

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 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): **February 2, 2021**

**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**

(IRS Employer  
Identification No.)

**7 Pinhas Sapir St., Floor 2  
Ness Ziona, Israel**

(Address of Principal Executive Offices)

**7414002**

(Zip Code)

**(+972) 72 394 2377**

(Registrant's telephone number, including area code)

**Not applicable**

(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 Unit	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 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 8.01. Other Events.**

On February 2, 2021, BiomX Inc., or the registrant, announced results of a first-in-human Phase 1a pharmacokinetic study of a phage cocktail targeting *Klebsiella pneumoniae* (*K. pneumoniae*) bacteria in the gut, which have been linked to the pathogenesis of both inflammatory bowel disease (IBD) and primary sclerosing cholangitis (PSC). The registrant further announced that BX002 was demonstrated to be safe and well tolerated, with no serious adverse events and no adverse events leading to discontinuation. In addition, the study met its objective of delivering high concentrations of viable phage to the gastrointestinal tract of approximately  $10^{10}$  PFU (plaque forming units). This equals approximately 1,000 times more viable phage compared to the bacterial burden of *K. pneumoniae* in IBD and PSC patients as measured in stool.

The study was a randomized, single-blind, multiple-dose, placebo-controlled Phase 1a pharmacokinetic study and was conducted under an investigational new drug application approved by the U.S. Food and Drug Administration. The study evaluated safety and tolerability of orally administered BX002 in 18 volunteers. Subjects were randomized to receive orally either BX002 (n=14) or placebo (n=4), twice daily for three days. Subjects were monitored for safety for seven days in a clinical unit, with follow-up for safety assessments done at 14 and 28 days after completion of dosing. Viable phage were detected at high concentrations in samples from all subjects in the BX002 group, compared to no detected levels prior to treatment.

Based on the Phase 1a study results, the registrant plans to advance to a Phase 1b/2a study evaluating the efficacy of BX003 for the reduction of *K. pneumoniae* in individuals that carry the target bacteria. In November 2020, BiomX announced the consolidation of its IBD and PSC programs to develop one product candidate with a broad host range for both indications, designated BX003. Results from the Phase 1b/2a study are expected by mid-2022.

**Warning Concerning Forward Looking Statements**

This Current Report on Form 8-K contains express or implied “forward-looking statements” within the meaning of the “safe harbor” provisions of the U.S. Private Securities Litigation Reform Act of 1995. For example, when the registrant discusses the safety and tolerability of its phage therapy and the conducting and timing of its expected Phase 1b/2a study, the registrant is making forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on registrant’s 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 registrant’s control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, investors should not rely on any of these forward-looking statements and should review the risks and uncertainties described under the caption “Risk Factors” in registrant’s Current Report on Form 8-K filed with the Securities and Exchange Commission (the “SEC”) on December 4, 2020 and additional disclosures the registrant makes in its filings with the SEC, which are available on the SEC’s website at [www.sec.gov](http://www.sec.gov). Forward-looking statements are made as of the date of this Current Report on Form 8-K, and except as provided by law the registrant expressly disclaims any obligation or undertaking to update forward-looking statements.

---

1

#### SIGNATURES

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.

#### BIOMX INC.

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

Date: February 2, 2021

---

2