

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

Form 8-K

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

Date of Report (Date of earliest event reported): May 14, 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 May 14, 2020, BiomX Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2020. A copy of the press release issued in connection with the announcement is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Item 7.01 Regulation FD Disclosure.

The Company from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On May 14, 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 attached to this Current Report on Form 8-K as Exhibit 99.2. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information in this report is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in Items 2.02, 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release dated May 14, 2020
99.2	Investor Presentation dated May 14, 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.

May 14, 2020

BIOMX INC.

By: /s/ Jonathan Solomon

Name: Jonathan Solomon

Title: Chief Executive Officer



BiomX Reports First Quarter 2020 Financial Results and Provides Business Update

Positive Phase 1 cosmetic clinical study results of BX001 in acne-prone skin reported; planned advance to Phase 2 study with readout expected in the second quarter of 2021

Initial BX002 Phase 1 clinical study readout in inflammatory bowel disease expected in the fourth quarter of 2020

Cash and equivalents of \$75.3 million expected to fund current operating plan for at least 24 months

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

Ness Ziona, Israel – May 14, 2020 – BiomX Inc. (NYSE: PHGE), a clinical-stage company developing natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the first quarter ended March 31, 2020.

“The highlight of the first quarter was the exciting positive topline data from our Phase 1 study of our lead candidate BX001 in subjects with acne-prone skin. Both doses of BX001 demonstrated excellent safety and tolerability, and the higher dose achieved a statistically significant reduction in target bacteria. These results represent an important step for the development of phage as a new modality – as proof of concept of phage’s potential to target bacteria in a safe and tolerable manner in a clinical setting,” said Jonathan Solomon, BiomX Chief Executive Officer. “We are very much looking forward to advancing BX001 into the Phase 2 program, as well as progressing our pipeline in inflammatory bowel disease (IBD), and primary sclerosing cholangitis (PSC).”

Following positive Phase 1 cosmetic clinical study results in acne-prone skin, the Company is advancing BX001 to a Phase 2 cosmetic clinical study, with a readout expected in the second quarter of 2021. The Phase 2 study in acne-prone skin is planned to be a 12-week randomized, double-blind, placebo-controlled trial in 100 individuals with mild-to-moderate acne. Enrolled individuals will be randomized into one of two cohorts: BX001 or placebo (vehicle). Findings from additional post hoc analyses of the Phase 1 data identified that several subject populations with a higher bacterial load at baseline, and also those with characteristics associated with a higher bacterial load at baseline, such as higher sebum levels, had an earlier and more pronounced reduction of *Cutibacterium acnes* (*C. acnes*) levels after BX001 treatment when compared to placebo (vehicle). Higher levels of bacteria result in an increased probability of interactions with phage, thereby potentially leading to a greater effect. As a result the Company plans to enrich the Phase 2 study subject population for these characteristics.

BiomX continues to drive forward its development programs in IBD and PSC, a rare liver disease. The Company expects to initiate the first-in-human Phase 1 clinical study of BX002 in IBD in 2020 and report pharmacokinetic and safety data from the study in healthy volunteers by the fourth quarter of 2020.

COVID-19 Update

In light of the evolving COVID-19 pandemic, BiomX has implemented recommended measures to safeguard the health and safety of its employees and the continuity of its business operations. Due to these precautions, along with challenges in clinical trial enrollment due to COVID-19, BiomX's guidance on the timing of certain clinical milestones has evolved. Updates to key upcoming milestones are detailed below.

Recent Highlights

- **Announced positive topline data from the Phase 1 cosmetic clinical study of BX001 in subjects with acne-prone skin.** In March 2020, BiomX announced that the study met its primary endpoint of safety and tolerability for both doses of BX001, with the high-dose BX001 treatment group achieving a statistically significant (p=0.036) reduction of *C. acnes* levels compared to placebo.
- **Announced dual listing on the Tel Aviv Stock Exchange (TASE).** In February 2020, the Company's common stock began public trading on the TASE.

Key Upcoming Milestones

- **Results from the Phase 2 cosmetic clinical study of BX001 expected in the second quarter of 2021.**
- **Results from the first-in-human Phase 1a study of BX002 in IBD expected in the fourth quarter of 2020.** The Phase 1a study will be conducted in healthy volunteers to provide pharmacokinetic and safety data. The Phase 1b/Phase 2a study will evaluate the eradication of the target bacteria, *Klebsiella pneumoniae*, in subjects carrying the identified bacteria with results expected in the second half of 2021.
- As the PSC program shares the same bacterial target (*Klebsiella pneumoniae*) as the IBD program, **BiomX plans to apply the Phase 1 study results in IBD to inform the PSC program, with the intention of progressing into Phase 2 development in PSC in 2022.**
- **Proof of concept in animal models in colorectal cancer by the second quarter of 2021.** BiomX' colorectal cancer program utilizes engineered phage with various payloads (such as immunostimulatory payloads) that target *Fusobacterium nucleatum* bacteria residing in the tumors of patients with colorectal cancer.

First Quarter 2020 Financial Results

- **Cash balance and short-term deposits as of March 31, 2020,** were \$75.3 million, compared to \$82.3 million as of December 31, 2019. The decrease was primarily due to net cash used in operating activities.
- **Research and development expenses** were \$3.9 million in the first quarter of 2020, compared to \$2.7 million in the same period of 2019. The increase was primarily due to the manufacturing of BX001 and BX002, the Company's product candidates for acne-prone skin and IBD, respectively, and the BX001 Phase 1 study.
- **General and administrative expenses** were \$2.1 million in the first quarter of 2020, compared to \$1.0 million in the same period in 2019. The increase was mostly due to expenses associated with public company infrastructure.
- **Net loss** was \$5.9 million in the first quarter of 2020, compared to \$3.2 million in the same period of 2019.
- **Net cash used in operating activities** of \$6.7 million in the first quarter of 2020, compared to \$3.0 million in the same period of 2019.

Financial Expectations

- The Company believes that its existing cash, cash equivalent and short-term deposits will be sufficient to fund its current operating plan for at least 24 months.

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 first quarter of 2020 and provide business updates. To participate in the conference call, please register at <http://dpregrister.com/10144165> ahead of the call to receive dial-in information or please dial 1-866-777-2509 for participants based in the United States, 1-412-317-5413 for participants based outside the United States, or 1-80-9212373 for participants based in Israel and ask to be joined into the BiomX first quarter earnings conference call. A live webcast of the call will be available on the Investors section of the BiomX website and a replay will be available after its completion.

About the Phase 1 Cosmetic Clinical Study of BX001 in Acne-Prone Skin

The Phase 1 cosmetic clinical study was a four-week randomized, double-blind, dose-finding, placebo-controlled single center trial which enrolled 75 individuals with mild-to-moderate acne. Enrolled individuals were randomized into one of three cohorts: a high dose cohort, a low dose cohort, and a placebo cohort (vehicle).

About Phage

Bacteriophage, or phage, are viruses that target bacteria and are considered inert to mammalian cells. Phage are designed to target and kill specific bacterial species or strains without disrupting other bacteria or the healthy microbiota. All of BiomX's phage-based product candidates derive from its proprietary platform, which is first used to discover and validate the association and biologic rationale of specific bacterial strains with human diseases or conditions, and is then used to develop rationally-designed phage combinations ("cocktails") of naturally occurring or synthetic phage to target pathogenic bacteria. The phage cocktails contain multiple phage with complementary functions optimized through in vitro and in vivo testing.

About BiomX

BiomX is a clinical-stage biotechnology company developing both natural and engineered phage cocktails designed to target and destroy bacteria that affect the appearance of skin, as well as harmful bacteria in chronic diseases, such as inflammatory bowel disease (IBD), primary sclerosing cholangitis (PSC), and colorectal cancer (CRC). BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.
www.biomx.com

Safe Harbor Language

This press release 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 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 additional disclosures we make in the Company's filings with the Securities and Exchange Commission (the "SEC"), which are available on the SEC's website at www.sec.gov.

Company Contact

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Noel Kurdi
VP, Investor Relations and Strategy
(646) 241-4400
noelk@biomx.com



BiomX

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 natural and engineered phage cocktails as precision medicines to target and destroy specific harmful bacteria that are causative agents in chronic diseases

Unique Position as Leader in Phage Technology

Technology	<ul style="list-style-type: none">• Phage discovery platform• Proprietary synthetic biology capabilities• Cutting-edge data science• In-house manufacturing of customized phage cocktails	 
Pipeline	<ul style="list-style-type: none">• 4 programs: acne-prone skin, IBD*, PSC* (a liver disease), colorectal cancer• Phase I data in acne-prone skin and IBD in 2020	
Clinical results	<ul style="list-style-type: none">• Positive Phase 1 double-blind, dose-finding, placebo-controlled study in acne-prone skin<ul style="list-style-type: none">• Excellent safety and tolerability• Statistically significant reduction in target bacteria	
Exclusive access to novel targets	<ul style="list-style-type: none">• Proprietary targets in IBD and PSC• Target discovery and validation platform steered by cutting-edge research of scientific founders	 
Partnerships	<ul style="list-style-type: none">• Acne collaboration with leading global cosmetic company• Biomarker discovery in IBD for key Janssen (J&J) IBD drug	
Support from leading life science and strategic investors	<ul style="list-style-type: none">• Approximately \$60M raised in 2 private rounds• On October 2019 public listing (NYSE:PHGE) through a merger raising an additional \$60M	    

* Inflammatory Bowel Disease (IBD) and Primary Sclerosing Cholangitis (PSC)



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

Cutibacterium acnes is associated with acne vulgaris

JID
JOURNAL OF INVESTIGATIVE DERMATOLOGY

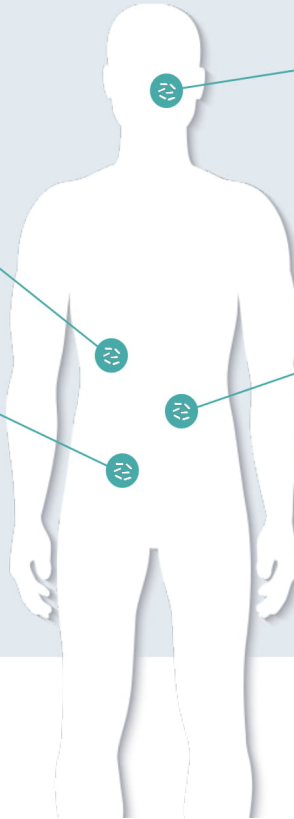
Fitz-Gibbon et al. (2013),
J Invest Dermatol

IBD

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

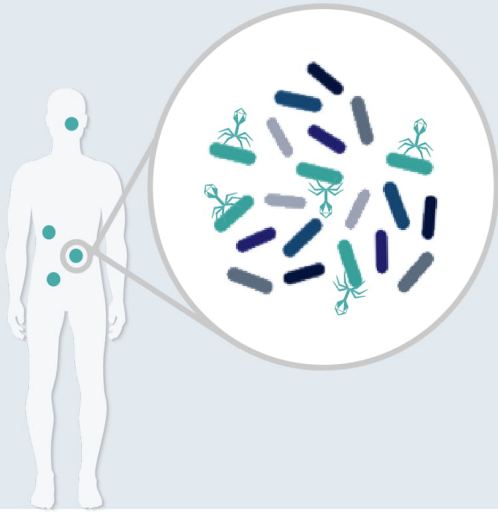
Science
MAGAZINE

Atarashi et al. (2017),
Science



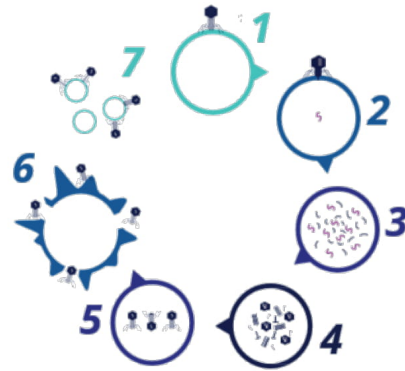
Phage: Nature's Precision Tool to Target Bacteria

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

Pipeline

	Phage discovery	Preclinical	Phase I	Phase II	Partners
Product Candidates					
Acne • BX001¹				<ul style="list-style-type: none"> Positive Phase 1 results Phase 2 results expected 2Q 2021 	Global cosmetics company
IBD • BX002²				<ul style="list-style-type: none"> Pre-IND meeting held 2H 2019 Phase 1a results expected 4Q 2020 	
PSC • BX003²				<ul style="list-style-type: none"> IBD Phase 1 to inform PSC product (same target bacteria) 	
Colorectal cancer					
	Biomarker discovery	Validation	Development		
Diagnostics					
IBD (responder/non-responder)					Janssen

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

(2) Inflammatory bowel disease (IBD) and primary sclerosing cholangitis (PSC)

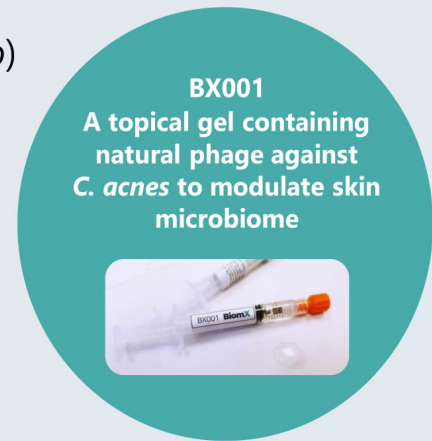
BiomX

Acne

Upcoming milestone: Phase 2 data expected in 2Q 2021

Acne • BX001: Natural Phage Cocktail Attributes

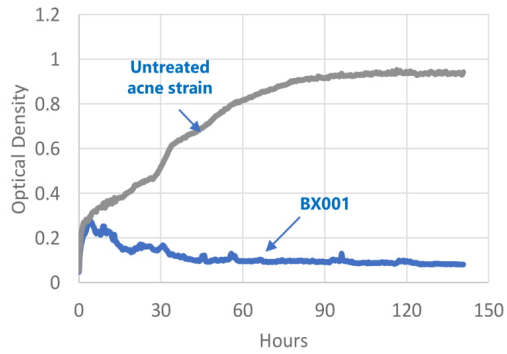
- Active against 96% of tested *C. acnes* clinical strains (*in-vitro*)
- Active against antibiotic-resistant strains (*in-vitro*)
- Self-amplifying: 50-100 phage per bacteria killed
- Penetrates biofilm
(in contrast to antibiotic erythromycin)
- Highly specific: Does not affect other skin microbiome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



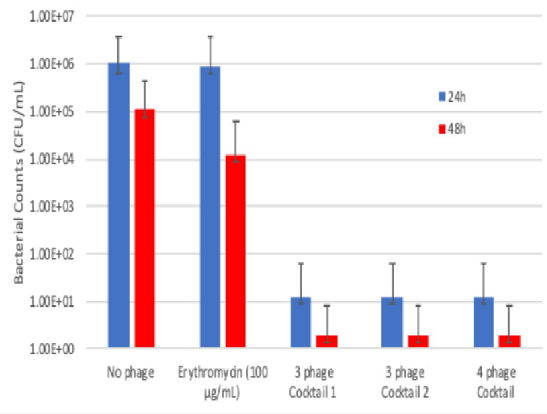
Source: Internal data

Acne • BX001 Targets *C. acnes*, Penetrates Biofilm In Vitro

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



Phage cocktails penetrate biofilm (in-vitro)



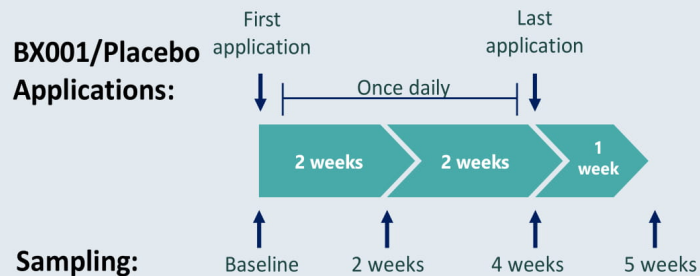
Source: Internal data

Acne • BX001: Phase 1 Clinical Trial Design

Phase 1 – Completed

4-week study (placebo-controlled)

- **Primary endpoints**
 - Safety & Tolerability
- **Exploratory endpoints**
 - Reduction of *C. acnes* (efficacy)
 - Skin microbiome evaluation
- **75 female subjects total over 3 cohorts**
 - 2 doses (high and low dose) + placebo (vehicle)
 - 25 subjects per cohort

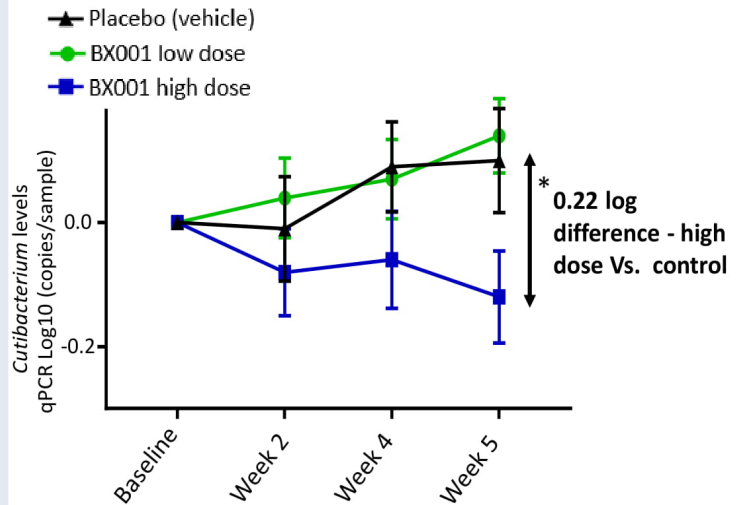


Acne • BX001: Phase 1 Results Demonstrate Statistically Significant Reduction in *C. acnes* Levels

BX001 safety and tolerability

- Excellent safety and tolerability at high and low doses of BX001
- Similar number of subjects with all-causality or treatment-related adverse events across BX001 and placebo groups
- Only 4 treatment-related adverse events reported in more than 1 subject in any group: exfoliation, dryness, erythema and pruritus
 - All mild to moderate
 - Short duration
 - Spontaneously resolved

Change in level of *Cutibacterium acnes* on skin**



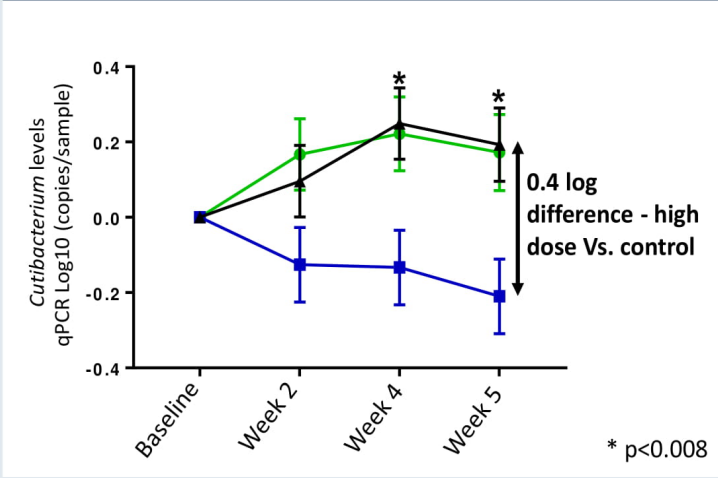
* p=0.036

** Measured by qPCR. *Cutibacterium acnes* (or *C. acnes*) comprised over 98% of *Cutibacterium* spp.

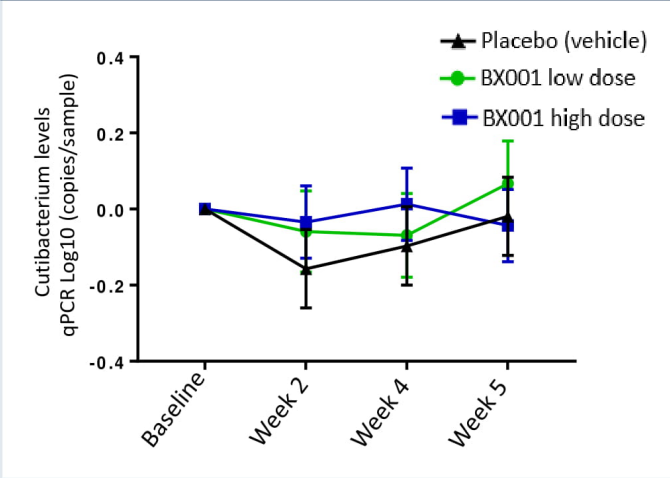


Acne • Phase 1 Results Show More Pronounced and Earlier Effect in Subjects with High Sebum Levels

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



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



Findings support enrichment of study population in the Phase 2 study



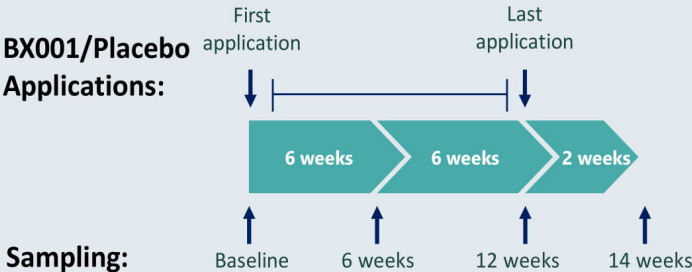
(1) Measured by qPCR. *Cutibacterium acnes* (or *C. acnes*) comprised over 98% of *Cutibacterium* spp.
 (2) Subjects were divided into high and low sebum level groups based on median level of sebum at baseline (133 µg/cm²)

Acne • BX001 Phase 2 Study Results Expected in 2Q 2021

Phase 2 Study Design

12-week study (placebo-controlled)

- **Primary endpoint**
 - Safety and tolerability
- **Exploratory endpoints**
 - Reduction of *C. acnes* (efficacy)
 - Skin microbiome evaluation
 - IGA and lesion numbers (efficacy)
- **100 female subjects over 2 cohorts**
 - Treatment or placebo (vehicle)
 - 50 subjects per cohort



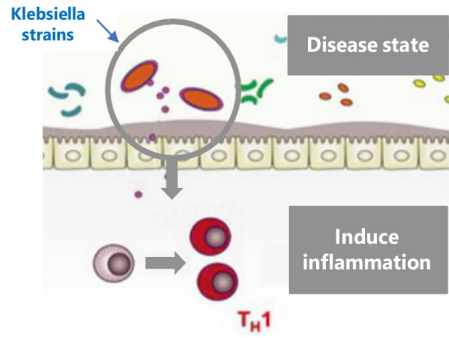
Inflammatory Bowel Disease (IBD), and Primary Sclerosing Cholangitis (PSC)

Upcoming milestone: Phase 1 pharmacokinetic data expected in 4Q
2020

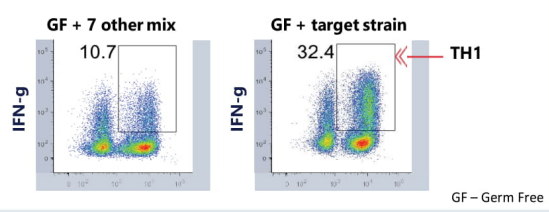
IBD • Identifying Potential Disease Causing Pro-inflammatory *Klebsiella* Strains



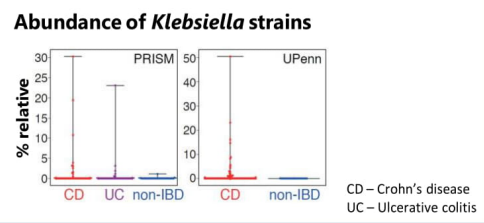
Pro-inflammatory *Klebsiella* strains affect IBD pathology



Inflammatory induction is seen in GF mice*



Higher abundance of *Klebsiella* strains in IBD patients



Activity of bacterial target confirmed by BiomX

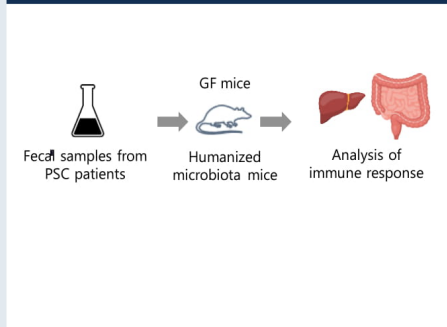
Source: Atarashi et al. (2017), Science
 * TH1 – A lineage of CD4+ effector T cell secreting IFNg and TNF. In IBD, TH1 cells accumulate in the intestinal tract of IBD patients and are directly associated with disease



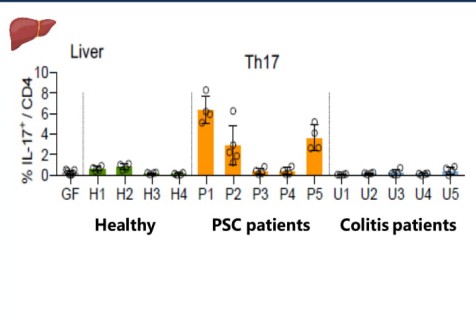
PSC • *Klebsiella* Identified as Possible Driver of “Leaky Gut”

nature
microbiology

Discovery approach



Th17* is induced in livers of GF mice inoculated with fecal samples from PSC patients



KP isolated from mice's lymph nodes colonized with patient samples

	Liver	MLN	Spleen
SPF mice	ND		ND
HC-gnotobiotite	ND		ND
PSC/UC-gnotobiotite	ND		ND

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

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

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

Source: Nakamoto et al. (2019), Nature Microbiology

*TH17 – A lineage of CD4⁺ 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

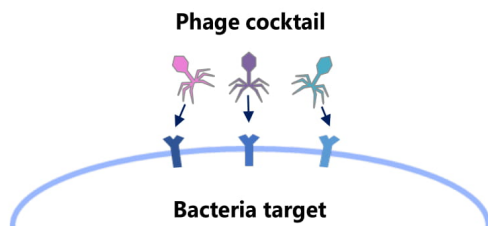
- Evidence that manipulation of microbiome impacts the disease
- Abnormal high abundance of bacteria found in bile fluid of patients
- Most PSC patients suffer from ulcerative colitis

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

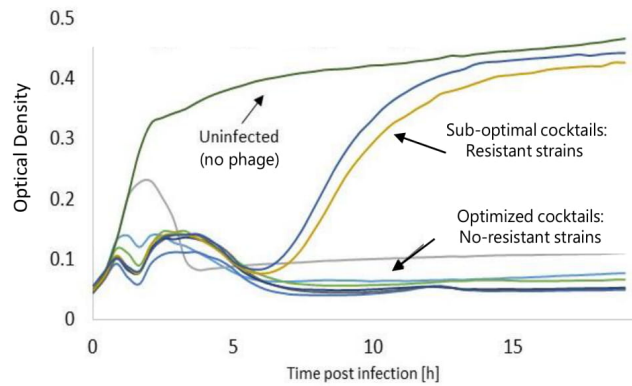
How a phage cocktail overcomes resistance



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

Infection dynamics of phage cocktails (*in vitro*)

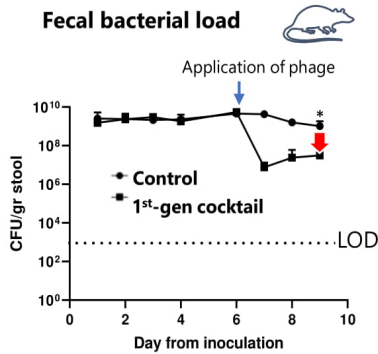
Comparing various phage cocktail combinations



Source: Internal data

IBD • BX002 Cocktail Composition Drives Activity

1st-generation phage cocktail (in-vivo)

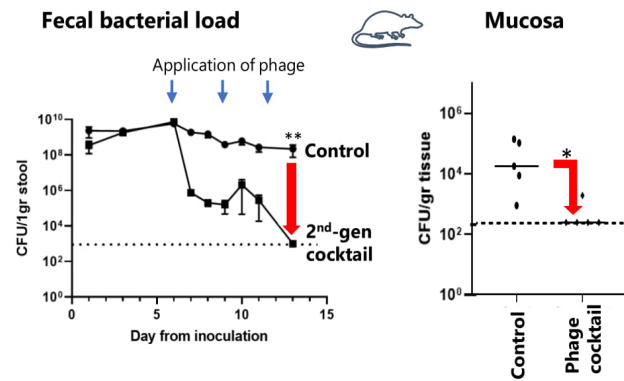


*P < 0.01

Adding 2 phages with new MOA



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



*P < 0.05; **P < 0.001

Source: Internal data

BiomX

IBD • Planned Phase 1/2 Clinical Development

Phase 1a
First-In-Human Pharmacokinetic Study

3-day multiple-dose study (placebo-controlled)

- **Objectives**
 - Safety and tolerability
- **Endpoints**
 - Detection of viable phage in stool
 - Evaluate effect of PPI
- **Study Population:** Healthy volunteers
- **24 subjects over 2 cohorts**
 - 2 cohorts: BX002 with and without PPI
 - 10 BX002 + 2 placebo per cohort

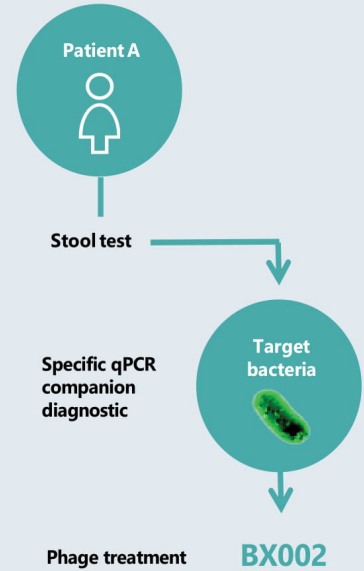
Data expected 4Q 2020

Phase 1b/2a
Proof-of-Principle

4-week study (placebo-controlled)

- **Objectives**
 - Safety and efficacy
- **Endpoints**
 - Safety and tolerability
 - Reduction of *K. pneumoniae*
 - Stool microbiome evaluation
- **Study Population:** Target bacteria carriers (Healthy volunteers or IBD patients)
- **20-30 subjects total over 2 cohorts**
 - BX002 or placebo
 - 10-15 subjects per cohort

Data expected 2H 2021



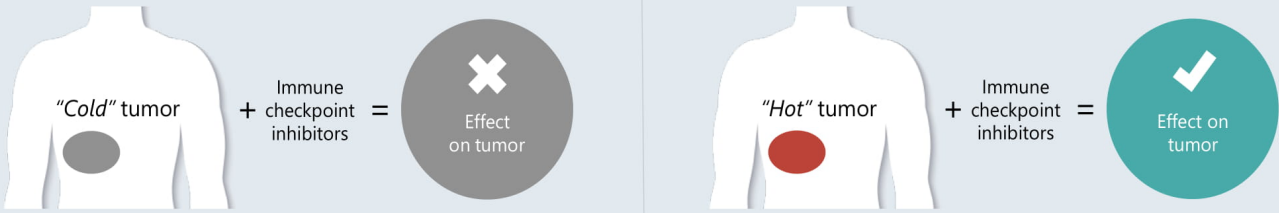
As the IBD and PSC programs share the same bacterial target, *Klebsiella pneumoniae*, the Phase 1 program in IBD will support progress of the PSC program to Phase 2 development in 2022.



Colorectal Cancer

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

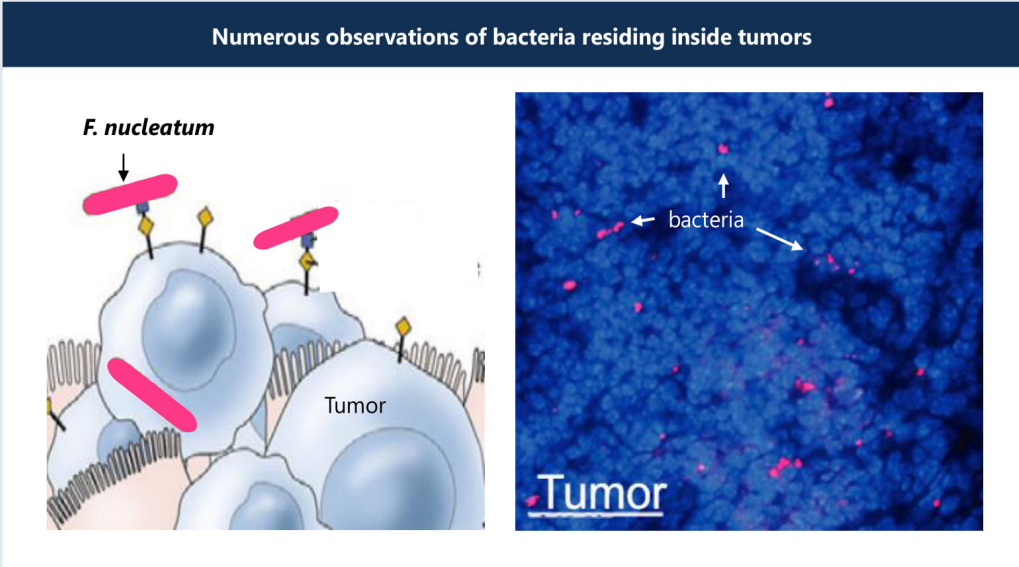
CRC • Most Colorectal Cancer (CRC) Patients do not Respond to Immunotherapy



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



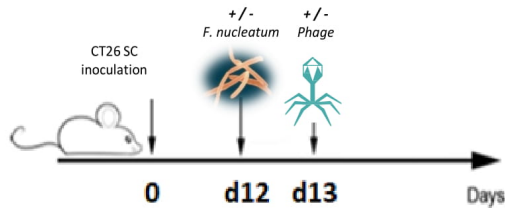
CRC • Bacteria Residing Inside Tumors Offer a Novel Targeted Intervention to “Uncloak” Tumors to “Hot”



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

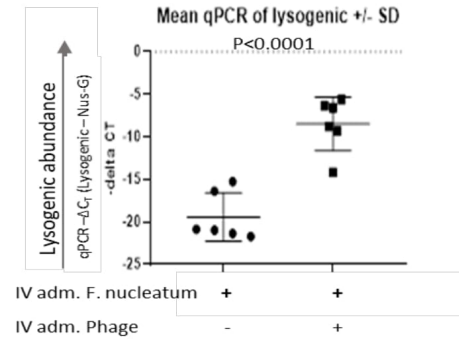
CRC • IV Delivery of Phage to Intra-tumor Bacteria has been Demonstrated

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

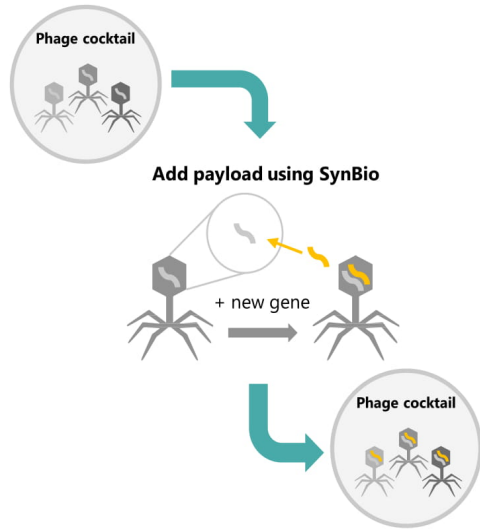


Detection of lysogenized intra-tumor *F. nucleatum* demonstrates phage delivered IV reached bacteria within tumor microenvironment and integrated stably into host bacteria genome

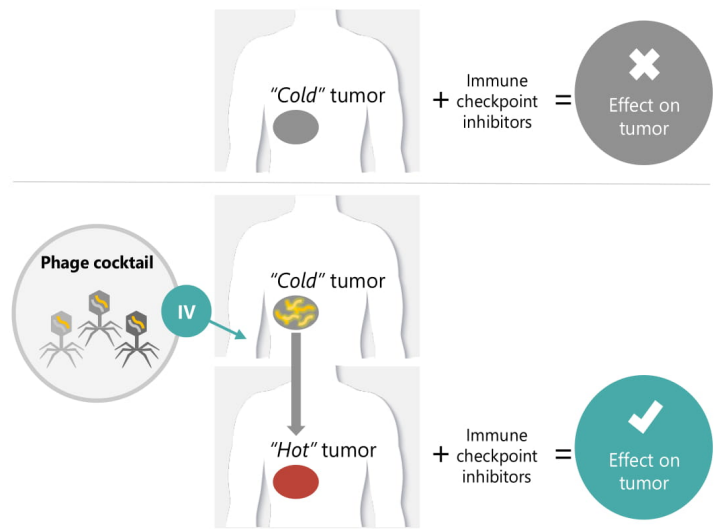
Source: Internal data

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

Phage are designed to carry payload targeting intra-tumor bacteria



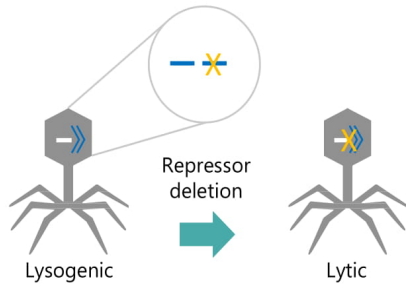
Phage cocktail with a payload turns cold tumors into hot



CRC • Multiple Payloads Added to Phage Using Proprietary Synthetic Engineering

Clinical *F. nucleatum* strain converted from lysogenic to lytic

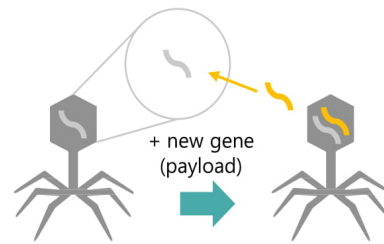
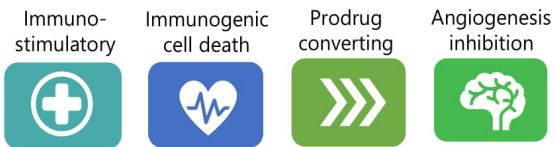
Lysogenic to lytic



The engineered lytic phage was isolated and verified through NGS

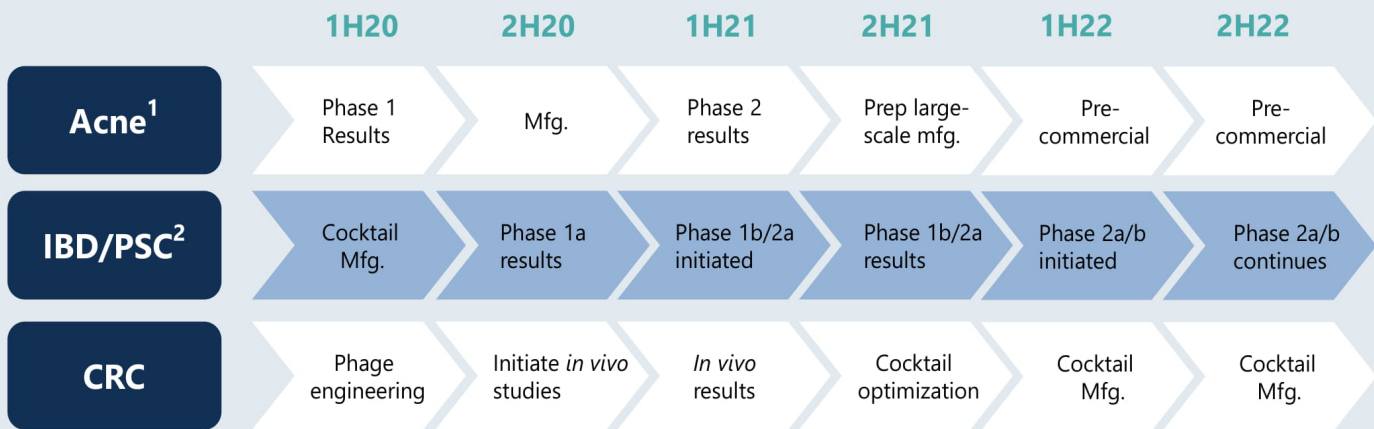
Addition of payload to a clinical *F. nucleatum* strain underway

Examples of payloads



Source: Internal data

Key Catalysts



Cash, cash equivalents and short-term deposits as of March 31st 2020: \$75.3 million



(1) Our acne product is developed under a cosmetic regulatory path and we currently do not anticipate any additional clinical trials beyond the Phase 2 study.

(2) As the IBD and PSC programs share the same bacterial target, *Klebsiella pneumoniae*, the Phase 1 program in IBD will support progress of the PSC program to Phase 2 development in 2022..

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



Erez Chimovits



Jonas Grossman



Gbola Amusa, MD



Yaron Breski



Lynne Sullivan



Jonathan Solomon



BiomX

Thank you

