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): May 12, 2022

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 2.02 Results of Operations and Financial Condition.

On May 12, 2022, Amylyx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the three months ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided in this Form 8-K, including Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company, dated May 12, 2022
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: May 12, 2022

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

Exhibit 99.1

Amylyx Pharmaceuticals Reports First Quarter 2022 Financial Results

- *Final stages of commercial launch readiness underway to support the launch of AMX0035 for the treatment of ALS in the U.S. and Canada, if approved*

- *Data published in Muscle & Nerve further demonstrate significant benefit of AMX0035 on survival in Phase 2 CENTAUR trial participants*

CAMBRIDGE, Mass. May 12, 2022 -- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today reported financial results for the quarter ended March 31, 2022.

"We are encouraged by the overall progress Amylyx made over the first quarter of 2022. We are continuing to engage with regulators throughout the review process to move AMX0035 toward potential regulatory approvals as quickly and efficiently as possible," said Josh Cohen, Co-CEO and Co-Founder of Amylyx. "We remain confident in the safety and efficacy data on AMX0035. These data have been published in the New England Journal of Medicine and Muscle & Nerve, and as we have heard from the ALS community, there is a crucial need for new and effective treatments in ALS."

Justin Klee, Co-CEO and Co-Founder of Amylyx, added, "We plan to be ready for a commercial launch in the United States and Canada over the next few months if we receive regulatory approvals. Our team has worked tirelessly as we know time is of the essence for people living with ALS and their families."

First Quarter 2022 and Year-to-Date Business Highlights:

- **Regulatory applications under review for AMX0035 for the treatment of amyotrophic lateral sclerosis (ALS) in the U.S., Canada, and Europe.**

    - New Drug Application (NDA) for AMX0035 for the treatment of ALS under Priority Review by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) date is June 29, 2022. The FDA held a Peripheral and Central Nervous System Drugs Advisory Committee (PCNSDAC) meeting on March 30, 2022. On the question, "Do the data from the single randomized, controlled trial and the open-label extension study [Phase 2 CENTAUR trial] establish a conclusion that sodium phenylbutyrate/taurursodiol [AMX0035] is effective in the treatment of patients with amyotrophic lateral sclerosis (ALS)?", the PCNSDAC voted 4 yes votes and 6 no votes.

    - New Drug Submission for AMX0035 for the treatment of ALS under review by Health Canada.

    - Marketing Authorisation Application for AMX0035 for the treatment of ALS under review with European Medicines Agency's Committee for Medicinal Products for Human Use.

- **Announced publication of new analyses from the CENTAUR trial, further demonstrating significant survival benefit of AMX0035 in peer-reviewed medical journal, Muscle & Nerve.** A post-hoc analysis using the rank-preserving structural failure time model (RPSFTM), a method frequently employed in oncology to account for placebo crossover, estimated a 10.6-month longer median survival duration for participants originally randomized to AMX0035 than participants originally randomized to placebo. In addition, participants randomized to receive AMX0035 and who continued into the open-label extension (OLE) phase showed an 18.8-month longer median survival duration than participants who never received AMX0035 in a subgroup analysis.

- **Announced the presentation of safety and tolerability data from the CENTAUR and PEGASUS trials in participants with ALS and Alzheimer's disease, respectively, at the 2022 American Academy of Neurology ("AAN") Annual Meeting.** The data support the overall safety profile of AMX0035 as findings

from these trials showed adverse event incidence was generally similar between AMX0035 and placebo groups in both sets of trial participants. Majority of treatment-emergent adverse events (TEAEs) associated with AMX0035 were gastrointestinal in both trials with no new safety signals identified. The data were presented on Monday, April 4, 2022, at the AAN Annual Meeting in Seattle, Washington.

- **Announced the presentation of safety and tolerability data from the CENTAUR and PEGASUS trials in participants with amyotrophic lateral sclerosis (ALS) and Alzheimer's disease (AD), respectively, at the 2022 American Academy of Neurology ("AAN") Annual Meeting.** The data support the overall safety profile of AMX0035 as findings from these trials showed adverse event incidence was generally similar between AMX0035 and placebo groups in both sets of trial participants. Majority of treatment-emergent adverse events (TEAEs) associated with AMX0035 were gastrointestinal in both trials with no new safety signals were identified. The data were presented on Monday, April 4, 2022, at the AAN Annual Meeting in Seattle, Washington.

- **Announced the launch of an Expanded Access Program (EAP) for AMX0035 in the U.S. for people living with ALS that meet program eligibility criteria.** The U.S. EAP is running in parallel with the ongoing global Phase 3 PHOENIX trial and the FDA marketing application review. People with ALS who are eligible for PHOENIX are not eligible for the U.S. EAP as the criteria for entry do not overlap.

Financial Results for the First Quarter Ended March 31, 2022

For the quarter ended March 31, 2022, research and development expenses were $21.5 million, compared to $6.9 million for the quarter ended March 31, 2021. The increase was mainly driven by costs associated with the PHOENIX Phase 3 trial of AMX0035 for the treatment of ALS, higher product manufacturing and development expenses, and increased personnel and related expenses due to increased headcount in anticipation of potential commercialization.

General and administrative expenses were $26.4 million for the quarter ended March 31, 2022, compared to $6.0 million for the quarter ended March 31, 2021. The increase was primarily due to higher personnel costs as a result of hiring additional employees to support launch preparation initiatives and an increase in professional service fees associated with commercial readiness activities.

Net loss for the quarter ended March 31, 2022 was $47.8 million, or $0.93 per share, compared to a net loss of $14.5 million, or $2.33 per share, in 2021.

Cash, cash equivalents and short-term investments were $255.2 million at March 31, 2022, compared to $96.1 million at December 31, 2021. The increase was primarily driven by the completion of an initial public offering of common stock in January 2022.

About AMX0035

AMX0035 is a proprietary oral fixed-dose combination of two small molecules: sodium phenylbutyrate (PB), which is a small molecular chaperone designed to reduce the unfolded protein response (UPR), preventing cell death resulting from the UPR, and taurursodiol (TURSO; also known as ursodoxicoltaurine), which is a Bax inhibitor designed to reduce cell death through apoptosis. PB and TURSO were combined in a fixed-dose formulation in an effort to reduce neuronal death and dysfunction. AMX0035 is designed to target the endoplasmic reticulum and mitochondrial-dependent neuronal degeneration pathways in ALS and other neurodegenerative diseases.

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 long-term follow-up phase. The trial met its primary efficacy endpoint of reducing functional decline as measured by the ALS Functional Rating Scale-Revised (ALSFRS-R).

Overall, reported rates of adverse events and discontinuations were similar between AMX0035 and placebo groups during the 24-week randomized phase; however, gastrointestinal events occurred with greater frequency (≥2%) in the AMX0035 group. Detailed data from CENTAUR is published in the New England Journal of Medicine (NEJM) and Muscle & Nerve.

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 the PEGASUS Trial

PEGASUS (NCT03533257) was a randomized, double-blind, multi-center, placebo-controlled trial evaluating the safety, tolerability and activity of AMX0035 in 95 adults with dementia or late mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) over 24 weeks of treatment. The trial was designed to evaluate tolerability in this patient population while also assessing efficacy measures and diverse, disease-relevant markers to allow for evaluation and correlation of imaging-based markers, neurobiological changes, functional measures, and cognitive outcomes in a broad group of people with AD.

About the PHOENIX Trial

The Phase 3 PHOENIX clinical trial (NCT05021536) is a 48-week, randomized placebo-controlled global clinical trial further evaluating the safety and efficacy of AMX0035 (PB/TURSO) in people with ALS. The primary efficacy outcome of the trial will be a joint assessment of Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R) total score progression over 48 weeks and survival. Secondary efficacy outcomes will include change in slow vital capacity (SVC), measured both at home using a self-administered spirometer to support virtual data collection and at clinic sites using standard spirometry, quality of life patient-reported outcome assessments, ventilation-free survival rates and other measures. More information on the PHOENIX trial can be found at www.clinicaltrials.gov and eudract.ema.europa.eu.

About Amylyx Pharmaceuticals

Amylyx Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company working on developing a novel therapeutic for amyotrophic lateral sclerosis (ALS) and other neurodegenerative diseases. For more information, visit amylyx.com 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: Amylyx' strategy, business plans and objectives for 2022 and beyond; the potential of AMX0035 as a treatment for ALS, the efficacy and safety profile of AMX0035 and the potential for regulatory approval of AMX0035 as a treatment for ALS in the U.S., Canada and Europe; the potential commercial launch of AMX0035 as a treatment for ALS, if approved, and the ability to scale operations to prepare for commercial launch; the timing, progress and results of our Phase 3 PHOENIX clinical trial of AMX0035; the potential of AMX0035 or other future therapeutic candidates as a treatment for neurodegenerative diseases generally; and expectations regarding our longer-term strategy. Any forward-looking statements in this statement 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: 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 timing of FDA review of AMX0035 for the treatment of ALS, Amylyx' ability to fund operations, and the impact that the ongoing COVID-19 pandemic will have on Amylyx' operations, as well as those risks and

uncertainties set forth in Amylyx' United States Securities and Exchange Commission (SEC) filings, including Amylyx' Annual Report on Form 10-K for the year ended December 31, 2021, 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. 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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AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED
(in thousands)

	March 31, 2022	December 31, 2021
Assets		
Cash, cash equivalents and short-term investments	$ 255,205	$ 96,118
Prepaid expenses and other current assets	10,283	5,392
Deferred offering costs	—	3,441
Other assets	8,950	663
Total assets	$ 274,438	$ 105,614
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Accounts payable and accrued expenses	$ 26,301	$ 17,396
Other liabilities	7,191	35
Total liabilities	33,492	17,431
Redeemable convertible preferred stock	—	239,351
Stockholders' equity (deficit)	240,946	(151,168)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 274,438	$ 105,614

AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
UNAUDITED
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 21,464	$ 6,864
General and administrative	26,350	6,004
Total operating expenses	47,814	12,868
Loss from operations	(47,814)	(12,868)
Other income (expense), net	112	(1,655)
Loss before income taxes	(47,702)	(14,523)
Provision for income taxes	146	—
Net loss	$ (47,848)	$ (14,523)
Net loss per share attributable to common stockholders —basic and diluted	$ (0.93)	$ (2.33)
Weighted-average shares used in computing net loss per share attributable to common stockholders—basic and diluted	51,604,310	6,234,637