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): June 23, 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 8.01 Other Events.

On June 23, 2023, Amylyx Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the Committee for Medicinal Products for Human Use of the European Medicines Agency has adopted a negative opinion on the application for conditional marketing authorisation of AMX0035 (sodium phenylbutyrate and ursodoxicoltaurine [also known as taurursodiol]), under the trade name ALBRIOZA®, for the treatment of adults with amyotrophic lateral sclerosis in the European Union. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company, dated June 23, 2023
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

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: June 23, 2023

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

Exhibit 99.1

Amylyx Pharmaceuticals Receives CHMP Negative Opinion on its Conditional Marketing Authorisation Application for AMX0035 for the Treatment of ALS in the European Union

- Amylyx will seek re-examination of its Conditional Marketing Authorisation Application

CAMBRIDGE, Mass. June 23, 2023 — Amylyx Pharmaceuticals, Inc. (NASDAQ: AMLX) ("Amylyx" or the "Company") today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on the application for conditional marketing authorisation of AMX0035 (sodium phenylbutyrate and ursodoxicoltaurine [also known as taurursodiol]), under the trade name ALBRIOZA®, for the treatment of adults with amyotrophic lateral sclerosis (ALS) in the European Union (EU). Today's update follows the Company's May 2023 announcement that the CHMP was trending toward a negative opinion.

"We are confident in the strength of our CENTAUR trial data, which we believe meets the criteria for conditional approval. These data were also the basis of the full approval received from the U.S. Food and Drug Administration and the approval with conditions from Health Canada," said Tammy Sarnelli, Global Head, Regulatory Affairs and Clinical Compliance at Amylyx. "We disagree with the CHMP's opinion and will request a formal re-examination procedure of the current Marketing Authorisation Application (MAA)."

CENTAUR met its prespecified primary outcome, and AMX0035 is the first ALS therapy to demonstrate, in the same trial, both a statistically significant benefit in function, as well as an observed benefit on overall survival in a longer-term post hoc analysis. AMX0035 demonstrated a generally well-tolerated safety profile in the CENTAUR trial, with similar reported rates of adverse events and discontinuations in AMX0035 and placebo groups during the 24-week randomized phase; however, gastrointestinal events occurred with greater frequency (≥2%) in the AMX0035 group.

The CENTAUR data were published in peer-reviewed medical journals, including the *New England Journal of Medicine*, *Muscle & Nerve*, and the *Journal of Neurology, Neurosurgery, and Psychiatry*.

"We will continue to engage with CHMP and EMA through the re-examination process with the goal of making ALBRIOZA available in Europe as it is in the United States and Canada. We know how precious time is for people with ALS and their families," said Joshua Cohen and Justin Klee, Co-CEOs of Amylyx.

The re-examination procedure is an approximately four-month process, which includes the appointment of a different rapporteur and co-rapporteur from the initial evaluation. At the end of the re-examination, the CHMP will adopt a final opinion.

"While our MAA continues to be under review, we will also work towards completing our global Phase 3 PHOENIX study, with topline results anticipated in mid-2024, which will provide important additional data on the efficacy and safety profile of ALBRIOZA," said Stéphanie Hoffmann-Gendebien, General Manager and Head of EMEA at Amylyx. "We remain committed to exploring all potential paths forward. There have been no new innovations approved in Europe for this devastating disease in over 25 years, and we recognize the urgent need of the ALS community in Europe to access new treatment options."

ALS affects approximately 29,000 people in the U.S. and more than 30,000 people are estimated to be living with ALS in Europe (EU and United Kingdom).

About RELYVRIO®/ ALBRIOZA™ / ALBRIOZA® / AMX0035

RELYVRIO®, an oral, fixed-dose combination of sodium phenylbutyrate and taurursodiol (known as ursodoxicoltaurine outside of the U.S.), is approved to treat amyotrophic lateral sclerosis (ALS) in adults in the U.S. and approved with conditions as ALBRIOZA™ for the treatment of ALS in Canada. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on the application for conditional marketing authorisation of AMX0035, under the trade name ALBRIOZA®, for the treatment of ALS in the European Union, and Amylyx will request a formal re-examination procedure of the current Marketing Authorisation Application. AMX0035 is being explored for the potential treatment of other neurodegenerative diseases. The formulation of RELYVRIO, ALBRIOZA, and AMX0035 are identical.

About the CENTAUR Trial

CENTAUR was a multicenter Phase 2 clinical trial in 137 participants with ALS encompassing a 6-month randomized placebo-controlled phase and an open-label extension (OLE) long-term follow-up phase. The trial met its primary efficacy endpoint.

Detailed safety and functional efficacy data from CENTAUR were published in the *New England Journal of Medicine*. Data from additional analyses from the CENTAUR trial were published in *Muscle & Nerve* in 2020 and 2022, and the *Journal of Neurology, Neurosurgery, and Psychiatry* in 2022.

The CENTAUR trial was funded, in part, by the ALS ACT grant and the ALS Ice Bucket Challenge, and was supported by The ALS Association, ALS Finding a Cure (a program of The Leandro P. Rizzuto Foundation), the Northeast ALS Consortium, and the Sean M. Healey & AMG Center for ALS at Mass General.

About ALS

ALS is a relentlessly progressive and fatal neurodegenerative disorder caused by motor neuron death in the brain and spinal cord. Motor neuron loss in ALS leads to deteriorating muscle function, the inability to move and speak, respiratory paralysis and eventually, death. More than 90% of people with ALS have sporadic disease, showing no clear family history. ALS affects approximately 29,000 people in the U.S. and more than 30,000 people are estimated to be living with ALS in Europe (European Union and United Kingdom). People living with ALS have a median survival of approximately two years from diagnosis.

About Amylyx Pharmaceuticals

Amylyx Pharmaceuticals, Inc. is committed to supporting and creating more moments for the neurodegenerative disease community through the discovery and development of innovative new treatments. Amylyx is headquartered in Cambridge, Massachusetts and has operations in Canada and EMEA. For more information, visit amylyx.eu and follow us on LinkedIn and Twitter. For investors, please visit investors.amylyx.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the timing and results of the global Phase 3 PHOENIX trial; the potential approval of AMX0035 for the treatment of ALS in countries other than the United States and Canada; the potential of AMX0035 as a treatment for ALS and the Company’s plans to explore the use of AMX0035 for other neurodegenerative diseases; the process and timing of the EMA’s formal re-examination procedure of the Company’s Marketing Authorisation Application for AMX0035 for the treatment of ALS in Europe; and expectations regarding our longer-term strategy. Any forward-looking statements in this press release are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: Amylyx’ ability to fund operations, the success, cost, and timing of Amylyx’ program development activities, Amylyx’ ability to execute on its commercial and regulatory strategy, regulatory developments, expectations regarding the outcome of the re-examination of AMX0035 for the treatment of ALS, and Amylyx’ reliance on third parties, including to conduct clinical trials and manufacture products, and the effect of global economic uncertainty and financial market volatility caused by economic effects of rising inflation and interest rates, the COVID-19 pandemic, geopolitical instability, changes in international trade relationships and military conflicts, as well as the risks and uncertainties set forth in Amylyx’ United States Securities and Exchange Commission (SEC) filings, including Amylyx’ Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, and subsequent filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Subject to any obligations under applicable law, Amylyx undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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