

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 19, 2025**

<b>BiomX Inc.</b>		
(Exact Name of Registrant as Specified in its Charter)		
<b>Delaware</b>	<b>001-38762</b>	<b>82-3364020</b>
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
<b>22 Einstein St., Floor 4</b> <b>Ness Ziona, Israel</b>		<b>7414003</b>
(Address of Principal Executive Offices)		(Zip Code)
Registrant's telephone number, including area code: <b>+972 723942377</b>		
<b>n/a</b>		
(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
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 8.01 Other Events.**

On August 19, 2025 BiomX Inc. ("BiomX" or the "Company") announced that the U.S. Food and Drug Administration ("FDA") has placed a clinical hold on the Company's Phase 2b study (the "Study") that is design to test the Company's drug candidate BX004 ("BX004") in treating Cystic Fibrosis ("CF") as the FDA reviews data submitted by the Company on a third-party nebulizer used in the Study to deliver BX004.

The FDA did not raise concerns in the clinical hold notification regarding BX004. Following the FDA's hold notification the Company submitted additional requested data. As a result of the FDA's notification, patient screening and enrollment in the U.S. portion of the Study have now been paused. In Europe, all components of the third-party nebulizer device are CE marked and thus have been deemed to meet applicable regulatory requirements. The Study in the EU has been approved and enrollment and dosing of patients are continuing in accordance with the protocol of the Study.

*Forward-Looking Statements*

This Current Report 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 refers to the clinical hold imposed by the FDA, the possibility that the data BiomX provided will allow the FDA to lift such clinical hold, that such clinical hold will be lifted soon, if at all, the timing, process and potential outcomes of review and other measures by the European regulatory authorities, resumption of patient enrollment and timing thereof and the impact of the FDA clinical hold on the BX004 Phase 2b trial, it is using 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. These risks and uncertainties include, but are not limited to, 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; decisions made by 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 25, 2025, and additional disclosures BiomX makes in its other filings with the SEC, which are available on the SEC’s website at [www.sec.gov](http://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.

**SIGNATURES**

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 19, 2025

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