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): March 30, 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 March 30, 2022, Amylyx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2021. 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 March 30, 2022

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: March 30, 2022

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

Exhibit 99.1

Amylyx Pharmaceuticals Reports Full Year 2021 Financial Results

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

- *FDA assigned PDUFA action date of June 29, 2022*

CAMBRIDGE, Mass. March 30, 2022 -- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today reported financial results for the full year ended December 31, 2021.

"2021 was a transformative year for Amylyx as we successfully executed against several clinical and regulatory milestones," said Justin Klee and Josh Cohen, Co-CEOs and Co-Founders of Amylyx. "There is an urgent need for new treatments in ALS, and we believe we have made meaningful progress in developing the first drug candidate that has demonstrated the potential to both improve function and extend life. If approved, we look forward to making AMX0035 available to as many eligible people living with ALS as possible. We look forward to continuing to engage with regulators and expanding our pipeline, including research of AMX0035 in additional indications."

James Frates, Chief Financial Officer of Amylyx added, "After a successful IPO, we began 2022 with a strong balance sheet and resources to support commercial launch preparations for AMX0035 for people living with ALS and to advance our research in neurodegenerative diseases."

Full Year 2021 and Year-to-Date 2022 Business Highlights:

- **Submitted regulatory applications for AMX0035 for the treatment of ALS to regulatory authorities in the U.S., Europe, and Canada, which were accepted for review.**

    - Received U.S. Food and Drug Administration (FDA) acceptance and Priority Review of New Drug Application (NDA) for AMX0035 for the treatment of amyotrophic lateral sclerosis (ALS). The FDA assigned a Prescription Drug User Fee Act (PDUFA) date of June 29, 2022 and today held a Peripheral and Central Nervous System Drugs Advisory Committee (PCNSDAC) meeting to review the Company's NDA for AMX0035 for the treatment of ALS.

    - Announced European Medicines Agency validation of Marketing Authorisation Application for AMX0035 for the treatment of ALS. The application is now under review with the Committee for Medicinal Products for Human Use.

    - Announced Health Canada accepted for review the New Drug Submission for AMX0035 for the treatment of ALS.

- **Announced 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 will run in parallel with the ongoing global Phase 3 PHOENIX trial and the FDA's marketing application review. People with ALS who are eligible for PHOENIX will not be eligible for the U.S. EAP as the criteria for entry do not overlap.

- **Completed a successful initial public offering.** The Company raised $196.9 million in net proceeds after deducting underwriting discounts, commissions, and offering expenses.

- **Presented clinical data from the PEGASUS Phase 2 clinical trial of AMX0035 for the treatment of Alzheimer's Disease at the Clinical Trials on Alzheimer's Disease Conference.** AMX0035 met the primary endpoint of safety and tolerability and was observed to have had a significant impact on multiple biomarkers of interest in Alzheimer's Disease.

- **Announced first participants dosed in the PHOENIX global Phase 3 clinical trial of AMX0035 in ALS.** The Phase 3 follow up clinical trial to the Phase 2 CENTAUR clinical trial is being conducted at approximately 65 sites in Europe and the U.S. in collaboration with TRICALS and Northeast ALS (NEALS) consortia, respectively. The trial will enroll approximately 600 participants. The Company has recruited approximately 150 participants to date, and we anticipate topline results in 2024.

- **Presented long-term survival data of AMX0035 for ALS from the CENTAUR trial at the 2021 Virtual American Academy of Neurology ("AAN") Annual Meeting.** The abstract was awarded the merit of distinction by the AAN and the Science Committee.

- **Strengthened corporate leadership team and Board of Directors.** With the addition of James Frates as Chief Financial Officer, Gina Mazzariello as Chief Legal Officer and General Counsel, Chris Aiello, Head, General Manager in Canada, and Stéphanie Hoffmann-Gendebien, MBA, as Head, General Manager in EMEA, the Company continues to build a world class, experienced leadership team. The Board of Directors was also strengthened by the appointments of two additional independent directors, Daphne Quimi and Paul Fonteyne.

Financial Results for the Year Ended December 31, 2021

For the year ended December 31, 2021, research and development expenses were $44.0 million, compared to $24.6 million for the year ended December 31, 2020. The increase was mainly driven by costs associated with the PHOENIX Phase 3 trial of AMX0035 for the treatment of ALS that commenced in 2021, and increased personnel and related expenses due to increased headcount. Included in research and development expenses are costs associated with product manufacturing development.

For the year ended December 31, 2021, general and administrative expenses were $38.9 million, compared to $15.1 million for the year ended December 31, 2020. The increase was primarily due to personnel and related expenses and professional service fees associated with commercial readiness activities.

Net loss for the year ended December 31, 2021 was $87.9 million, or $13.35 per share, compared to a net loss of $42.3 million, or $6.96 per share, in 2020.

Cash, cash equivalents and short-term investments were $96.1 million at December 31, 2021, compared to $12.9 million at December 31, 2020. The December 31, 2021 balance excludes aggregate net proceeds from our initial public offering of $196.9 million after deducting underwriting discounts and commissions and other offering costs, as the transaction closed in 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 clinical 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, GI events occurred with greater frequency (≥2%) in the AMX0035 group.

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 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, NCT05021536.

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 www.amylyx.com and follow us on LinkedIn and Twitter. For investors, please visit www.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 the of 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 approval of AMX0035 for the treatment of ALS; the potential of AMX0035 as a treatment for ALS; 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; 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 filings. 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.

AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED
(in thousands)

	December 31,	
	2021	2020
Assets		
Cash, cash equivalents and short-term investments	$ 96,118	$ 12,877
Prepaid expenses and other current assets	5,392	762
Deferred offering costs	3,441	—
Other assets	663	465
Total assets	$ 105,614	$ 14,104
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Accounts payable and accrued expenses	$ 17,396	$ 7,326
Other liabilities	35	1,441
Total liabilities	17,431	8,767
Redeemable convertible preferred stock	239,351	72,062
Stockholders' deficit	(151,168)	(66,725)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 105,614	$ 14,104

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

	Year Ended December 31,	
	2021	2020
Grant revenue	$ 285	$ 650
Operating expenses:		
Research and development	44,040	24,594
General and administrative	38,933	15,061
Total operating expenses	82,973	39,655
Loss from operations	(82,688)	(39,005)
Other income (expense), net	(5,243)	(3,275)
Net loss	(87,931)	(42,280)
Net loss per share attributable to common stockholders —basic and diluted	$ (13.35)	$ (6.96)
Weighted-average shares used in computing net loss per share attributable to common stockholders—basic and diluted	6,586,349	6,077,758

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