

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

Form 8-K

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

Date of Report (Date of earliest event reported): **March 28, 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 March 31, 2020, BiomX Inc. (the “Company”) issued a press release announcing positive topline Phase 1 cosmetic clinical trial results for its BX001 product candidate. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The Company will host an investor conference call on March 31, 2020 at 8:00 a.m. ET to discuss the BX001 Phase 1 results. The conference call may be accessed by dialing 1-877-270-2148 for participants based in the United States, or 1-412-902-6510 for participants based outside the United States, and asking to be joined into the BiomX Inc. conference call. A live webcast of the conference call will be available on the Company’s website at <http://www.biomx.com/events-2/>, and a replay will be available after its completion.

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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press Release dated March 31, 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.

March 31, 2020

BIOMX INC.

By: /s/ Jonathan Solomon
Name: Jonathan Solomon
Title: Chief Executive Officer



BiomX Announces Positive Topline Data from Phase 1 Study
for Lead Candidate BX001 for Acne-Prone Skin

*BX001 demonstrates excellent safety, tolerability, and
a statistically significant reduction of C. acnes levels on skin*

Company to host conference call at 8:00 a.m. Eastern Time (U.S.)

Ness Ziona, Israel – March 31, 2020 – BiomX Inc. (NYSE: PHGE), a clinical-stage company developing both natural and engineered phage therapies that target specific pathogenic bacteria, today announced positive topline results from its Phase 1 cosmetic clinical study of BX001 in subjects with acne-prone skin. The study met its primary endpoint of safety and tolerability for both doses of BX001, as well as a statistically significant ($p=0.036$) reduction of *Cutibacterium acnes* (*C. acnes*) levels for the high dose of BX001 compared to placebo. *C. acnes* are bacteria implicated in the pathophysiology of acne vulgaris.

“We are excited to announce positive data demonstrating for the first time that this topically applied phage cocktail, developed through our proprietary discovery platform, showed activity against a bacterial target and was able to demonstrate a statistically significant reduction in *C. acnes* levels on the skin in a safe and tolerable manner. These results warrant advancing the program to a Phase 2 study,” said Jonathan Solomon, CEO of BiomX. “We are carrying out additional analyses on the BX001 clinical data, as well as evaluating the implications of the ongoing Covid-19 pandemic on our clinical development timelines, and intend to provide an update on the timing of the Phase 2 trial when we report our first quarter 2020 financial results.”

BX001 is a topical gel comprised of a cocktail of naturally-occurring phage targeting *C. acnes* to improve the appearance of acne-prone skin. Following application of the gel once daily for four weeks, measurement of *C. acnes* levels using qPCR showed a statistically significant reduction of *C. acnes* levels in the high dose cohort of BX001 compared to placebo ($p=0.036$) at week five (one week after end of treatment), the final study time point. At this time point, a 0.12 log reduction, which translates to a 24% reduction in *C. acnes* levels, was observed in the high dose cohort compared to baseline, while a 0.1 log increase, which translates to a 26% increase from baseline, was observed in the placebo cohort. As anticipated for a relatively short-duration study of four weeks, exploratory endpoints measuring reductions in inflammatory and non-inflammatory lesions were not statistically significant versus placebo. The planned Phase 2 trial will have a 12-week duration similar to most acne studies and will be powered to demonstrate a clinical effect.

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).

The Phase 2 cosmetic clinical study 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).

Conference Call Details

BiomX management will host an investor conference call today at 8:00 a.m. ET to discuss the BX001 Phase 1 results. The conference call may be accessed by dialing 1-877-270-2148 for participants based in the United States, or 1-412-902-6510 for participants based outside the United States, and asking to be joined into the BiomX, Inc. 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 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 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.

Company Contact

BiomX, Inc.

Assaf Oron

Chief Business Officer

+972 (54) 222-8901

assafo@biomx.com

Investor Contact

Stern IR, Inc.

Kerry Conlin

+1 (212) 362-1200

kerry.conlin@sternir.com
