

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 15, 2023 (May 11, 2023)**

BiomX Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction
of incorporation)

001-38762

(Commission File Number)

82-3364020

(I.R.S. Employer
Identification No.)

**22 Einstein St., Floor 4
Ness Ziona, Israel**

(Address of Principal Executive Offices)

7414003

(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 May 15, 2023, BiomX Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2023. 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensation Arrangements of Certain Officers.

On May 11, 2023, the Board of Directors of the Company (the "Board"), pursuant to a recommendation of the Nominating and Corporate Governance Committee of the Board (the "Nominating Committee"), appointed each of Jason M. Marks and Michael E. Dambach to serve as Class II Directors of the Company, with terms expiring at the Company's 2025 annual meeting of stockholders, in order to fill two of the three existing vacancies on the Board. In addition, Mr. Marks was appointed to the Compensation Committee of the Board and Mr. Dambach was appointed to the Audit Committee of the Board. Furthermore, Mr. Alan Moses was appointed to the Nominating Committee.

Mr. Marks, age 47, most recently held the position of Executive Vice President, Chief Legal and Compliance Officer & Corporate Secretary, and then as Senior Advisor, of Amarin Corporation plc ("Amarin"), a global pharmaceutical company focused on cardiovascular disease, where he worked from August 2021 to March 2023. Prior to Amarin, Mr. Marks served as Chief Legal Officer and Head of Corporate Development at TerrAscend Corp. ("TerrAscend"), a publicly traded company where he also acted as head of compliance and corporate secretary from August 2020 to August 2021. Prior to his role at TerrAscend, Mr. Marks was Chief Legal Officer, General Counsel and Corporate Secretary of InflaRx N.V., a publicly traded biotechnology company headquartered in Germany, where he also had responsibility for compliance and U.S. operations, from January 2019 to August 2020. Prior to that, from November 2016 to December 2018, Mr. Marks held roles including, Senior Vice President, Head of Legal Branded Rx (Salix) and Global Litigation and Government Investigations at Bausch Health Companies Inc., a multinational publicly traded pharmaceutical company. Mr. Marks has also held

senior roles at Novartis's Alcon division, from June 2012 to November 2016, including as head of legal for North America and Global Litigation & Government Investigations, leading functions including Global Trade Compliance, Global Legal HR and Global Records Management, and at Stryker Corporation, between 2008 and 2012, in Europe and the United States. He started his legal career in 2001 in private practice in Chicago, Illinois. Mr. Marks received a J.D. *with honors* from the George Washington University Law School and an A.B. in History from the University of Chicago.

Mr. Dambach, age 56, is the Vice President and Treasurer of Biogen Inc., a biotechnology company ("Biogen"), a position he has held since 2010. Mr. Dambach also served as the Assistant Treasurer of Biogen from August 2007 to October 2010. Prior to joining Biogen, Mr. Dambach served as the acting Treasurer for Thermo Fisher Scientific Inc., a laboratory supply and biotechnology company, from May 2006 to August 2007 and Assistant Treasurer at Fisher Scientific International Inc. from October 2004 to May 2006. Prior to that, Mr. Dambach served as Senior Vice President of FleetBoston Financial Corporation, an international bank, from 1999 to May 2004, as well as Senior Trader and other positions at BankBoston from 1994 to 1999. Mr. Dambach has been a Chartered Financial Analyst for over 20 years. Mr. Dambach currently serves on the Board of Biomedical Science Careers Program. Mr. Dambach received an MBA, with honors, from Boston University and a B.S. in business administration from the University of New Hampshire.

There is no arrangement or understanding between Mr. Marks or Mr. Dambach and any other person pursuant to which Mr. Marks or Mr. Dambach, respectively, was selected as a Director. There are no transactions, relationships or agreements between Mr. Marks or Mr. Dambach and the Company that would require disclosure pursuant to Item 404(a) of Regulation S-K promulgated under the Securities Exchange Act of 1934, as amended.

The Board concluded that each of Mr. Marks and Mr. Dambach is qualified to serve as a Director and is independent under the rules of the NYSE American LLC. For their service as Directors, Mr. Marks and Mr. Dambach will be entitled to the compensation the Company generally provides to its Directors, with the annual cash fees prorated.

In connection with their appointments, the Company entered into an indemnification agreement with each of Mr. Marks and Mr. Dambach, effective as of May 11, 2023, on substantially the same terms as the agreements previously entered between the Company and each of its other Directors. The form of indemnification agreement entered into between the Company and its Directors is filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed on May 15, 2023, and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated May 15, 2023 (furnished herewith)
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.

May 15, 2023

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

BiomX Reports First Quarter 2023 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”); Results from Part 2 Expected in Third Quarter of 2023

Second and Final Closing of PIPE Investment Completed, Raising Total Gross Proceeds of \$7.5 million; Cash Runway into the Third Quarter of 2024

Jason M. Marks and Michael E. Dambach Appointed to Board of Directors

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

CAMBRIDGE, Mass. and NESS ZIONA, Israel – May 15, 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 first quarter ended March 31, 2023.

“Based on the better-than-expected results from Part 1 of our cystic fibrosis (“CF”) trial, I am pleased to note that the BX004 program continues to gain increased visibility among patients and physicians,” said Jonathan Solomon, Chief Executive Officer of BiomX. “Part 1 results demonstrated that treatment with BX004 was safe, well-tolerated, and resulted in notable reductions in *P. aeruginosa* bacterial counts. Part 2 of the study is underway with enrollment rate as planned. In Part 2 CF patients will be dosed with BX004 twice a day and over a longer, 10-day treatment period compared to Part 1. Part 2 of the study will provide additional data on safety and reduction in *P. aeruginosa* bacterial burden, along with other exploratory clinical endpoints. We expect to report results from Part 2 in the third quarter of 2023.

“The growing interest in our BX004 program has also allowed us to strengthen our balance sheet during the quarter, and I am pleased to announce that we closed the second part of our private placement earlier this month. We would like to thank our existing shareholders, including OrbiMed and the Cystic Fibrosis Foundation, for this continued financial support, which will provide us with additional funding through the expected Part 2 data readout. I am also pleased to note the addition of Jason Marks and Michael Dambach to our Board of Directors, who both bring a wealth of talent and experience spanning across multiple areas of finance, regulatory, governance and legal expertise.”

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) were reduced by more than 90%: -1.42 log₁₀ CFU/g (BX004) vs. -0.28 log₁₀ CFU/g (placebo). This reduction occurred in the presence of standard of care inhaled antibiotics
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- 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 (First-second Forced Expiratory Volume)
- 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 24 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 of the trial are expected in the third quarter of 2023.
 - As previously announced, BiomX has received a Therapeutics Development Award of up to \$5 million from the Cystic Fibrosis Foundation (“CF Foundation”). The award was structured as an equity investment in which the CF Foundation 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 completed its second tranche investment of \$2 million through its participation in the Company’s recently announced \$7.5 million private placement.

Atopic Dermatitis (“AD”) (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

- On May 12, 2023, the Company announced the appointments of Jason M. Marks and Michael E. Dambach, CFA to its Board of Directors. Mr. Marks most recently served as Executive Vice President, Chief Legal and Compliance Officer & Corporate Secretary/Senior Advisor with Amarin Corporation plc, and Mr. Dambach serves as Vice President and Treasurer of Biogen Inc.

- 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 CF Foundation. The financing closed in two parts. The first closing for gross proceeds of \$1.5 million occurred in February 2023. The second closing, which was contingent upon approval by the Company’s stockholders in accordance with NYSE American rules, closed in May 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.

First Quarter 2023 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of March 31, 2023, were \$30.3 million, compared to \$34.3 million as of December 31, 2022. The decrease was primarily due to net cash used in operating activities. During the quarter, the Company raised \$1.5 million in gross proceeds through a private placement. Inclusive of net proceeds from the private placement, the Company estimates its cash runway is sufficient to fund operations into the third quarter of 2024.
- **Research and development (“R&D”) expenses, net** were \$4.6 million for the three months ended March 31, 2023, compared to \$4.9 million for the same period in 2022. The decrease was primarily due to reduced salaries and related expenses and stock-based compensation expenses that resulted from a reduction in workforce, as part of a corporate restructuring the Company announced in May 2022 (the “Corporate Restructuring”); as well as deprioritizing pre-clinical and clinical activities related to our AD product candidate, BX005, partially offset by expenses related to conducting the Phase 1b/2a clinical trial of our CF product candidate, BX004.
- **General and administrative expenses** were \$1.6 million for the three months ended March 31, 2023, compared to \$2.5 million for the same period in 2022. The decrease was primarily due to reduced salaries and related expenses and stock-based compensation expenses due to a reduction in the workforce, as part of the corporate restructuring, as well as a decrease in the premium of the Company’s directors and officers’ insurance policy.
- **Net loss** for the first quarter of 2023 was \$6.4 million, compared to \$8.2 million for the same period in 2022.
- **Net cash used in operating activities** for the three months ended March 31, 2023 was \$5.0 million, compared to \$7.4 million for the same period in 2022.

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 the first quarter of 2023. 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 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, design and patient enrollment of Part 2 of the Phase 1b/2a study and the potential of targeted phage therapy to treat infections in CF patients, when it refers to other programs, such as the program to treat Atopic Dermatitis, and when it discusses the estimate of the sufficiency of its cash runway, 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 29, 2023 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)
(unaudited)

	As of	
	March 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	29,346	31,332
Restricted cash	956	962
Short-term deposits	-	2,000
Other current assets		
	<u>2,632</u>	<u>2,587</u>
Total current assets	32,934	36,881
Non-current assets		

Other assets	129	-
Operating lease right-of-use assets	3,767	3,860
Property and equipment, net	4,577	4,790
Total non-current assets	8,473	8,650
	<u>41,407</u>	<u>45,531</u>

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

	As of	
	March 31, 2023	December 31, 2022
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade accounts payable	1,359	820
Current portion of lease liabilities	669	687
Other accounts payable	2,956	2,150
Current portion of long-term debt	5,216	4,282
Total current liabilities	<u>10,200</u>	<u>7,939</u>
Non-current liabilities		
Contract liability	1,976	1,976
Long-term debt, net of current portion	9,306	10,591
Operating lease liabilities, net of current portion	3,587	3,798
Other liabilities	192	188
Total non-current liabilities	<u>15,061</u>	<u>16,553</u>
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock, \$0.0001 par value; Authorized - 1,000,000 shares as of March 31, 2023 and December 31, 2022. No shares issued and outstanding as of March 31, 2023 and December 31, 2022.	-	-
Common Stock, \$0.0001 par value; Authorized - 120,000,000 shares as of March 31, 2023 and December 31, 2022. Issued – 33,181,772 shares as of March 31, 2023 and 29,982,282 shares as of December 31, 2022. Outstanding –33,176,072 shares as of March 31, 2023 and 29,976,582 shares as of December 31, 2022.	2	2
Additional paid in capital	159,306	157,838
Accumulated deficit	(143,162)	(136,801)
Total stockholders' equity	<u>16,146</u>	<u>21,039</u>
	<u>41,407</u>	<u>45,531</u>

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BIOMX INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(USD in thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31, 2023	2022
Research and development (“R&D”) expenses, net	4,564	4,929
Amortization of intangible assets	-	380
General and administrative expenses	1,644	2,477
Operating loss	<u>6,208</u>	<u>7,786</u>
Other income	(91)	-
Interest expenses	565	461
Finance income, net	(327)	(87)
Loss before tax	<u>6,355</u>	<u>8,160</u>
Tax expenses	6	9

Net loss	6,361	8,169
Basic and diluted loss per share of Common Stock	0.20	0.27
Weighted average number of shares of Common Stock outstanding, basic and diluted	<u>32,125,227</u>	<u>29,754,240</u>

BiomX Contacts

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Source: BiomX Inc.