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): **April 3, 2024**

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 April 3, 2024, BiomX Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter ended December 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	**Description**
99.1	Press Release dated April 3, 2024 (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.

April 3, 2024

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

BiomX Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

Recent acquisition of Adaptive Phage Therapeutics creates leader in phage therapy with advanced, clinical-stage pipeline

Closed concurrent $50 million financing to support BX004 and BX211 programs through key data readouts expected in 2025

Patient recruitment on track in BX211 Phase 2 trial in Diabetic Foot Osteomyelitis ("DFO"), with topline results expected in Q1 2025

Company will host a conference call and webcast today at 8:00 am ET

CAMBRIDGE, MA and NESS ZIONA, Israel – April 3, 2024 – 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 for the fourth quarter and full year ended December 31, 2023, and provided a business update.

"2023 marked a year of great progress for BiomX, highlighted by the positive results from our Phase 1b/2a trial which demonstrated that a short course of treatment with BX004 can result in a favorable treatment effect in Cystic Fibrosis ("CF") patients with chronic *P. aeruginosa* infections. Results from this trial take us one step closer toward bringing forward a new and effective phage-based treatment option to address these deadly pulmonary infections impacting so many CF patients," said Jonathan Solomon, Chief Executive Officer of BiomX. "As BX004 continues to advance, our recent acquisition of Adaptive Phage Therapeutics provides BiomX with a second, exciting Phase 2 asset, BX211, which has the potential to address serious infections in DFO. The concurrent $50 million financing we closed provides the capital needed to reach important clinical milestones over the next 12-24 months."

Business Update

- In March 2024, the Company announced the closing of its acquisition of Adaptive Phage Therapeutics, Inc. ("APT"). The acquisition creates a leading phage therapy company with an advanced pipeline that includes two Phase 2 assets, BX004 for the treatment of chronic pulmonary infections in CF patients and BX211 for the treatment of DFO.

- In March 2024, and concurrent with the closing the APT acquisition, the Company announced the closing of a private placement financing of $50 million led by top institutional healthcare investors, including affiliates of Deerfield Management and the AMR Action Fund, and additional investors including the Cystic Fibrosis Foundation, Orbimed, and Nantahala Capital. Proceeds from the private placement are expected to provide funding through the results from a planned Phase 2b trial that will evaluate BiomX's lead product candidate, BX004, for the treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa* (*P. aeruginosa*) in CF patients expected in the third quarter of 2025 and Phase 2 results from APT's clinical-stage product candidate, BX211, for the treatment of Staphylococcus aureus (*S. aureus*) infections in DFO patients expected in the first quarter of 2025.

- In December 2023, the Company hosted a virtual KOL Event to discuss the positive topline results from Part 2 of the Phase 1b/2a trial of BX004 in CF patients with chronic *P. aeruginosa* infections. To access a replay of the event, pleaseclick here.

Clinical Program Updates

Cystic Fibrosis (BX004)

- In January 2024, the Company announced that BX004 was granted Orphan Drug Designation by the United States Food and Drug Administration ("FDA"), for the treatment of chronic pulmonary infection caused by *P. aeruginosa* in patients with CF.

- In November 2023, the Company announced positive safety and efficacy results from Part 2 of the Phase 1b/2a trial evaluating the Company's novel phage cocktail, BX004, for the treatment of chronic pulmonary infections caused by *P. aeruginosa* in CF patients. Highlights from the Part 2 data included:

  - Study drug was safe and well-tolerated, with no related SAEs (serious adverse events) or related APEs (acute pulmonary exacerbations) to study drug.

  - In the BX004 arm, 3 out of 21 (14.3%) patients converted to sputum culture negative for*P. aeruginosa* after 10 days of treatment (including 2 patients after 4 days) compared to 0 out of 10 (0%) in the placebo arm.[1]

  - BX004 vs. placebo showed a clinical effect in a predefined subgroup of patients with reduced baseline lung function (FEV1<70%). Difference between groups at Day 17: relative FEV1 improvement of 5.67% (change from baseline +1.46 vs. -4.21) and +8.87 points in CFQR respiratory symptom scale (change from baseline +2.52 vs. -6.35).

  - In full population, BX004 vs. placebo *P. aeruginosa* levels were more variable in sputum, potentially driven by the standard of care antibiotic treatment regimen. In a prespecified subgroup of patients on standard of care inhaled antibiotics on continuous regimen, BX004 vs. placebo reduced sputum *P. aeruginosa* levels at Day 10: difference in change from baseline between groups of -2.8 log10 CFU/g sputum (change from baseline -2.91 vs -0.11), exceeding Part 1 results.

  - Alternating/cycling background antibiotic regimen were likely associated with fluctuations in P. aeruginosa levels potentially confounding the ability to observe a*P. aeruginosa* reduction in this subgroup.

  - During the study period, based on current available data, no evidence of treatment-related phage resistance was observed in patients treated with BX004 compared to placebo.

[1] In patients that had quantitative CFU levels at study baseline

Diabetic Foot Osteomyelitis (BX211)

- BX211 is a personalized phage treatment that BiomX is now developing following the acquisition of APT. BX211 is being developed for the treatment of DFO associated with *S. aureus*. The safety, tolerability, and efficacy of BX211 is currently being evaluated in a randomized, double-blind, placebo-controlled, multi-center Phase 2 trial for subjects with DFO. Target enrollment for the study is 45 patients, and to date, 32 patients have been enrolled. Initial top line results of the Phase 2 trial are expected in the first quarter of 2025.

Atopic Dermatitis ("AD") (BX005)

- We have paused development efforts for BX005 due to prioritizing resources towards our CF and DFO programs, and we cannot provide guidance on resuming its development.

Full Year 2023 Financial Results

- **Cash balance, short-term deposits and restricted cash** as of December 31, 2023, were $15.9 million, compared to $34.3 million as of December 31, 2022. The decrease was primarily due to net cash used in operating activities.

- In March 2024, and concurrent with closing of the APT acquisition, the Company announced the closing of a private placement financing of $50 million. Additionally, in March 2024, the Company fully repaid its remaining balance of $10.4 million under its loan agreement with Hercules Capital, Inc. The Company estimates its cash, cash equivalents and short-term deposits are sufficient to fund its operations for at least 12 months from the issuance date of our financial statements. However, our financial statements contain an explanatory paragraph regarding substantial doubt about our ability to continue as a going concern. This is mainly due to the potential risk of our stockholders not approving the conversion of the Convertible Preferred Stock that were issued as part of the acquisition of APT and the concurrent investment.

- **Research and development expenses, net** were $16.7 million for the year ended December 31, 2023, compared to $16.2 million for the prior year. The increase was primarily attributed to an increase in expenses related to conducting the clinical trial of the Company's CF product candidate, BX004. This was partially offset by reduced salaries and related expenses and stock-based compensation expenses that resulted from a workforce reduction and the appreciation of the U.S. dollar against the NIS, which led to reduced salaries and related expenses in BiomX's Israeli subsidiary, as well as reduced expenses due to pausing in the development of BX005. In addition, increased consideration from research collaborations resulted in reduced expenses.

- **General and administrative expenses** were $8.7 million for the year ended December 31, 2023, compared to $9.5 million for the prior year. The decrease primarily resulted from a reduction in the premium for the Company's directors' and officers' insurance policy.

- **Net loss** for 2023 was $26.2 million, compared to $28.3 million for the prior year.

- **Net cash used in operating activities** for the year ended December 31, 2023, was $21.3 million, compared to $29.1 million for the same period in 2022.

Conference Call and Webcast Details

BiomX will host a conference call and webcast on April 3, 2024, at 8:00 a.m. ET to discuss its fourth quarter and full year 2023 financial results and to provide a corporate update.

Conference Call Dial-In Information:

Participant Dial-In Number:	+1 877-407-0724
Participant International Dial-In	+1 201-389-0898
Webcast:	Link

About BX004

BiomX is developing BX004, a fixed multi-phage cocktail, for the treatment of CF patients with chronic pulmonary infections caused by *P. aeruginosa*, a main contributor to morbidity and mortality in patients with CF. In November 2023, BiomX announced positive topline results from Part 2 of the Phase 1b/2a trial where BX004 demonstrated improvement in pulmonary function associated with a reduction in *P. aeruginosa* burden compared to placebo in a predefined subgroup of patients with reduced lung function[1].

BiomX expects to initiate a randomized, double blind, placebo-controlled, multi-center Phase 2b trial in CF patients with chronic *P. aeruginosa* pulmonary infections in the fourth quarter of 2024. The trial is designed to enroll approximately 60 patients randomized at a 2:1 ratio to BX004 or placebo. Treatment is expected to be administered via inhalation twice daily for a duration of 8 weeks. The trial is designed to monitor the safety and tolerability of BX004 and is designed to demonstrate improvement in microbiological reduction of *P. aeruginosa* burden and evaluation of effects on clinical parameters such as lung function measured by FEV1 and patient reported outcomes. Trial results are expected in the third quarter 2025. The FDA has granted BX004 Fast Track designation and Orphan Drug Designation.

About BX211

BX211 is a personalized phage treatment for the treatment of DFO associated with *S. aureus*. The personalized phage treatment tailors a specific phage selected from a proprietary phage-bank according to the specific strain of *S. aureus* biopsied and isolated from each patient. DFO is a bacterial infection of the bone that usually develops from an infected foot ulcer and is a leading cause of amputation in patients with diabetes.

[1] In patients that had quantitative CFU levels at study baseline

The ongoing randomized, double-blind, placebo-controlled, multi-center Phase 2 trial investigating the safety, tolerability, and efficacy of BX211 for subjects with DFO associated with *S. aureus* is expected to enroll approximately 45 subjects randomized at a 2:1 ratio to BX211 or placebo. BX211 or placebo is designed to be administered weekly, by topical and IV route at Week 1 and by the topical route only at each of Weeks 2-12. Over the 12-week treatment period, all subjects are expected to continue to be treated in accordance with standard of care which will include antibiotic treatment as appropriate. A first readout of study topline results is expected at Week 13 evaluating healing of the wound associated with osteomyelitis, followed by a second readout at Week 52 evaluating amputation rates and resolution of osteomyelitis based on X-ray, clinical assessments, and established biomarkers (ESR and CRP). These readouts are expected in the first quarter of 2025 and the first quarter of 2026, respectively.

About BiomX

BiomX is a clinical-stage company developing both natural and engineered phage cocktails and personalized phage treatments 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 expected timing of clinical trials, key data readouts and topline results, its cash runway and sufficiently of capital to meet milestones and the potential benefits of BX004 and BX211, 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. In addition, past and current pre-clinical and clinical results, as well as compassionate use, are not indicative and do not guarantee future success of BiomX clinical trials. 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, as a result of various important factors, including risks and uncertainties related to the ability to recognize the anticipated benefits of the acquisition of APT; the outcome of any legal proceedings that may be instituted against BiomX following the acquisition and related transactions; the ability to obtain or maintain the listing of the common stock of BiomX on the NYSE American following the acquisition; costs related to the acquisition; changes in applicable laws or regulations; the possibility that BiomX may be adversely affected by other economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in BiomX's drug discovery, preclinical and clinical development activities, the risk that the results of preclinical studies and early clinical trials may not be replicated in later clinical trials, BiomX's ability to enroll patients in its clinical trials, and the risk that any of its clinical trials may not commence, continue or be completed on time, or at all; decisions made by the FDA and other regulatory authorities; investigational review boards at clinical trial sites and publication review bodies with respect to our development candidates; BiomX's ability to obtain, maintain and enforce intellectual property rights for its platform and development candidates; its potential dependence on collaboration partners; competition; uncertainties as to the sufficiency of BiomX's cash resources to fund its planned activities for the periods anticipated and BiomX's ability to manage unplanned cash requirements; and general economic and market conditions. 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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BIOMX INC.
CONSOLIDATED BALANCE SHEETS
(USD in thousands, except share and per share data)

	As of December 31,	
	2023	2022
ASSETS		
Current assets		
Cash and cash equivalents	14,907	31,332
Restricted cash	957	962
Short-term deposits	-	2,000
Other current assets	1,768	2,587
Total current assets	17,632	36,881
Non-current assets		
Operating lease right-of-use assets	3,495	3,860
Property and equipment, net	3,902	4,790
Total non-current assets	7,397	8,650

	25,029	45,531

	As of December 31,	
	2023	2022
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade account payables	1,381	820
Current portion of lease liabilities	666	687
Other account payables	3,344	2,150
Current portion of long-term debt	5,785	4,282
Total current liabilities	11,176	7,939
Non-current liabilities		
Contract liability	1,976	1,976
Long-term debt, net of current portion	5,402	10,591
Operating lease liabilities, net of current portion	3,239	3,798
Other liabilities	155	188
Total non-current liabilities	10,772	16,553
Commitments and Contingencies (Note 10)		
Stockholders' equity		
Preferred Stock, $0.0001 par value; Authorized - 1,000,000 shares as of December 31, 2023 and December 31, 2022. No shares issued and outstanding as of December 31, 2023 and December 31, 2022.	-	-
Common stock, $0.0001 par value ("Common Stock"); Authorized - 120,000,000 shares as of December 31, 2023 and December 31, 2022. Issued – 45,979,930 and 29,982,282 as of December 31, 2023 and 2022, respectively. Outstanding – 45,979,930 and 29,976,582 as of December 31, 2023 and 2022, respectively.	3	2
Additional paid in capital	166,048	157,838
Accumulated deficit	(162,970)	(136,801)
Total Stockholders' equity	3,081	21,039
	25,029	45,531

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

	Year ended December 31,	
	2023	2022
Research and development ("R&D") expenses, net	16,698	16,244
Amortization of intangible assets	-	1,519
General and administrative expenses	8,650	9,456
Operating loss	25,348	27,219
Other income	(357)	(134)
Interest expenses	2,404	2,069
Finance income, net	(1,249)	(902)
Loss before tax	26,146	28,252
Tax expenses	23	65
Net Loss	26,169	28,317
Basic and diluted loss per share of Common Stock	0.51	0.95
Weighted average number of shares of Common Stock outstanding, basic and diluted	51,330,324	29,854,003