

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 29, 2023**

BiomX Inc.		
(Exact Name of Registrant as Specified in its Charter)		
Delaware	001-38762	82-3364020
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
22 Einstein St., Floor 4 Ness Ziona, Israel	7414003	
(Address of Principal Executive Offices)	(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	PHGE	NYSE American
Warrants, each exercisable for one-half of a share of common stock, \$0.0001 par value, at an exercise price of \$11.50 per share	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 March 29, 2023, BiomX Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter ended December 31, 2022. 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 5.08 Shareholder Director Nominations.

On March 28, 2023, the Board of Directors of the Company established that the Company's 2023 Annual Meeting of Stockholders (the "Annual Meeting") will be held on Tuesday, June 20, 2023 and has fixed the closing of business on April 27, 2023 as the record date for the Annual Meeting. Because the date of the Annual Meeting has been changed by more than 30 days from the anniversary date of the 2022 Annual Meeting of Stockholders, which was held on August 24, 2022, the deadlines for any stockholder proposals pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and for any stockholder nomination or proposal outside of Rule 14a-8, as listed in the Company's 2022 Proxy Statement on Schedule 14A, as filed with the Securities and Exchange Commission (the "SEC") on July 7, 2022, are no longer applicable.

In accordance with Rule 14a-5(f) and Rule 14a-8(e) under the Exchange Act, the deadline for receipt of stockholder proposals for inclusion in the Company's proxy statement for the Annual Meeting pursuant to Rule 14a-8 will be no later than 5:00 p.m., Eastern Time, April 17, 2023. Stockholder proposals must comply with all of the applicable requirements set forth in the rules and regulations of the Securities and Exchange Commission, including Rule 14a-8 under the Exchange Act and the Company's Bylaws.

Item 9.01. Financial Statements and Exhibits.

Exhibit	Description
99.1	Press Release dated March 29, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL documents)

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.

BIOMX INC.

March 29, 2023

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

BiomX Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Update

Announced Positive Results from Part 1 of Ongoing Phase 1b/2a Trial of BX004 for Treatment of Lung Infections in Cystic Fibrosis ("CF")

Patient Enrollment Continues in Part 2 of Phase 1b/2a Trial with Results Expected in Third Quarter of 2023

Cash Runway Through at Least Mid-2024

Company Will Host a Conference Call and Webcast Today at 8:00 am ET

CAMBRIDGE, Mass. and NESS ZIONA, Israel – March 29, 2023 – BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage company advancing novel natural and engineered phage therapies that target specific pathogenic bacteria, today reported financial results and provided a business update for the fourth quarter and full year ended December 31, 2022.

"2023 is shaping up to be a very exciting year for our company, and the field of phage therapeutics. Based on the highly encouraging results from Part 1 of our ongoing Phase 1b/2a trial, we believe the BX004 program is fast-emerging as one of the most promising new treatments for CF patients suffering from chronic *Pseudomonas aeruginosa* infections," said Jonathan Solomon, Chief Executive Officer of BiomX. "BX004 not only demonstrated excellent safety, but also resulted in notable reductions in bacterial load in the lungs of CF patients. We have already dosed patients in Part 2 of the Phase 1b/2a study and remain on track to report results in the third quarter of 2023.

"There is a growing body of clinical evidence, including data from compassionate use programs, that phage-based therapies such as BX004 may represent an important new modality for treating the thousands of CF patients who suffer from chronic, life-threatening lung infections. In Part 2, we will dose at least 24 CF patients with BX004 twice a day and over a longer, 10-day treatment period. Results from Part 2 will provide important additional safety data and should provide clinical insights, particularly regarding the reduction in *Pseudomonas aeruginosa* bacterial burden, that will help us advance BX004 into pivotal testing. Other clinical endpoints including CF patients reported outcomes and lung function also will be assessed."

Clinical Program Updates

Cystic Fibrosis (BX004)

- In February 2023, BiomX announced positive results from Part 1 of the Phase 1b/2a trial evaluating the Company's novel phage cocktail, BX004, for the treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa* (or *P. aeruginosa*) in patients with cystic fibrosis. Highlights from the data included:
 - o No safety events related to treatment with BX004
-
- o Mean *P. aeruginosa* colony forming units (CFU) at Day 15 (compared to baseline): -1.42 log₁₀ CFU/g (BX004) vs. -0.28 log₁₀ CFU/g (placebo), a reduction of greater than 90%. This reduction was seen on top of standard of care inhaled antibiotics
 - o Phages were detected in all patients treated with BX004 during the dosing period, including in several patients up to Day 15 (one week after end of therapy); no phages were detected in patients receiving placebo
 - o There was no emerging bacterial resistance to BX004 during or after treatment with BX004
 - o As expected, likely due to the short course of therapy, there was no detectable effect on % predicted FEV1
- Dosing of patients in Part 2 of the Phase 1b/2a trial has been initiated; results from Part 2 are expected in the third quarter of 2023.
 - BX004 is being developed for the treatment of chronic respiratory infections caused by *P. aeruginosa*, a main contributor to morbidity and mortality in patients with CF. The Phase 1b/2a trial is composed of two parts. Part 1 of the study evaluated the safety, pharmacokinetics, and microbiologic/clinical activity of BX004 in nine CF patients in a single ascending dose and multiple dose design. Part 2 of the study will evaluate the safety and efficacy of BX004 in at least 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio.
 - As previously announced, BiomX has received a Therapeutics Development Award of up to \$5 million from the Cystic Fibrosis Foundation ("CF Foundation"). The award is structured as an equity investment in which the CF Foundation has agreed to purchase up to \$5 million of BiomX common stock across two separate tranches. The first tranche was received on December 21, 2021, with the CF Foundation making an initial equity investment of \$3 million. Following the results from Part 1 of the ongoing Phase 1b/2a trial, the CF Foundation is making its second tranche investment of \$2 million through its participation in the Company's recently announced \$7.5 million private placement.

Atopic Dermatitis (BX005)

- The Company is collaborating with Maruho Co. Ltd., a leading dermatology-focused pharmaceutical company in Japan, supporting a range of pre-clinical activities to move this program forward and working on evaluating timelines for a clinical trial.

RECENT CORPORATE HIGHLIGHTS

- In February 2023, the Company announced a \$7.5 million private placement with a select group of institutional and individual investors, including existing investors OrbiMed and the Cystic Fibrosis Foundation. The financing is expected to close in two parts. The first closing for gross proceeds of \$1.5 million occurred in February 2023. The second closing for the remaining Securities, which is contingent upon approval by the Company's stockholders in accordance with NYSE American rules, is expected to take place in the second quarter of 2023. BiomX expects to use the net proceeds from the PIPE, together with existing cash and cash equivalents, to fund clinical development of BX004 for the treatment of lung infections in patients with CF, the development of other programs, and research activities as well as working capital and other general corporate purposes.

Fourth Quarter and Full Year 2022 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of December 31, 2022, were \$34.3 million, compared to \$63.1 million as of December 31, 2021. The decrease was primarily due to net cash used in operating activities. Following the close of the fourth quarter of 2022, the Company raised \$7.5 million in gross proceeds through a private placement, \$6 million of which are contingent upon shareholders' approval. Inclusive of net proceeds from the private placement, the Company estimates its cash runway is sufficient to fund operations through at least mid-2024.
- **Research and development ("R&D") expenses, net** were \$16.2 million for the year ended December 31, 2022, compared to \$22.7 million for the prior year. The decrease was primarily due to a decrease in salaries and related expenses and stock-based compensation expenses due to a reduction in workforce, as a result of a corporate restructuring; as well as discontinuing pausing the development of BX003, our product candidate for inflammatory bowel disease and delaying the development of BX005, our product candidate for atopic dermatitis.
- **General and administrative expenses** were \$9.5 million for the year ended December 31, 2022, compared to \$11.3 million for the prior year. The decrease was primarily due to a decrease in salaries and related expenses and stock-based compensation expenses due to a reduction in workforce, as well as a decrease in recruitment and employee related expenses, both as a result of a corporate restructuring.
- **Net loss** for 2022 was \$28.3 million, compared to \$36.2 million for the prior year.
- **Net cash used in operating activities** for the year ended December 31, 2022 was \$29.1 million, compared to \$27.6 million for the same period in 2021.

Conference Call and Webcast Information

BiomX management will host a conference call and webcast today at 8:00 am ET to report financial results and business updates for 2022. To participate in the conference, please dial 1-877-407-0724 (U.S.), 1-809-406-247 (Israel), or 1-201-389-0898 (International). A live and archived webcast of the call will be available on the Investors section of the Company's website at www.biomx.com, the content of which does not form a part of this press release.

About BiomX

BiomX is a clinical-stage company developing both natural and engineered phage cocktails designed to target and destroy bacteria that target and destroy bacteria in the treatment of chronic diseases. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets. For more information, please visit www.biomx.com, the content of which does not form a part of this press release.

Safe Harbor

This press release 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. 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. For example, when BiomX discusses the potential safety or efficacy of BX004, the expected timing of Part 2 of the Phase 1b/2a study and the potential of targeted phage therapy to treat infections in CF patients, as well as other when it refers to other programs, such as the program to treat Atopic Dermatitis, BiomX is making forward-looking statements. 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'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 BiomX's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 30, 2022 and additional disclosures BiomX makes in its other filings with the SEC, which are available on the SEC's website at www.sec.gov. Forward-looking statements are made as of the date of this press release, and except as provided by law BiomX expressly disclaims any obligation or undertaking to update forward-looking statements

BIOMX INC.
CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)

	As of December 31,	
	2022	2021
ASSETS		
Current assets		
Cash and cash equivalents	31,332	62,099
Restricted cash	962	996
Short-term deposits	2,000	-
Other current assets	2,587	3,543
Total current assets	36,881	66,638
Non-current assets		
Operating lease right-of-use assets	3,860	4,139
Property and equipment, net	4,790	5,694
Intangible assets, net	-	1,519
Total non-current assets	8,650	11,352
	45,531	77,990

	As of December 31,	
	2022	2021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade account payables	820	2,795
Current portion of lease liabilities	687	819
Contract liability	-	1,976
Other account payables	2,150	5,453
Current portion of long-term debt	4,282	-
Total current liabilities	7,939	11,043
Non-current liabilities		
Contract liability	1,976	-
Long-term debt, net of current portion	10,591	14,410
Operating lease liabilities, net of current portion	3,798	4,787
Other liabilities	188	215
Total non-current liabilities	16,553	19,412
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock, \$0.0001 par value; Authorized - 1,000,000 shares as of December 31, 2022 and December 31, 2021. No shares issued and outstanding as of December 31, 2022 and December 31, 2021.	-	-
Common stock, \$0.0001 par value ("Common Stock"); Authorized - 120,000,000 shares as of December 31, 2022 and 60,000,000 shares as of December 31, 2021. Issued - 29,982,282 and 29,753,238 as of December 31, 2022 and 2021, respectively. Outstanding - 29,976,582 and 29,747,538 as of December 31, 2022 and 2021, respectively.	2	2
Additional paid in capital	157,838	156,017
Accumulated deficit	(136,801)	(108,484)
Total Stockholders' equity	21,039	47,535
	45,531	77,990

CONSOLIDATED STATEMENTS OF OPERATIONS
(USD in thousands, except share and per share data)

	Year ended December 31,	
	2022	2021
Research and development ("R&D") expenses, net	16,244	22,676
Amortization of intangible assets	1,519	1,519
General and administrative expenses	9,456	11,267
Operating loss	27,219	35,462
Other income	(134)	-
Interest expenses	2,069	699
Financial income, net	(902)	(2)
Loss before tax	28,252	36,159
Tax expenses	65	67
Net Loss	28,317	36,226
Basic and diluted loss per share of Common Stock	0.95	1.39
Weighted average number of shares of Common Stock outstanding, basic and diluted	29,854,003	26,007,947

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