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 9, 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 2.02 Results of Operations and Financial Condition.

On November 9, 2023, Amylyx Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 2023. 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, shall not be deemed “filed” for 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, 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 9, 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: November 9, 2023

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

Exhibit 99.1

Amylyx Pharmaceuticals Reports Third Quarter 2023 Financial Results

- *Third quarter 2023 product revenue of $102.7 million; bringing total product revenue to $272.3 million in the first three full quarters of U.S. launch*
- *Strong financial position supported by $20.9 million of net income during the third quarter of 2023 and cash, cash equivalents and short-term investments of $355.0 million at September 30, 2023*
- *Management to host a conference call and webcast today at 8:00 a.m. Eastern Time*

CAMBRIDGE, Mass. November 9, 2023 – Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today reported financial results for the third quarter ended September 30, 2023.

"We are encouraged by the strong launch of RELYVRIO over the last year. We remain confident in the design and execution of our Phase 3 PHOENIX trial and now expect topline data in the second quarter of 2024," said Joshua Cohen and Justin Klee, co-CEOs of Amylyx. "We are incredibly pleased with the rapid adoption of RELYVRIO at major ALS centers and focused on the work that we still need to do to reach more people living with ALS as we work towards our goal of transforming the way that ALS is treated."

Third Quarter 2023 and Recent Business Highlights:

- **Continued progress of commercial launches of RELYVRIO® in the U.S. and ALBRIOZA™ in Canada, also known as AMX0035.** Net product revenue for the three months ended September 30, 2023 was $102.7 million, compared to net product revenue of $98.2 million for the three months ended June 30, 2023.
- **A post hoc survival analysis comparing the CENTAUR clinical trial to historical clinical trial control was published in October 2023 in the *Annals of Clinical and Translational Neurology*; results were consistent with the data previously presented at the 2023 American Academy of Neurology Annual Meeting.** The results of this post hoc analysis demonstrated that the median overall survival was 10.4 months longer in the CENTAUR AMX0035 group than in the historical clinical trial control group.
- **RELYVRIO and AMX0114, the Company's investigational antisense oligonucleotide targeting calpain-2, data were presented at 22nd Annual Northeast ALS Consortium (NEALS) meeting in October 2023.**
  - An update on kinetic profiling experiments of AMX0114 was presented as well as results from a collaboration with Dr. Sami Barmada and his team at the University of Michigan School of Medicine in which the impact of AMX0114 on survival was evaluated in human iPSC-derived motor neurons. The Company is advancing AMX0114 through investigational new drug (IND) enabling studies and the goal is to enter the clinic during 2024.
  - Additionally, the Company presented an update on work to develop a composite diagnostic biomarker for ALS. The goal of this program is to create a tool that allows for earlier diagnosis of ALS which may result in earlier treatment and better outcomes.
  - A poster detailing survey results on real-world experiences related to RELYVRIO's taste was also presented. Findings included that taste did not appear to impact survey participants' willingness to take, adherence to, or planned future use of RELYVRIO.
  - The Company also presented preliminary experience with RELYVRIO in a U.S. Expanded Access Program (EAP). Despite differences in study populations, the safety and tolerability of AMX0035 in the EAP were consistent with the AMX0035 arm from CENTAUR.
  - Additionally, Amylyx presented a poster outlining ongoing and planned RELYVRIO studies, including two collaborative real-world studies of RELYVRIO in people living with ALS currently underway.

- Lastly, findings from a study evaluating the use of RELYVRIO with different types of feeding tubes and containers were presented, supporting that RELYVRIO can be used in a variety of feeding tubes and dosing container combinations.

Full posters can be found in the “Publications” section of the Amylyx website.

- **Amylyx presented the clinical trial design of ORION, a Phase 3 global study of AMX0035 in Progressive Supranuclear Palsy (PSP), at the Neuro2023 PSP and CBD International Research Symposium in October 2023.** ORION is a global, randomized, double-blind, placebo-controlled Phase 3 clinical trial designed to assess the efficacy, safety, and tolerability of AMX0035 compared to placebo. Approximately 600 participants will be enrolled across North America, Europe, and Japan, with study initiation anticipated by the end of 2023 starting in the United States.

- **The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) confirmed its initial negative opinion adopted in June 2023 on the Marketing Authorisation Application (MAA) for AMX0035 for the treatment of ALS in the European Union (EU).** The CHMP opinion will be forwarded to the European Commission, who will adopt the final decision on this application anticipated by the end of 2023. The Company continues to focus on the completion of the PHOENIX Phase 3 clinical trial. If PHOENIX is supportive, the Company plans to seek approval in the EU as quickly as possible. Topline results are anticipated in Q2 2024.

- **Amylyx continues to progress R&D programs.** The Company continues to expect data from the Phase 2 clinical trial of AMX0035 in Wolfram syndrome in 2024. Additionally, Amylyx has been working on a new taste-masked formulation of RELYVRIO for several years. This formulation may allow for new intellectual property. The Company is planning to file an IND and conduct Phase 1 testing for this innovative formulation in 2024**.**

Financial Results for the Third Quarter Ended September 30, 2023

Net product revenue was $102.7 million and cost of sales were $5.2 million for the three months ended September 30, 2023, compared to net product revenue of $0.3 million and cost of sales of $0.2 million for the three months ended September 30, 2022. The increase was primarily driven by units of RELYVRIO sold in the U.S. following regulatory approval in late September 2022.

Research and development expenses were $30.0 million for the three months ended September 30, 2023, compared to $24.9 million for the same period in 2022. The increase was primarily driven by an increase in personnel-related expenses due to added headcount to support research and development efforts, an increase in spending on AMX0035 for the treatment of PSP to support the initiation of the Phase 3 ORION trial, and an increase in preclinical development activities.

Selling, general and administrative expenses were $48.7 million for the three months ended September 30, 2023, compared to $29.9 million for the same period in 2022. The increase was primarily driven by higher personnel-related expenses due to added headcount to support the Company’s launch, commercialization initiatives, and operations as a public company.

Net income for the three months ended September 30, 2023 was $20.9 million, or $0.30 on a fully diluted per share basis, compared to a net loss of $53.8 million, or $0.92 on a fully diluted per share basis for the same period in 2022.

Cash, cash equivalents, and short-term investments were $355.0 million at September 30, 2023, compared to $357.3 million at June 30, 2023.

Investor Conference Call Information
Amylyx' management team will host a conference call and webcast today, November 9, 2023, at 8:00 a.m. ET to discuss financial results and provide an update on the business. To access the conference call, please dial (833) 816-1395 (U.S.) or +1 (412) 317-0488 (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™ /AMX0035

RELYVRIO® (also known as AMX0035), 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. AMX0035 is being studied as an investigational drug in several other regions for the potential treatment of ALS and other neurodegenerative diseases. The formulation of RELYVRIO, ALBRIOZA, and AMX0035 are identical.

RELYVRIO® (sodium phenylbutyrate and taurursodiol) Safety Information for United States

WARNINGS AND PRECAUTIONS

Risk in Patients with Enterohepatic Circulation Disorders, Pancreatic Disorders, or Intestinal Disorders
RELYVRIO contains taurursodiol, which is a bile acid. In patients with disorders that interfere with bile acid circulation, there may be an increased risk for worsening diarrhea, and patients should be monitored appropriately for this adverse reaction. Pancreatic insufficiency, intestinal malabsorption, or intestinal diseases that may alter the concentration of bile acids may also lead to decreased absorption of either of the components of RELYVRIO. Because different enterohepatic circulation, pancreatic, and intestinal disorders have varying degrees of severity, consider consulting with a specialist. Patients with disorders of enterohepatic circulation (e.g., biliary infection, active cholecystitis), severe pancreatic disorders (e.g., pancreatitis), and intestinal disorders that may alter concentrations of bile acids (e.g., ileal resection, regional ileitis) were excluded from the study; therefore, there is no clinical experience in these conditions.

Use in Patients Sensitive to High Sodium Intake
RELYVRIO has a high salt content. Each initial daily dosage of 1 packet contains 464 mg of sodium; each maintenance dosage of 2 packets daily contains 928 mg of sodium. In patients sensitive to salt intake (e.g., those with heart failure, hypertension, or renal impairment), consider the amount of daily sodium intake in each dose of RELYVRIO and monitor appropriately.

ADVERSE REACTIONS
The most common adverse reactions (at least 15% and at least 5% greater than placebo) with RELYVRIO were diarrhea, abdominal pain, nausea, and upper respiratory tract infection. Gastrointestinal-related adverse reactions occurred throughout the study but were more frequent during the first 3 weeks of treatment.

Please click here for RELYVRIO Full U.S. Prescribing Information.

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 X, formerly known as 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 a final decision from the European Commission regarding whether to approve AMX0035 for the treatment of ALS in Europe; the potential of AMX0035 (sodium phenylbutyrate and taurursodiol) as a treatment for ALS and other neurodegenerative diseases including Wolfram syndrome and PSP; the ongoing commercialization of RELYVRIO and ALBRIOZA; expectations regarding the timing of initiation of the Company’s Phase 3 ORION trial of AMX0035 for the treatment of PSP and of the results of the Company’s Phase 2 HELIOS trial of AMX0035 for the treatment of Wolfram syndrome; the timing of the results of the Company’s Phase 3 PHOENIX trial of AMX0035 for the treatment of ALS; s expectations regarding the results of the Phase 3 PHOENIX trial and of the potential for future approval of AMX0035 in the EU; the timing of filing IND applications for AMX0114 and for a new formation of RELYVRIO; expectations regarding the potential continued market acceptance and market opportunity for RELYVRIO and ALBRIOZA and opportunities for growth; the potential for new pipeline programs and clinical indications for AMX0035; statements regarding regulatory developments; the Company’s expectations with respect to its progress through IND enabling studies of AMX0114 and other advancements in its pipeline; the Company’s expectations regarding its financial performance; and expectations regarding the Company’s longer-term strategy. Any forward-looking statements in this press release and related comments in the Company's earnings conference call 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 commercialize RELYVRIO in the United States and ALBRIOZA in Canada; Amylyx’ ability to execute on its commercial and regulatory strategy; that data from later-stage trials may not reflect data from earlier-stage trials, including other indications; regulatory developments; expectations regarding the timing of a decision from the European Commission regarding AMX0035 for the treatment of ALS; Amylyx’ ability to fund operations, and the impact that global macroeconomic uncertainty, geopolitical instability and public health events, such as COVID-19, 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 June 30, 2023, and subsequent filings with the SEC. All forward-looking statements contained in this press release and related comments in our earnings conference call 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, except as required by law.

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

	September 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and short-term investments	$ 355,045	$ 346,945
Accounts receivable, net	29,353	15,306
Inventories	56,703	9,769
Prepaid expenses and other current assets	17,338	10,113
Other assets	8,145	9,320
Total assets	$ 466,584	$ 391,453
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Accounts payable and accrued expenses	$ 43,416	$ 44,569
Other liabilities	4,768	6,277
Total liabilities	48,184	50,846
Stockholders' equity	418,400	340,607
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 466,584	$ 391,453

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,	
	2023	2022	2023	2022
Product revenue, net	$ 102,693	$ 345	$ 272,337	$ 345
Operating expenses:				
Cost of sales	5,218	172	16,081	172
Research and development	30,037	24,914	83,273	70,637
Selling, general and administrative	48,718	29,940	136,115	86,284
Total operating expenses	83,973	55,026	235,469	157,093
Income (loss) from operations	18,720	(54,681)	36,868	(156,748)
Other income, net	3,691	800	10,953	1,272
Income (loss) before income taxes	22,411	(53,881)	47,821	(155,476)
Provision (benefit) for income taxes	1,518	(125)	3,281	195
Net income (loss)	$ 20,893	$ (53,756)	$ 44,540	$ (155,671)
Net income (loss) per share attributable to common stockholders				
Basic	$ 0.31	$ (0.92)	$ 0.66	$ (2.77)
Diluted	$ 0.30	$ (0.92)	$ 0.63	$ (2.77)
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders				
Basic	67,414,669	58,533,226	67,124,407	56,163,194
Diluted	69,748,547	58,533,226	70,143,659	56,163,194

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