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): **August 9, 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

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 August 9, 2023, BiomX Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	**Description**
99.1	Press Release dated August 9, 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.

August 9, 2023

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

Exhibit 99.1

BiomX Reports Second Quarter 2023 Financial Results and Provides Business Update

Patient Screening Completed in Part 2 of Phase 1b/2a Trial of BX004 with patient enrollment expected to exceed original estimates

FDA grants BX004 Fast Track designation

Initial Data from Part 2 Now Expected in November 2023

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

CAMBRIDGE, Mass. and NESS ZIONA, Israel – Aug 9, 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 second quarter ended June 30, 2023.

"Our BX004 clinical program in cystic fibrosis ("CF") continues to build significant momentum," said Jonathan Solomon, Chief Executive Officer of BiomX. "We recently completed patient screening in Part 2 of our ongoing Phase 1b/2a trial with patient enrollment expected to exceed original estimates, which reflects continued execution by our clinical team and a growing awareness within the CF patient community of the BX004 program. I am also pleased to announce that BX004 just received Fast Track designation from the FDA, which provides further recognition that our BX004 program is addressing one of the most serious and challenging unmet medical needs facing the CF community.

"In June, we presented our positive Part 1 results at the recent European Cystic Fibrosis Conference ("ECFC") meeting, which highlighted the excellent safety of BX004 along with its notable activity in reducing *P. aeruginosa* bacteria burden. In Part 2, we are testing BX004 in a larger number of CF patients who are dosed 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 bacterial burden, along with other exploratory clinical endpoints. Based on our current estimates, we now believe the Part 2 data analysis will take an additional 4-6 weeks to complete. We therefore expect to report initial results from Part 2 in November 2023."

Clinical Program Updates

Cystic Fibrosis (BX004)

- In August 2023, the U.S. Food and Drug Administration ("FDA") granted BX004 Fast Track designation for the treatment of chronic respiratory infections caused by Pseudomonas aeruginosa (PsA) bacterial strains in patients with CF. The FDA's Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and address significant unmet medical needs. The FDA defines addressing a significant unmet medical need as providing a therapy where none exists or providing a therapy which may be potentially better than available therapies. The benefits of Fast Track designation include but are not limited to early and frequent communication with the FDA throughout the entire drug development and review process. In addition, a drug with Fast Track designation is eligible for rolling submission and priority review of its Biologics License Application and/or New Drug Application. These assure that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.[1]

- In June 2023, during the Late-Breaking Science Session at the 46th ECFC, BiomX presented positive results from Part 1 of the Phase 1b/2a trial evaluating BX004 for the treatment of chronic pulmonary infections caused by P. aeruginosa bacteria in patients with CF. Highlights from the Part 1 data, which were initially reported in February 2023, were also presented at a poster session during the ECFC meeting (link to poster) and included:
    - No safety events related to treatment with BX004
    - 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
    - Phages were detected in the sputum of 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
    - There was no emerging bacterial resistance to BX004 during or after treatment with BX004
    - 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 at least 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 November 2023.
- As previously announced, BiomX has received a Therapeutics Development Award of $5 million from the Cystic Fibrosis Foundation. The award was structured as an equity investment in which the Cystic Fibrosis Foundation purchased $5 million of BiomX common stock across two separate tranches.

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.
- On May 5, 2023, the Company announced the second closing of its $7.5 million private placement investment ("PIPE"). The Company expects to use the aggregate 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 phage therapy programs and research activities, as well as working capital and other general corporate purposes.

Second Quarter 2023 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of June 30, 2023, were $30.7 million, compared to $34.3 million as of December 31, 2022. The decrease was primarily due to net cash used in operating activities. 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 $3.8 million for the three months ended June 30, 2023, compared to $4.6 million for the same period in 2022. The decrease was primarily attributed 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 the Company's AD product candidate, BX005, and higher proceeds from collaboration agreements in the 2023 period. These were partially offset by expenses related to conducting the Phase 1b/2a clinical trial of the Company's CF product candidate, BX004.

- **General and administrative expenses** were $2.3 million for the three months ended June 30, 2023, compared to $2.4 million for the same period in 2022. The decrease primarily resulted from a reduction in the premium for the Company's directors' and officers' insurance policy.

- **Net loss** for the second quarter of 2023 was $6.4 million, compared to $7.5 million for the same period in 2022.

- **Net cash used in operating activities** for the six months ended June 30, 2023, was $9.1 million, compared to $16.4 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 second 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.

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Source: BiomX Inc.

1 Source: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

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

(unaudited)

	Note	As of June 30, 2023	As of December 31, 2022
ASSETS			
Current assets			
Cash and cash equivalents		29,711	31,332
Restricted cash		951	962
Short-term deposits		-	2,000
Other current assets	4	2,528	2,587
Total current assets		33,190	36,881
Non-current assets			
Operating lease right-of-use assets		3,673	3,860
Property and equipment, net		4,390	4,790
Total non-current assets		8,063	8,650
		41,253	45,531

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

	Note	As of June 30, 2023	As of December 31, 2022
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities			
Trade accounts payable		2,228	820
Current portion of lease liabilities		654	687
Other accounts payable	5	3,394	2,150
Current portion of long-term debt	7	5,391	4,282
Total current liabilities		11,667	7,939
Non-current liabilities			
Contract liability		1,976	1,976
Long-term debt, net of current portion	7	8,159	10,591
Operating lease liabilities, net of current portion		3,396	3,798
Other liabilities		190	188
Total non-current liabilities		13,721	16,553
Commitments and Contingencies	6		
Stockholders' equity	8		
Preferred Stock, $0.0001 par value; Authorized - 1,000,000 shares as of June 30, 2023 and December 31, 2022. No shares issued and outstanding as of June 30, 2023 and December 31, 2022.		-	-
Common Stock, $0.0001 par value; Authorized - 120,000,000 shares as of June 30, 2023 and December 31, 2022. Issued –45,979,730 shares as of June 30, 2023 and 29,982,282 shares as of December 31, 2022. Outstanding 45,974,030 shares as of June 30, 2023 and 29,976,582 shares as of December 31, 2022.		3	2
Additional paid in capital		165,435	157,838
Accumulated deficit		(149,573)	(136,801)
Total stockholders' equity		15,865	21,039
		41,253	45,531

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

	Note	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022

Research and development ("R&D") expenses, net		3,818	4,584	8,382	9,513
Amortization of intangible assets		-	379	-	759
General and administrative expenses		2,255	2,361	3,899	4,838
Operating loss		6,073	7,324	12,281	15,110
Other income		(90)	-	(181)	-
Interest expenses		745	488	1,310	949
Finance income, net		(325)	(339)	(652)	(426)
Loss before tax		6,403	7,473	12,758	15,633
Tax expenses		8	9	14	18
Net loss		6,411	7,482	12,772	15,651
Basic and diluted loss per share of Common Stock	9	0.12	0.25	0.31	0.53
Weighted average number of shares of Common Stock outstanding, basic and diluted		51,552,923	29,774,709	41,860,338	29,764,588