

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): February 22, 2024

AMYLYX PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41199

(Commission File Number)

46-4600503
(IRS Employer
Identification No.)

43 Thorndike, St.,
Cambridge, MA
(Address of Principal Executive Offices)

02141
(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 February 22, 2024, Amylyx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

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 (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 February 22, 2024
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: February 22, 2024

By: /s/ James M. Frates

James M. Frates

Chief Financial Officer

Amylyx Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results

- *Reported \$380.8 million in net product revenue for the full year 2023, including \$108.4 million in the fourth quarter*
- *Delivered \$49.3 million in net income for the full year 2023, including \$4.7 million in the fourth quarter, and ended the year with cash, cash equivalents and short-term investments of \$371.4 million*
- *Management to host conference call and webcast today at 8:00 a.m. Eastern Time*

CAMBRIDGE, Mass. February 22, 2024 – Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) (“Amylyx” or the “Company”) today reported financial results for the fourth quarter and full year ended December 31, 2023.

“In 2023, we made significant strides towards transforming the way ALS is treated. We delivered RELYVRIO, also known as ALBRIOZA and AMX0035, the first and only ALS therapy that has been shown to slow disease progression, help maintain functional independence, and extend overall survival in the same clinical trial, to thousands of people living with ALS in North America,” said Joshua Cohen, co-CEO of Amylyx. “As we reflect on the many stories that we have heard from people living with ALS who are taking RELYVRIO, we are working with urgency to continue expanding our U.S. and international presence in 2024 and bringing RELYVRIO to more people living with ALS.”

“We look forward to sharing topline data from our Phase 3 PHOENIX trial during or before the second quarter of 2024. PHOENIX will provide additional efficacy and safety data in a larger population of people living with ALS, building on the robust and positive results observed in the CENTAUR study,” said Justin Klee, co-CEO of Amylyx. “We also remain focused on advancing our pipeline, which includes studying AMX0035 in Progressive Supranuclear Palsy in the Phase 3 ORION trial. We look forward to several expected upcoming milestones for our pipeline in 2024, including data from our Phase 2 HELIOS trial in Wolfram syndrome and our antisense oligonucleotide, AMX0114, entering the clinic.”

Full Year 2023 and Recent Business Highlights:

- **Commercial launches of RELYVRIO[®] in the U.S. and ALBRIOZA[™] in Canada, also known as AMX0035, continued to progress, and eligible people living with ALS in multiple countries are also accessing RELYVRIO through early access pathways.** Net product revenue for the three months ended December 31, 2023 was \$108.4 million, compared to net product revenue of \$102.7 million for the three months ended September 30, 2023. The vast majority of Amylyx’ net product revenue is generated in the U.S.; revenue in Canada and from named patient sales programs in international markets represented an important source of revenue growth in three months ended December 31, 2023 relative to the Company’s financial results for the three months ended September 30, 2023.
- **Amylyx announced the first patient dosed in the Global Phase 3 ORION Study of AMX0035 in Progressive Supranuclear Palsy (PSP).** 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. The first participant was dosed in December 2023, and topline results are anticipated in 2025 or 2026.
- **Amylyx continues to progress its R&D programs.** The Company announced completion of enrollment in the HELIOS study, a Phase 2 clinical trial of AMX0035 for the treatment of Wolfram syndrome and continues to expect data from the study in 2024. The Company is also working on a novel composite diagnostic test to assist in diagnosing ALS earlier. Additionally, Amylyx is working on a new taste-masked formulation of RELYVRIO that may allow for new intellectual property.
- **Amylyx added new members to its executive leadership team and U.S. commercial leadership team.** In November 2023, the Company announced the appointment of Camille L. Bedrosian, MD, as Chief Medical Officer. Dr. Bedrosian has nearly 30 years of experience addressing unmet medical needs for people with rare and serious diseases through successful clinical and translational research programs.

In addition, during 2024, Linda Arsenault joined as the Company's new Chief Human Resources Officer and Dan Monahan joined as General Manager and Head of U.S. Commercial Markets. Ms. Arsenault has over 30 years of human resources leadership experience, including in the biopharmaceutical sector, most recently from Sunovion Pharmaceuticals where she served as Chief Human Resources Officer. Mr. Monahan has over 20 years of experience in sales, marketing, and market access, including his most recent position as VP of CNS Marketing and Portfolio Strategy at Otsuka Pharmaceutical Companies.

- **A post hoc survival analysis comparing the CENTAUR clinical trial to historical clinical trial control was published in the [Annals of Clinical and Translational Neurology](#).** 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.
- **Post hoc analyses on CENTAUR trial participants were published in [Journal of Neurology, Neurosurgery and Psychiatry](#).** The results of the post hoc analyses demonstrated a significant reduction in plasma concentrations of YKL-40 (also known as chitinase-3-like protein 1) and the systemic inflammatory biomarker C-reactive protein (CRP), two plasma neuroinflammatory biomarkers in ALS, over 24 weeks, with reductions observed as early as Week 12 in participants from the CENTAUR trial.
- **Data on RELYVRIO and AMX0114, the Company's investigational antisense oligonucleotide targeting calpain-2, were presented at the 34th International Symposium on ALS/MND.** 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 with an ALS associated mutation in TDP43. The Company is advancing AMX0114 through investigational new drug (IND) enabling studies and the goal is to enter the clinic during 2024. Additional information, including copies of each of the posters presented at the event, are available in the in the "[Publications](#)" section of the Amylyx website.

Financial Results for the Fourth Quarter and Year Ended December 31, 2023

Net product revenue: Net product revenue was \$108.4 million for the three months ended December 31, 2023, compared to net product revenue of \$21.9 million for the same period in 2022. Net product revenue for the year ended December 31, 2023 was \$380.8 million, compared to net product revenue of \$22.2 million for the same period in 2022. The increase was primarily driven by units of RELYVRIO sold in the U.S. following regulatory approval in late September 2022.

Cost of Sales: Cost of sales were \$9.4 million in the three months ended December 31, 2023, compared to cost of sales of \$2.8 million for the same period in 2022. For the year ended December 31, 2023, cost of sales were \$25.4 million, compared to cost of sales of \$3.0 million for the year ended December 31, 2022.

R&D Expenses: Research and development expenses for the fourth quarter of 2023 were \$44.9 million, compared to \$22.8 million for the same period in 2022, and \$128.2 million for the year ended December 31, 2023 compared to \$93.5 million for the year ended December 31, 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 related to the initiation of the Phase 3 ORION trial of AMX0035 in PSP, and an increase in preclinical development activities.

SG&A Expenses: Selling, general, and administrative expenses for the fourth quarter of 2023 were \$52.2 million, compared to \$40.8 million for the same period in 2022 and \$188.4 million for the year ended December 31, 2023, compared to \$127.1 million for the year ended December 31, 2022. The increase was primarily driven by higher personnel-related expenses due to added headcount to support the launch, commercialization initiatives, and operations as a public company.

Net Income: Net income for the three months ended December 31, 2023 was \$4.7 million, or \$0.07 on a fully diluted per share basis, compared to a net loss of \$42.7 million, or \$0.65 per share for the same period in 2022. Net income

for the year ended December 31, 2023 was \$49.3 million, or \$0.70 on a fully diluted per share basis, compared with a net loss of \$198.4 million, or \$3.39 per share for the year ended December 31, 2022.

Cash Position: Cash, cash equivalents, and short-term investments were \$371.4 million at December 31, 2023, compared to \$355.0 million at September 30, 2023.

Investor Conference Call Information

Amylyx' management team will host a conference call and webcast today, February 22, 2024, at 8:00 a.m. ET to discuss financial results and provide an update on the business. To access the conference call, please dial +1 (800) 836-8184 (U.S. & Canada) or +1 (646) 357-8785 (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, EMEA, and Japan. 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, the potential of AMX0035 (sodium phenylbutyrate and taurursodiol) as a treatment for ALS and other neurodegenerative diseases including Wolfram syndrome and PSP; the Company’s beliefs regarding the benefits of AMX0035 in ALS and other neurodegenerative diseases, the potential of AMX0035 to be a foundational therapy for ALS and a potential, future cure; the ongoing commercialization of RELYVRIO and ALBRIOZA; the potential to expand global approvals for AMX0035 in ALS and other neurodegenerative diseases; expectations regarding the timing of the announcement of results from the Phase 3 PHOENIX trial of AMX0035 for the treatment of ALS, the Company’s Phase 3 ORION trial of AMX0035 for the treatment of PSP, and the Company’s Phase 2 HELIOS trial of AMX0035 for the treatment of Wolfram syndrome; 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, regulatory developments, expectations regarding the timing of results of the global Phase 3 PHOENIX trial of 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’ Annual Report on Form 10-K for the year ended December 31, 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.

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

	December 31,	
	2023	2022
Assets		
Cash, cash equivalents and short-term investments	\$ 371,362	\$ 346,945
Accounts receivable, net	40,050	15,306
Inventories	83,280	9,769
Prepaid expenses and other current assets	14,931	10,113
Other assets	7,831	9,320
Total assets	<u>\$ 517,454</u>	<u>\$ 391,453</u>
Liabilities and Stockholders' Equity		
Accounts payable and accrued expenses	\$ 79,785	\$ 44,569
Other liabilities	4,237	6,277
Total liabilities	<u>84,022</u>	<u>50,846</u>
Stockholders' equity	433,432	340,607
Total liabilities, redeemable convertible preferred stock and stockholders' equity	<u>\$ 517,454</u>	<u>\$ 391,453</u>

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Product revenue, net	\$ 108,449	\$ 21,885	\$ 380,786	\$ 22,230
Operating expenses:				
Cost of sales	9,360	2,821	25,441	2,993
Research and development	44,914	22,813	128,187	93,450
Selling, general and administrative	52,241	40,844	188,356	127,128
Total operating expenses	<u>106,515</u>	<u>66,478</u>	<u>341,984</u>	<u>223,571</u>
Income (loss) from operations	1,934	(44,593)	38,802	(201,341)
Other income, net	4,542	2,468	15,495	3,740
Income (loss) before income taxes	6,476	(42,125)	54,297	(197,601)
Provision for income taxes	1,745	579	5,026	774
Net income (loss)	<u>\$ 4,731</u>	<u>\$ (42,704)</u>	<u>\$ 49,271</u>	<u>\$ (198,375)</u>
Net income (loss) per share				
Basic	\$ 0.07	\$ (0.65)	\$ 0.73	\$ (3.39)
Diluted	\$ 0.07	\$ (0.65)	\$ 0.70	\$ (3.39)
Weighted-average shares used in computing net income (loss) per share				
Basic	67,414,669	65,416,712	67,234,465	58,495,587
Diluted	69,196,421	65,416,712	69,991,340	58,495,587

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