Statements

Statements contained in the exhibit to this report relating to future plans, results, performance, expectations, achievements and the like contain 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 the Company 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 the Company’s control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. The Company undertakes no obligation to revise or update any forward-looking statements except as may be required by applicable law. Therefore, you should not rely on any of these forward-looking statements. You should review additional disclosures the Company makes in its filings with the Securities and Exchange Commission (the “SEC”), which are available on the SEC’s website at www.sec.gov.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Investor Presentation

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.

January 9, 2020

BIOMX INC.

By: /s/ Jonathan Solomon

Name: Jonathan Solomon

Title: Chief Executive Officer

The logo for BiomX, featuring the word "Biom" in a dark blue, bold, sans-serif font, followed by a large "X" in a teal color.

Company Introduction



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. 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.



Mission Statement



We develop precision medicines using both natural and engineered phage cocktails targeting harmful bacteria in chronic diseases and conditions such as acne, Inflammatory Bowel Disease, liver disease and cancer.

Unique Position as Leader in Phage Technology

Technology

- Phage discovery platform
- Proprietary synthetic biology capabilities
- Cutting-edge data science
- In-house manufacturing of customized phage cocktails



Pipeline

- Initial 4 programs: acne, IBD, PSC (a liver disease), colorectal cancer
- Phase I data in acne expected in Q1 2020
- Phase I data in IBD expected in H2 2020
- Phase I/II data in PSC expected in 2021

Exclusive access to novel targets

- Proprietary targets in IBD and PSC
- Target discovery and validation platform steered by cutting-edge research of scientific founders



Partnerships

- Acne collaboration with leading global cosmetic company
- Biomarker discovery in IBD for key Janssen (J&J) IBD drug



Leading life science and strategic investors

- On Oct. 2019 publicly listed (**NYSE:PHGE**) through a merger with \$60 million at closing






BiomX

Credentialed Leadership Team

Management Team

Jonathan Solomon CEO and Board Member	  
Assaf Oron CBO	  
Sailaja Puttagunta, MD CMO	    
Merav Bassan, PhD CDO	 

Scientific Founders

Prof. Rotem Sorek	
Prof. Eran Elinav	
Prof. Timothy K. Lu	



Credentialed Leadership Team

Board of Directors

Russell Greig, PhD



Rob Woodman, PhD



Erez Chimovits



Jonas Grossman



Gbola Amusa, MD



Yaron Breski



Lynne Sullivan



Growing Evidence of Role of Harmful Bacteria in Acne and Chronic Diseases

PSC

Klebsiella pneumoniae strains induce leaky gut and initiate liver inflammation and fibrosis

nature
microbiology

Nakamoto et al. (2019),
Nature Microbiology

Colorectal cancer

Reducing *Fusobacterium* load results in reduced cancer cell proliferation and tumor growth

Cell

Bullman et al. (2017),
Cell

Acne

Propionibacterium acnes is associated with acne vulgaris

JID
JOURNAL OF INVESTIGATIVE DERMATOLOGY

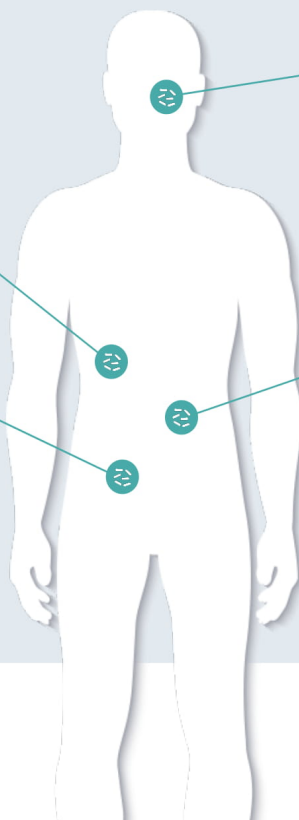
Fitz-Gibbon et al. (2013),
J Invest Dermatol

IBD

Klebsiella pneumoniae strains cause aberrant activation and stimulation of the immune system

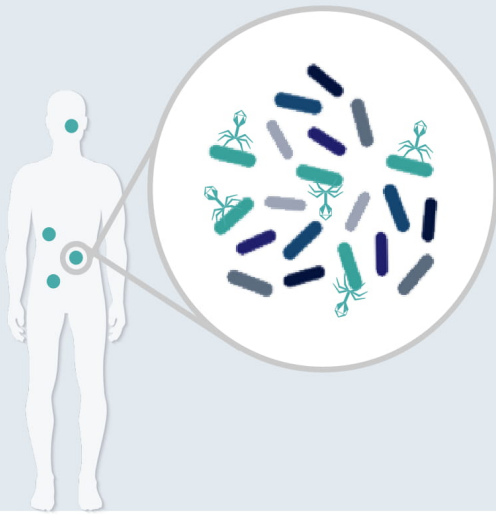
Science

Atarashi et al. (2017),
Science



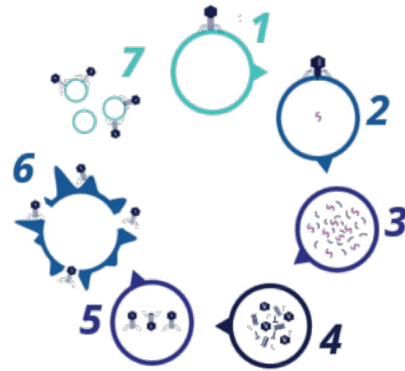
Phage: Nature's Precision Targeting Vector

Phage bind 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

Innovative Phage Technology Platform

Phage Hunting

- Sample sourcing
- Automated sample processing
- SynBio prophage extraction



Phage Engineering (SynBio)

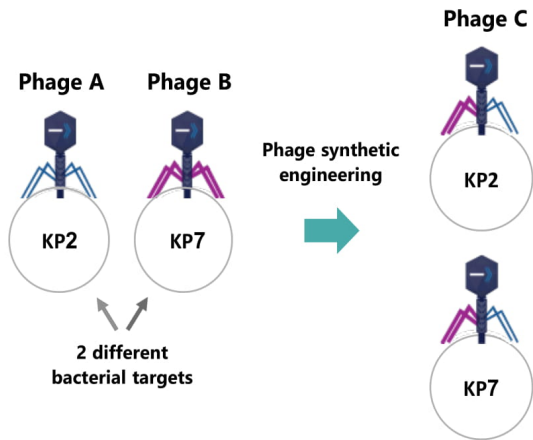
- Applied selectively when required
- Includes : Host range expansion, lysogenic to lytic conversion, payload incorporation

Cocktail Optimization

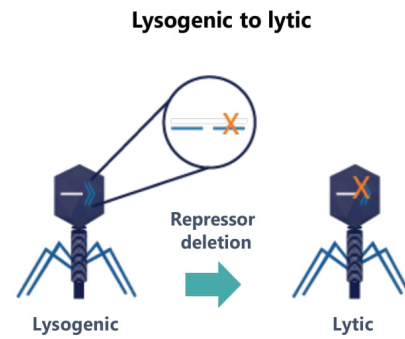
- Multi-dimensional optimization *in vitro* and *in vivo* for characteristics such as: host range, resistance and biofilm degradation

Proprietary Synthetic Biology Capabilities

Expanding phage host range against multiple targets




Switching phage mode of action from lysogenic to lytic



Source: Internal experiments

Pipeline

	Phage discovery	Preclinical	Phase I	Phase II	Partners
Product Candidates					
Acne • BX001⁽¹⁾	<div></div>		<ul style="list-style-type: none"> Phase I results expected 1Q20 Phase II results expected 2H20 		Global cosmetics company
IBD • BX002	<div></div>		<ul style="list-style-type: none"> Pre-IND meeting held 2H19 Phase I results expected 2H20 		
PSC • BX003	<div></div>		<ul style="list-style-type: none"> Pre-IND meeting expected 2H20 Phase I/II results expected 2H21 		
Colorectal cancer	<div></div>				
	Biomarker discovery	Validation	Development		
Diagnostics					
IBD (responder/non-responder)	<div></div>				janssen 

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

BiomX

Acne • BX001 Natural Phage Cocktail Attributes

- Active against 96% of tested *P. 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

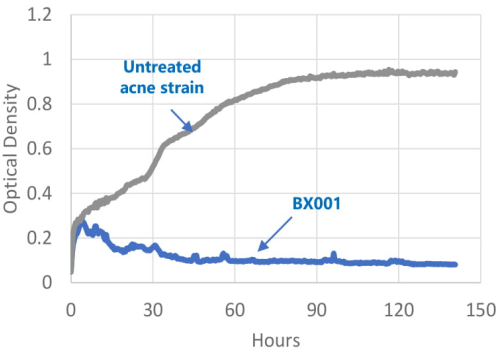
BX001
A topical gel containing
natural phage against
P. acnes to modulate skin
microbiome



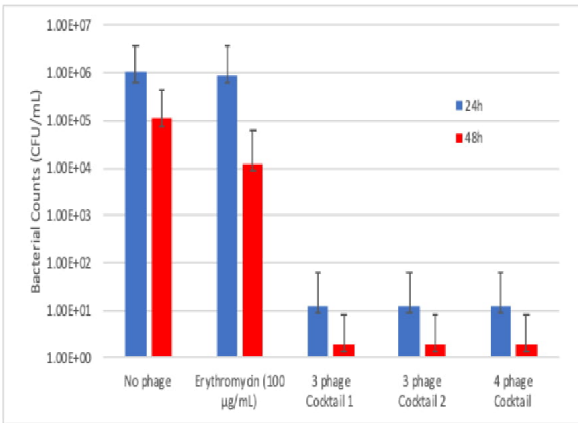
Sources: Internal experiments;

Acne • BX001 Preclinical Results

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



Phage cocktails penetrate biofilm (in-vitro)

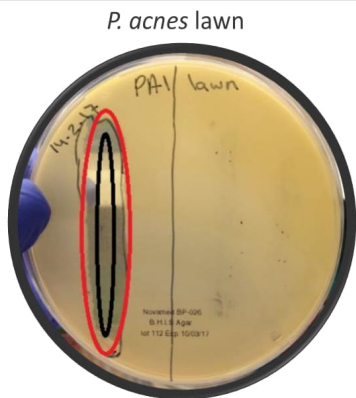


Source: Internal experiments



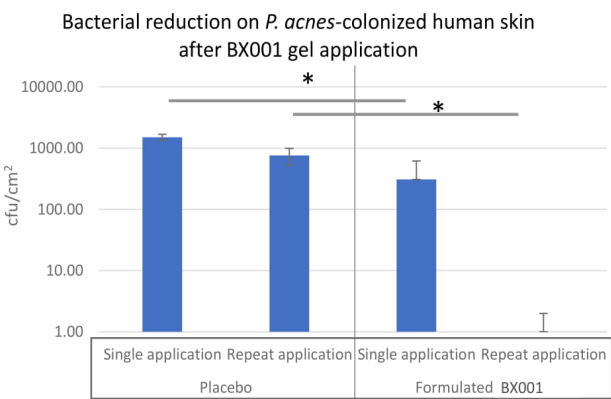
Acne • BX001 Preclinical Results

Release of active phage from BX001 gel
on *P. acnes* bacterial lawn eradicated *P. acnes*



Black: Where gel with BX001 was applied
Red: Area of phage activity (eradicated *P. acnes*)

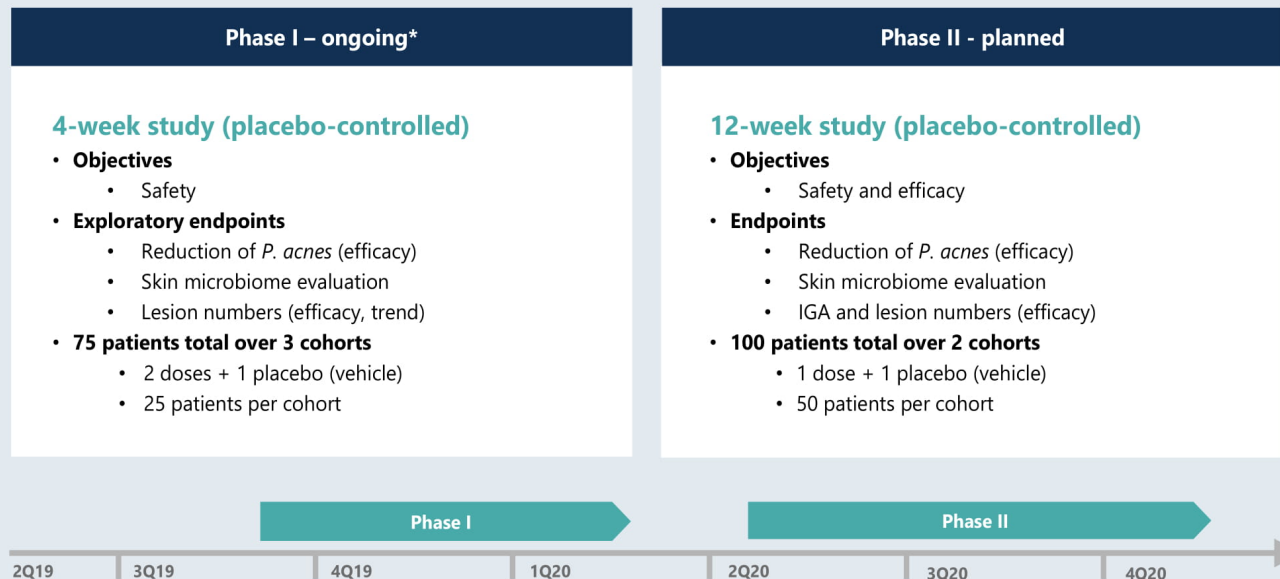
Release of active phage from BX001 gel on *P. Acnes* – artificially
infected human skin



*P<0.05

Source: Internal experiments

Acne • BX001 Clinical Trial Design

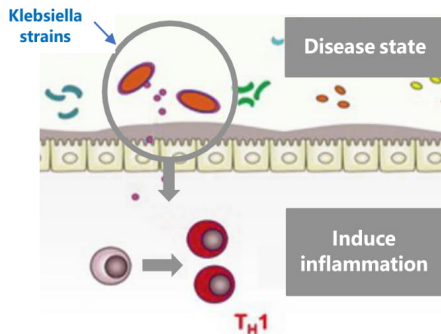


**An additional smaller single blinded, single application, placebo-controlled clinical trial to evaluate alternative methods of topical application is being conducted and expected to be completed in 1Q2020.*

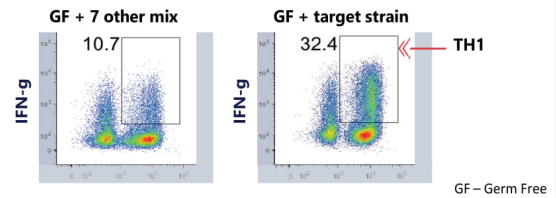
IBD • Targeting Harmful Pro-inflammatory *Klebsiella* Strains

Science

Pro-inflammatory *Klebsiella* strains affect IBD pathology

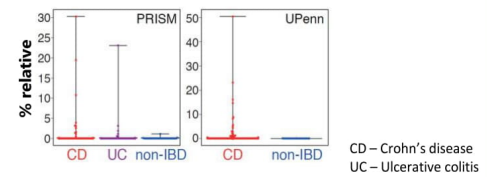


Inflammatory induction is seen in GF mice*



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

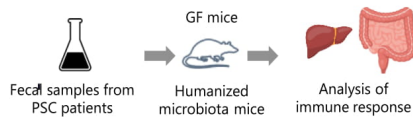
* TH1 – A lineage of CD4+ effector T cell secreting IFN γ and TNF. In IBD, TH1 cells accumulate in the intestinal tract of IBD patients and are directly associated with disease

BiomX

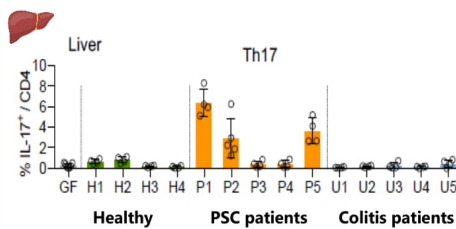
PSC • *Klebsiella* Identified as Novel Pathobiont*

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-gnotobiot	ND		ND
PSC/UC-gnotobiot	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

* Pathobiont – potentially pathological organism that under normal conditions lives as a non-harming symbiont

**TH17 – A lineage of CD4⁺ effector T cell secreting IL17A⁺, promoting inflammation and fibrosis within the liver

BiomX

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

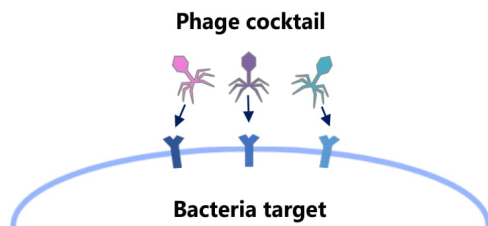
- Evidence that manipulation of microbiome impacts the disease
- Abnormal high abundance of bacteria found in bile fluid of patients
- Most PSC patients suffer from ulcerative colitis

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

Source: NEJM 2016, PSC Review, LaRusso and Lazaridis

IBD • BX002 Cocktail Designed to Address Resistance by Using Phage Cocktails

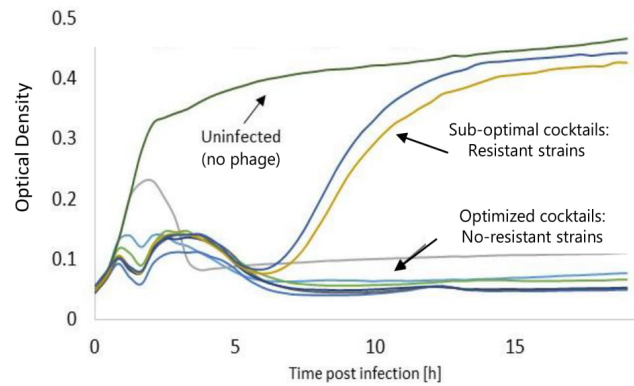
How a phage cocktail overcomes resistance



Phage cocktails are rationally optimized to prevent resistance by targeting multiple bacterial receptors and defense mechanisms

Infection dynamics of phage cocktails (*in vitro*)

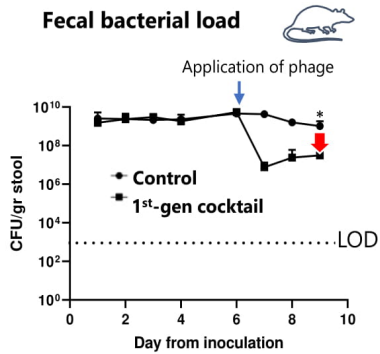
Comparing various phage cocktail combinations



Source: Internal experiments

IBD • BX002 Cocktail Composition Drives Activity

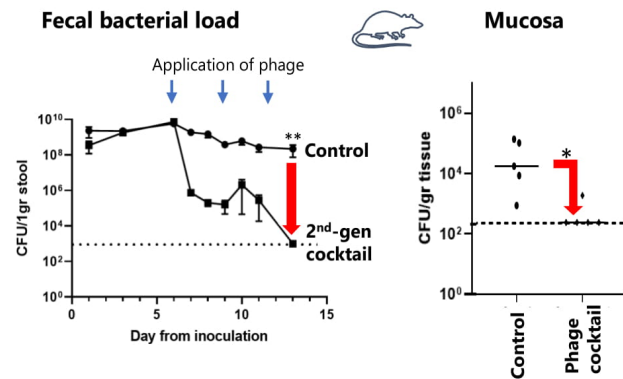
1st-generation phage cocktail (in-vivo)



*P < 0.01

Adding 2
phages with
new MOA

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



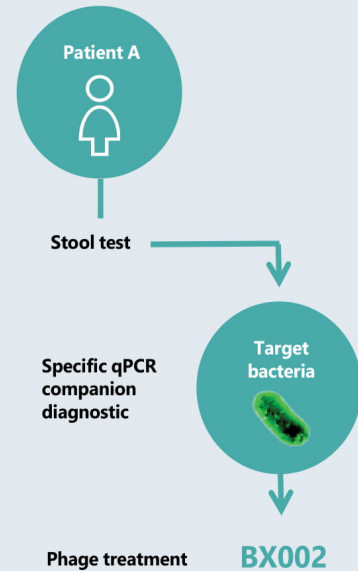
*P<0.05 ; **P < 0.001

Source: Internal experiments

BiomX

IBD • Planned Clinical Development - Phase 1

Study	Phase 1a/b
Study objectives	<ul style="list-style-type: none">▪ Primary:<ul style="list-style-type: none">• Safety and tolerability of orally-administered BX002▪ Secondary:<ul style="list-style-type: none">• Reduction of target bacteria levels in stool• Evaluation of microbial composition in stool▪ Exploratory:<ul style="list-style-type: none">• Local inflammatory
Population	<ul style="list-style-type: none">▪ Target bacteria carriers – patients or healthy individuals
Cohorts	<ul style="list-style-type: none">▪ 30-45 patients across 3 cohorts▪ 2 dose levels + placebo (vehicle)▪ 10-15 patients per cohort
Treatment route, duration	<ul style="list-style-type: none">▪ Oral route▪ 4 weeks, daily administration

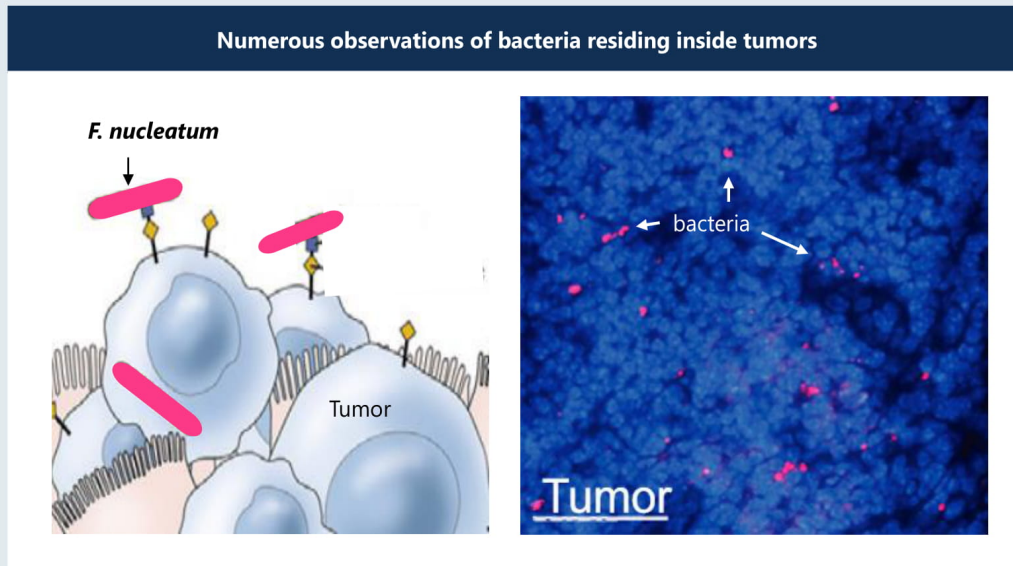


CRC • Most Colorectal Cancer (CRC) Patients Do Not Respond to Immunotherapy



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

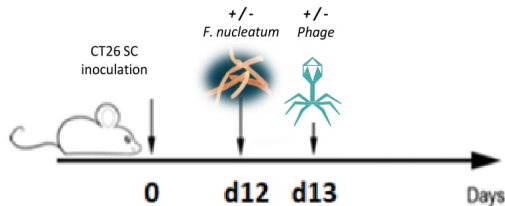
CRC • Bacteria Residing Inside Tumors Offer a Novel Targeted Intervention to “Uncloak” Tumors to “Hot”



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

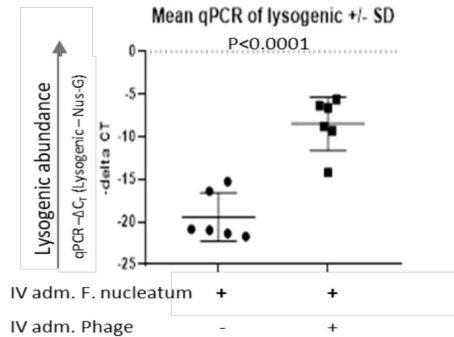
CRC • IV Delivery of Phage to Intra-tumor Bacteria has been Demonstrated

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

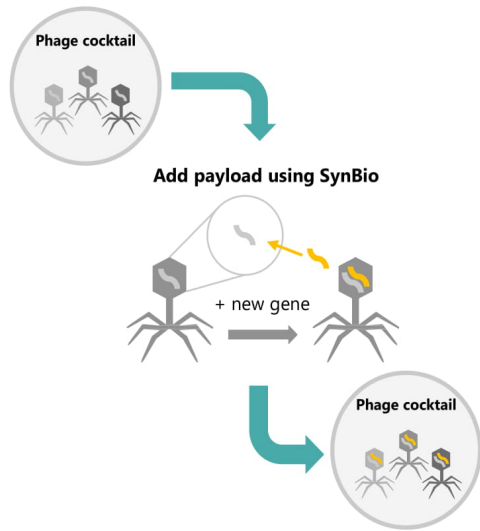


Detection of lysogenized intra-tumor *F. nucleatum* demonstrates phage delivered IV reached bacteria within tumor microenvironment and integrated stably into host bacteria genome

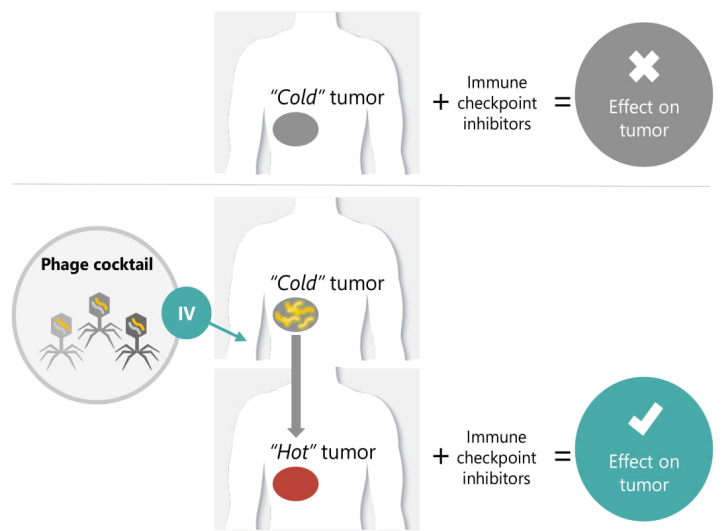
Source: Internal experiments

CRC • Engineered Phage Designed to Bring Immune-stimulating Payload to Bacteria in Tumors

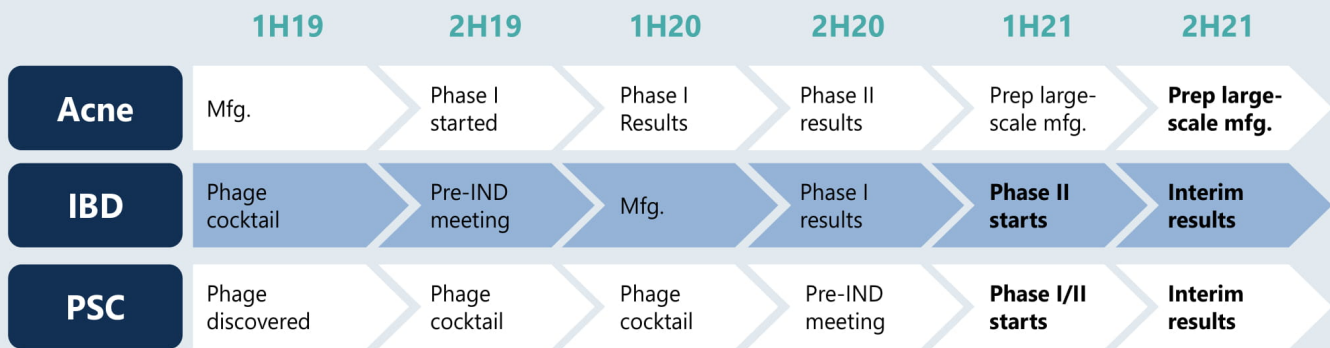
Phage are designed to carry payload targeting intra-tumor bacteria



Phage cocktail with a payload turns cold tumors into hot



Key Catalysys



Cash and cash equivalents as of Nov. 29th 2019: \$85 million

BiomX

Thank you

