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): February 14, 2023

AMYLYX PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-41199**	**46-4600503**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

43 Thorndike, St., Cambridge, MA	**02141**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 682-0917

Not Applicable
(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 per share	AMLX	Nasdaq Global Select Market

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 7.01 Regulation FD Disclosure.

On Tuesday, February 14, 2023, Amylyx Pharmaceuticals, Inc. (the "Company") will present at the SVB Securities Global Biopharma Conference. During the presentation, the Company will provide a corporate update, including information on the commercial launch of RELYVRIO® in the U.S., among other topics.

The Company has observed higher demand for RELYVRIO in the U.S. than initially anticipated pre-launch and, as a result, expects to meaningfully exceed fourth quarter and full-year 2022 Wall Street research analyst consensus estimates for revenue. The Company will provide fourth quarter and year-end 2022 financial results on its conference call in early March 2023.

Amylyx will also provide an update on access and insurance coverage in the U.S. At this point, insurers representing about a quarter of covered lives in the U.S. have published their coverage policies nearly all of which provide broad access to RELYVRIO. The Company continues to expect the majority of payers to formalize their coverage decision policies during the first half of 2023.

The Company recently learned that certain prescriptions were being reported to third-party data vendors. Starting on February 19, Amylyx expects data from its pharmacy network will no longer flow to these third-party data reporting vendors consistent with the closed pharmacy network model.

Amylyx continues to expect a decision in the European Union on its Marketing Authorisation Application for AMX0035 for the treatment of ALS in the first half of 2023. The Company received the Day 180 List of Outstanding Questions, which it has responded to. As expected, the Committee for Medicinal Products for Human Use (CHMP) will hold a Scientific Advisory Group meeting this month as part of the regulatory review process. The Company is also preparing for a potential Oral Explanation in the case that CHMP decides to conduct one as part of the review process. If the Company receives EU approval based on the Phase 2 CENTAUR data, the Company continues to expect the approval to be a conditional marketing authorization, with the completion of the Phase 3 PHOENIX clinical trial as a post-marketing condition.

On February 2, 2023, the Company announced completion of enrollment in PHOENIX, which enrolled 664 participants. The Company anticipates topline results from the trial in mid-2024.

The information contained in Item 7.01 of this Current Report on Form 8-K is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

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 thereunto duly authorized.

AMYLYX PHARMACEUTICALS, INC.

Date: February 14, 2023

By: /s/ James M. Frates
James M. Frates
Chief Financial Officer