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): November 10, 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 November 10, 2022, Amylyx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2022. A copy of the press release is furnished as Exhibit 99.1 hereto.

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 November 10, 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: November 10, 2022

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

Exhibit 99.1

Amylyx Pharmaceuticals Reports Third Quarter 2022 Financial Results

- *RELYVRIO™ (sodium phenylbutyrate and taurursodiol) approved for the treatment of ALS in adults and now commercially available in the U.S., representing second product launch for Amylyx worldwide*

- *Commercial launch of ALBRIOZA™ (sodium phenylbutyrate and ursodoxicoltaurine) in Canada continues to progress*

- *Management to host conference call and webcast today at 4:30 p.m. Eastern Time*

CAMBRIDGE, Mass. Nov. 10, 2022 -- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today reported financial results for the quarter ended September 30, 2022.

"The third quarter has proven to be a transformative time for Amylyx and the ALS community, marked by the regulatory approval of our new oral therapy for the treatment of ALS in the United States and commercial availability of our first product in Canada," said Joshua Cohen and Justin Klee, Co-CEOs of Amylyx. "We are thrilled that RELYVRIO and ALBRIOZA are now available to people living with ALS in the U.S. and Canada, and we are encouraged by the early trajectory of enrollment in our Amylyx Care Team (ACT) Support Program as well as the rate of new prescriptions for this important new therapeutic option. We continue to work expeditiously during the early stages of our commercial launch to ensure every elibible person living with ALS will gain access as quickly and efficiently as possible."

Third Quarter 2022 and Recent Business Highlights:

- **Announced FDA approval of RELYVRIO™ (sodium phenylbutyrate and taurursodiol) for the treatment of adults with amyotrophic lateral sclerosis (ALS) on September 29.** This decision represents Amylyx' first regulatory approval in the U.S. and second worldwide. Shipments of RELYVRIO, previously known as AMX0035, commenced on October 24.

- **Announced availability of ALBRIOZA™ (sodium phenylbutyrate and ursodoxicoltaurine) in Canada for the treatment of ALS.** Commercial launch of ALBRIOZA, previously known as AMX0035, in Canada commenced on July 29. This announcement marked the first commercial availability of AMX0035 worldwide.

- **Marketing Authorisation Application (MAA) for AMX0035 for the treatment of ALS under review with European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).** The Company has received the Rapporteurs Day 150 Joint Assessment Report, which is provided to applicants as a reference as the CHMP collects comments to responses made to the Day 120 List of Questions. The Company has resolved certain major objections from the Day 120 List of Questions and will continue to work to address those remaining as part of the MAA review process. The Company currently expects a decision from the EMA in the first half of 2023. Preparations are underway for commercialization of AMX0035 in the European Union if remaining objections are resolved and approval is received.

- **Announced publication of preclinical data showing the combined potential synergistic effect of sodium phenylbutyrate and taurursodiol, compared to the individual compounds, in the peer-reviewed medical journal, *Annals of Clinical and Translational Neurology*.** These data on the transcriptomic and metabolomic profiles of primary skin fibroblasts from adults with sporadic ALS and adults without ALS showed that combined sodium phenylbutyrate and taurursodiol had a greater and more distinct effect on genes and metabolites involved in ALS-relevant pathways compared to either sodium phenylbutyrate or taurursodiol (also known as ursodoxicoltaurine) alone.

- **Presented preclinical data at the Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS) Annual Meeting on AMX0114, a new, internally developed compound targeting Calpain-2 (CAPN2), a critical effector of axonal degeneration.** AMX0114 is in Investigational New Drug (IND)-enabling studies.

- **Completed an upsized public offering.** In October, the Company raised $230.8 million in net proceeds after deducting underwriting discounts, commissions, and offering expenses in a public offering of common stock.

Financial Results for the Third Quarter Ended September 30, 2022

For the quarter ended September 30, 2022, net product revenue was $0.3 million and cost of sales were $0.2 million. Both net product revenue and cost of sales during the period were attributable to sales of ALBRIOZA in Canada. There were no product revenues or cost of sales for the comparable period in 2021.

Research and development expenses were $24.9 million for the quarter ended September 30, 2022, compared to $12.9 million for the quarter ended September 30, 2021. The increase was mainly driven by higher product manufacturing and development expenses in support of the global Phase 3 PHOENIX clinical trial and launch preparation activities for commercialization, as well as additional personnel-related expenses due to new headcount to support research and development efforts.

Selling, general and administrative expenses were $29.9 million for the quarter ended September 30, 2022, compared to $10.4 million for the quarter ended September 30, 2021. The increase was mainly driven by higher personnel-related expenses to support launch preparation initiatives as well as increased expenses for commercial readiness activities and operations as a public company.

Net loss for the quarter ended September 30, 2022, was $53.8 million, or $0.92 per share, compared to a net loss of $23.1 million, or $3.42 per share, for the same period in 2021.

Cash, cash equivalents and short-term investments were $162.6 million at September 30, 2022, compared to $206.7 million at June 30, 2022. The September 30, 2022 balance excludes aggregate net proceeds from Amylyx' upsized public offering of common stock of $230.8 million after deducting underwriting discounts and commissions and offering expenses, which closed on October 11, 2022.

Investor Conference Call Information
Amylyx' management team will host a conference call and webcast today, November 10, 2022, at 4:30 p.m. Eastern Time to discuss financial results and provide an update on the business. To access the conference call, please dial (877) 870-4263 (local) or (412) 317-0790 (international) at least 10 minutes prior to the start time and ask to be joined into the Amylyx Pharmaceuticals call. A live audio webcast of the call will be available under "Events and Presentations" in the Investor section of the Company's website, https://investors.amylyx.com/news-events/events. The webcast will be archived and available for replay for 90 days following the event.

Available Information
We periodically provide other information for investors on our corporate website, https://amylyx.com, and our investor relations website, https://investors.amylyx.com. This includes press releases and other information about financial performance, information on corporate governance, and details related to our annual meeting of stockholders. We intend to use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Accordingly, investors should monitor our website, in addition to following the Company's press releases, SEC filings, and public conference calls and webcasts.

About RELYVRIO™/ALBRIOZA™

RELYVRIO™ (sodium phenylbutyrate and taurursodiol) is an oral, fixed-dose medication approved to treat amyotrophic lateral sclerosis (ALS) in adults in the U.S. and approved with conditions as ALBRIOZA™ (sodium phenylbutyrate and ursodoxicoltaurine) for the treatment of ALS in Canada. Additionally, the European Medicines

Agency (EMA) is reviewing the Company's Marketing Authorisation Application for AMX0035 for the treatment of ALS in Europe. AMX0035 is being explored for the potential treatment of other neurodegenerative diseases.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR RELYVRIO (sodium phenylbutyrate and taurursodiol), for oral suspension

INDICATION
RELYVRIO is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

IMPORTANT SAFETY INFORMATION
Before you receive RELYVRIO, tell your doctor about all of your medical conditions, including if you:

- Have pancreas, liver, or intestinal problems
- Have heart failure, including congestive heart failure
- Have high blood pressure
- Have kidney problems
- Are pregnant or plan to become pregnant. It is not known if RELYVRIO will harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if RELYVRIO passes into your breast milk. You and your doctor should decide the best way to feed your baby

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements and any taurursodiol products, such as tauroursodeoxycholic acid (TUDCA).

RELYVRIO may affect the way other medicines work, and other medicines may affect how RELYVRIO works.

What are the possible side effects of RELYVRIO?
RELYVRIO may cause serious side effects, including:

- **Changes in bile acid levels.** RELYVRIO may increase bile acid levels and cause worsening diarrhea if you already have problems with your liver, bile ducts, or pancreas. Your doctor should monitor you for these side effects. Some disorders of the pancreas, bile ducts, or intestines may also make it harder to absorb RELYVRIO
- **Salt (sodium) retention.** RELYVRIO contains a high amount of salt. For people who are sensitive to salt intake, such as people with heart failure, high blood pressure, or kidney problems, limit the amount of salt you eat and drink. Talk to your doctor about the total amount of daily salt that is right for you. Your doctor will monitor you for signs and symptoms of salt retention during your treatment with RELYVRIO

The most common side effects of RELYVRIO include diarrhea, abdominal pain, nausea, and upper respiratory tract infection.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of RELYVRIO. Call your doctor for medical advice about side effects.
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about RELYVRIO, please see the full Prescribing Information and Medication Guide.

About Amylyx Pharmaceuticals
Amylyx Pharmaceuticals, Inc. is committed to supporting and creating more moments for the neurodegenerative 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.com and follow us on LinkedIn and Twitter. For investors, please visit investors.amylyx.com.

Forward-Looking Statements

Statements contained in this press release and related comments in our earnings conference call 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 potential approval of sodium phenylbutyrate and taurursodiol for the treatment of ALS in countries other than the United States and Canada; the timing of an anticipated decision from the EMA regarding whether to approve AMX0035 for the treatment of ALS and our ability to resolve remaining major objections as part of the MAA process; the potential of sodium phenylbutyrate and taurursodiol as a treatment for ALS and the Company's plans to explore the use of sodium phenylbutyrate and taurursodiol for other neurodegenerative diseases; the potential market acceptance and market opportunity for RELYVRIO and ALBRIOZA; the initial demand for RELYVRIO and our expectations around the timing of receipt of revenue from RELYVRIO; the anticipated timing of coverage and policy decisions by insurance plans related to RELYVRIO and whether those decisions will be favorable; the Company's ability to maintain commercial availability of RELYVRIO in the United States and ALBRIOZA in Canada, as well as access to and coverage for RELYVRIO; our expectations with respect to recruitment and completion of our ongoing PHOENIX trial; the anticipated ramp in our selling, general and administrative expenses; and expectations regarding the Company's 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: the success, cost, and timing of Amylyx' program development activities, Amylyx' ability to successfully launch RELYVRIO in the United States, Amylyx' ability to execute on its commercial and regulatory strategy, regulatory developments, expectations regarding the timing of EMA review of AMX0035 for the treatment of ALS, Amylyx' ability to fund operations, and the impact that the ongoing COVID-19 pandemic, global macroeconomic uncertainty and geopolitical instability will have on Amylyx' operations, 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 September 30, 2022, 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.

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

	September 30, 2022	December 31, 2021
Assets		
Cash, cash equivalents and short-term investments	$ 162,593	$ 96,118
Prepaid expenses and other current assets	8,336	5,392
Accounts receivable, net	137	—
Inventories	563	—
Deferred offering costs	570	3,441
Other assets	9,244	663
Total assets	$ 181,443	$ 105,614
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Accounts payable and accrued expenses	$ 30,657	$ 17,396
Other liabilities	6,758	35
Total liabilities	37,415	17,431
Redeemable convertible preferred stock	—	239,351
Stockholders' equity (deficit)	144,028	(151,168)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 181,443	$ 105,614

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 345	$ —	$ 345	$ —
Grant revenue	—	285	—	285
Total revenues	345	285	345	285
Operating expenses:				
Cost of sales	172	—	172	—
Research and development	24,914	12,853	70,637	30,646
Selling, general and administrative	29,940	10,350	86,284	24,012
Total operating expenses	55,026	23,203	157,093	54,658
Loss from operations	(54,681)	(22,918)	(156,748)	(54,373)
Other income (expense), net	800	(224)	1,272	(5,214)
Loss before income taxes	(53,881)	(23,142)	(155,476)	(59,587)
(Benefit) provision for income taxes	(125)	—	195	—
Net loss	$ (53,756)	$ (23,142)	$ (155,671)	$ (59,587)
Net loss per share attributable to common stockholders —basic and diluted	$ (0.92)	$ (3.42)	$ (2.77)	$ (9.20)
Weighted-average shares used in computing net loss per share attributable to common stockholders—basic and diluted	58,533,226	6,757,152	56,163,194	6,477,140

Contacts

Media
Becky Gohsler
Finn Partners
(646) 307-6307
amylyxmediateam@amylyx.com

Investors
Lindsey Allen
Amylyx Pharmaceuticals, Inc.
(857) 320-6244
Investors@amylyx.com