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 16, 2021**

BiomX Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**0001-38762**	**82-3364020**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

22 Einstein St., Floor 5 Ness Ziona, Israel	**7414002**
(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, included as part of the Units	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 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 16, 2021, BiomX Inc., or the Company, issued a press release announcing its financial results for the second quarter ended June 30, 2021. 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 16, 2021

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 16, 2021

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

BiomX Reports Second Quarter 2021 Financial Results and Provides Business Update

Up to $45 Million Secured from Recent Capital Raises Extends Cash Runway to at Least Mid-2023

Expecting Four Clinical Data Readouts by Mid-2022

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

NESS ZIONA, Israel – Aug 16, 2021 --BiomX Inc. (NYSE American: PHGE) ("BiomX" or the "Company"), a clinical-stage microbiome company advancing novel natural and engineered phage cocktails that target specific pathogenic bacteria, today reported financial results and provided a business update for the second quarter ended June 30, 2021.

"BiomX is approaching several important potential inflection points, with expected Phase 1b/2a or Phase 2 data readouts in four distinct indications by mid-2022, including a first readout from our Phase 2 acne study of BX001 expected in October," said Jonathan Solomon, Chief Executive Officer of BiomX. "Following our $15 million equity financing in July, which included participation by all of the members of our Board of Directors, and an up to $30 million venture debt agreement, BiomX is well-funded through these clinical data readouts, and to at least mid-2023. Entering a data-rich period for our company, we believe BiomX remains uniquely positioned at the forefront of developing precision medicines that target pathogenic bacteria to address the significant unmet medical need remaining in indications such as cystic fibrosis, atopic dermatitis, acne-prone skin, and inflammatory bowel disease."

RECENT HIGHLIGHTS AND KEY UPCOMING MILESTONES

Completion of a Registered Direct Financing in July Raising Gross Proceeds of $15 Million

On July 26, 2021, BiomX announced a registered direct offering of the Company's common stock and warrants for gross proceeds of $15 million, before fees and expenses and assuming that none of the warrants are exercised. The offering closed on July 28, 2021.

$30 Million Venture Debt Financing Agreement with Hercules Capital

BiomX also announced today that it has entered into a $30 million debt financing agreement with Hercules Capital, Inc. (NYSE: HTGC) ("Hercules"), a leader in customized debt financing for companies in life sciences and technology-related markets.

The first $15 million tranche is available upon closing. Two subsequent tranches of $10 million and $5 million will become available upon the achievement of certain milestones. The loan is for a term of 48 months and, during the first 18 months, BiomX is expected to pay only interest on the principal. The loan term and the interest only period may be extended to up to 60 and 30 months, respectively, upon satisfaction of certain milestones. No warrants were issued in connection with the debt financing.

Clinical Program Updates

Acne-Prone Skin (BX001)

- In May 2021, BiomX announced completion of enrollment in its Phase 2 cosmetic clinical study of BX001. BX001 is a topical gel that includes a combination of naturally occurring phage that specifically target *Cutibacterium acnes*. The study is evaluating reduction in *Cutibacterium acnes* burden as well as improvement in the appearance of acne-prone skin in 140 subjects with mild-to-moderate acne vulgaris. The trial is a 12-week randomized, single center, double-blind, placebo-controlled study.
- Topline results from Study BMX-001-007 were on track to be reported following the 8- and 12week treatment periods in the third and fourth quarters of 2021, respectively. Because enrollment in this study was completed two weeks ahead of schedule, a decision was made to forego the interim 8-week analysis, continue the blinded status of the study until study completion, and conduct all analyses (8-week and 12-week) at the same time. Hence, we expect the full study readout will be available at end of October, only a few weeks after the planned interim analysis.

Inflammatory Bowel Disease ("IBD") and Primary Sclerosing Cholangitis ("PSC") (BX003)

- On May 26, 2021, BiomX hosted a Key Opinion Leader ("KOL") webinar focusing on BX003, the Company's microbiome-based therapeutic, for IBD. The event featured KOL, Ryan Balfour Sartor, M.D., who discussed the IBD treatment landscape as well as the unmet medical need for these patients. Dr. Sartor was also joined by BiomX management, who provided updates on the BX003 program for IBD and PSC.
- Based on the previous promising results from the Phase 1a trial of BX002, which showed that orally administered BX002 was safe, well-tolerated and met its key objective of delivering viable phage at high concentrations to the lower gut, BiomX plans to initiate a Phase 1b/2a study to evaluate the safety, tolerability, and activity of BX003 in 60 subjects. The goal of this study is to demonstrate reduction of the target bacteria, *Klebsiella pneumoniae*, as measured in stool of target bacteria carriers. Results from this study are expected in the second quarter of 2022.

Cystic Fibrosis ("CF") (BX004)

- In June 2021, at the 44th European Cystic Fibrosis Conference, BiomX presented preclinical data highlighting *in vitro* results showing that BX004 was able to penetrate biofilm and was efficacious in significantly reducing levels of embedded *Pseudomonas aeruginosa* , as compared to two different antibiotics. BX004 is being developed for the treatment of chronic respiratory infections caused by *Pseudomonas aeruginosa*, a main contributor to morbidity and mortality in patients with CF.
- In May 2021, BiomX updated its CF clinical trial design and timelines by advancing BX004 into a two-part Phase 1b/2a trial in CF patients with chronic respiratory infections caused by *Pseudomonas aeruginosa.* Part 1 of the trial will evaluate the safety, pharmacokinetics and microbiologic/clinical activity of BX004 in eight CF patients in a single ascending dose and multiple dose design, with results expected in the first quarter of 2022. Part 2 of the trial will evaluate the safety and efficacy of BX004 in 21 CF patients randomized to a treatment or placebo cohort in a 2:1 ratio. Results from Part 2 are expected by the second quarter of 2022.

Atopic Dermatitis (BX005)

- In June 2021, preclinical results with BX005 for atopic dermatitis were presented at the Revolutionizing Atopic Dermatitis 2021 Virtual Conference and the International Conference on Phage Therapy and Bacteriophages. BX005 demonstrated broad target bacteria host range and efficient eradication of Staphylococcus aureus (S. aureus) strains with no emergence of resistant mutants for 24 hours in vitro, By reducing S. aureus burden, BX005 is designed to shift the skin microbiome composition of atopic dermatitis patients to its "pre-flare" state to potentially result in clinical improvement.
- The Company expects results from a Phase 2 proof-of-concept trial evaluating the safety and efficacy of BX005 in atopic dermatitis patients in the first half of 2022.

Colorectal Cancer

- BiomX is exploring phage-mediated delivery of therapeutic payloads, such as immunestimulating proteins, GM-CSF and IL-15, for the treatment of colorectal cancer, by targeting *Fusobacterium nucleatum* bacteria, which are present within a majority of colorectal tumors.
- BiomX expects to report results from preclinical *in vivo* studies evaluating the use of phage therapy for colorectal cancer in the fourth quarter of 2021.

Second Quarter 2021 Financial Results

- **Cash balance and short-term deposits** as of June 30, 2021, were $47.3 million, compared to $57.1 million as of December 31, 2020. The decrease was primarily due to net cash used in operating activities. Not yet included in the $47.3 million cash balance are financings completed after June 30, 2021, namely the completed $15 million registered direct equity financing and the initial $15 million tranche of the venture debt financing agreement. Including the net proceeds from these two offerings, the Company expects existing cash, cash equivalents and short-term deposits to be sufficient to fund the Company's current operating plan until at least mid-2023.
- **Research and development (R&D) expenses, net** were $3.8 million for the three months ended June 30, 2021, compared to $3.7 million for the same period in 2020. The increase was primarily due to increased expenses related to conducting pre-clinical and clinical trials of our product candidates and an increase in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees in R&D and clinical activities, partially offset by an increase in IIA grants that were recorded during the period.
- **General and administrative expenses** were $3.1 million for the three months ended June 30, 2021, compared to $2.3 million for the same period in 2020. The increase was primarily due to an increase in stock-based compensation and salaries and related expenses, mainly due to the growth in the number of employees, due to an increase in expenses associated with operating as a public company, such as directors' and officers' insurance and due to expenses from moving into new premises.
- **Net loss** for the second quarter of 2021 was $7.3 million, compared to $6.2 million for the same period in 2020.
- **Net cash used in operating activities** for the six months ended June 30, 2021 was $12.8 million, compared to $11.4 million for the same period in 2020.

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 2021 ended June 30, 2021. 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.

About BiomX

BiomX is a clinical-stage microbiome company developing both natural and engineered phage cocktails designed to target and destroy bacteria that affect the appearance of skin, as well as target bacteria in the treatment of chronic diseases, such as inflammatory bowel disease, primary sclerosing cholangitis, cystic fibrosis, atopic dermatitis and colorectal cancer. BiomX discovers and validates proprietary bacterial targets and customizes phage compositions against these targets.

Additional information is available at 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 its expectations regarding the sufficiency of cash, cash equivalents and short-term deposits to fund the Company's current operating plan until at least mid-2023, the ability of its products to address unmet medical needs, the potential for up to $15 million in additional loan tranches if certain milestones are met, the potential for extensions of the loan term and interest periods if certain milestones are met, the capabilities of the BOLT platform, the design, aim, expected timing and results of its preclinical and clinical trials, readouts and studies, as well as its pipeline and the potential of its product candidates, 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 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 June 30, 2021 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 STATEMENTS OF OPERATIONS (unaudited)

USD in thousands, except share and per share data

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development ("R&D") expenses, net	3,824	3,717	9,494	7,246
Amortization of intangible assets	380	380	759	759

General and administrative expenses	3,098	2,297	5,591	4,355
Operating loss	7,302	6,394	15,844	12,360
Financial expenses (income), net	31	(188)	(112)	(253)
Loss before tax	7,333	6,206	15,732	12,107
Tax expenses	3	-	6	-
Net Loss	7,336	6,206	15,738	12,107
Basic and diluted loss per share of Common Stock	0.30	0.27	0.65	0.53
Weighted average number of shares of Common Stock outstanding, basic and diluted	24,320,259	22,969,075	24,134,065	22,944,482

BIOMX INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

USD in thousands

	As of	
	June 30, 2021	**December 31, 2020**
ASSETS		
Current assets		
Cash and cash equivalents	46,271	36,477
Restricted cash	982	763
Short-term deposits	-	19,851
Other current assets	2,585	3,576
Total current assets	49,838	60,667
Property and equipment, net	5,122	2,228
Intangible assets, net	2,279	3,038
Operating lease right-of-use assets	4,410	4,430
Total non-current assets	11,811	9,696
	61,649	70,363

	As of	
	June 30, 2021	**December 31, 2020**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Trade account payables	1,769	2,320
Other account payables	5,199	3,978
Current portion of operating lease liabilities	791	863
Total current liabilities	7,759	7,161
Non-current liabilities		
Operating lease liabilities, net of current portion	4,879	5,032
Contingent considerations	419	701
Total non-current liabilities	5,298	5,733
Commitments and Contingent Considerations		
Stockholders' equity		
Preferred stock, $0.0001 par value; Authorized - 1,000,000 shares as of June 30, 2021 and December 31, 2020. No shares issued and outstanding as of June 30, 2021 and December 31, 2020.	-	-
Common stock, $0.0001 par value; Authorized - 60,000,000 shares as of June 30, 2021 and December 31, 2020. Issued – 24,434,776 shares as of June 30, 2021 and 23,270,337 shares as of December 31, 2020. Outstanding – 24,429,076 shares as of June 30, 2021 and 23,264,637 shares as of December 31, 2020.	2	2
Additional paid in capital	136,586	129,725
Accumulated deficit	(87,996)	(72,258)
Total stockholders' equity	48,592	57,469
	61,649	70,363

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Source: BiomX Inc