Amylyx Pharmaceuticals Reports Second Quarter 2023 Financial Results

August 10, 2023 at 4:01 PM EDT

- *Second quarter 2023 product revenue of $98.2 million; demand and insurance coverage for RELYVRIO® in U.S. and ALBRIOZA™ in Canada continued to grow*
- *Strong financial position supported by $22.1 million of net income during the second quarter of 2023 and cash, cash equivalents and short-term investments of $357.3 million at June 30, 2023*
- *Management to host conference call and webcast today at 4:30 p.m. Eastern Time*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 10, 2023-- Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today reported financial results for the second quarter ended June 30, 2023.

"We made strong and steady progress on our commercial launches in the second quarter, supporting people living with ALS with increased access to RELYVRIO/ALBRIOZA in the U.S. and Canada," said Joshua Cohen and Justin Klee, co-CEOs of Amylyx. "We continued to execute on our long-term R&D strategy, which includes exploring the full potential of our therapy in other neurodegenerative diseases. We are on track to initiate our global Phase 3 ORION trial of AMX0035 for the treatment of progressive supranuclear palsy later this year. Our Phase 2 HELIOS study of AMX0035 for the treatment of Wolfram syndrome is enrolling participants, and we continue to expect topline results next year."

Second Quarter 2023 and Recent Business Highlights:

- **Commercial launches of RELYVRIO® in the U.S. and ALBRIOZA™ in Canada, also known as AMX0035, continued to progress.** Net product revenue for the three months ended June 30, 2023 was $98.2 million, compared to net product revenue of $71.4 million for the three months ended March 31, 2023.
- **Five Canadian provinces announced public reimbursement of ALBRIOZA.** Following the completion of the Company's negotiation process with the pan-Canadian Pharmaceutical Alliance, the Company entered into a Product Listing Agreement with Ontario for the public reimbursement of ALBRIOZA through the Ontario Drug Benefit Program, effective June 22, 2023. Since June, the provinces of Quebec, British Columbia, New Brunswick, and Alberta committed to offering public coverage for ALBRIOZA by listing the therapy on their drug benefit formularies. Amylyx expects ALBRIOZA coverage to be in place for the vast majority of publicly insured lives in Canada by the end of August. By the end of 2023, the Company expects to finalize and sign product listing agreements with the remaining federal, provincial, and territorial public drug plans that have yet to include ALBRIOZA on their formulary.
- **Plans underway to initiate a global, pivotal Phase 3 trial of AMX0035 for the treatment of progressive supranuclear palsy (PSP).** PSP is a rare, progressive neurological disorder that affects body movements, walking and balance, and eye movement and is typically fatal within 6 to 8 years. There are currently no approved disease-modifying therapies for the treatment of PSP, and the disease affects seven in 100,000 people worldwide. PSP is characterized by widespread neurodegeneration associated with tau protein deposition in subcortical regions of the brain. Based on biomarker analyses from the Phase 2 PEGASUS trial of AMX0035 in Alzheimer's disease and preclinical data, AMX0035 was shown to significantly lower levels of tau and other markers of neurodegeneration. The Company plans to initiate the pivotal Phase 3 ORION trial by year-end and intends to enroll approximately 600 adult participants across the U.S., Canada, Europe, and Japan.
- **In July, the Company hosted a virtual webcast with Prof. Dr. Günter Höglinger to discuss the treatment landscape for people living with PSP, the scientific rationale for studying AMX0035 in PSP, and the Company's clinical development plans.** Prof. Dr. Höglinger, a leading expert in PSP, serves as the Director of the Department of Neurology at LMU Hospital, Ludwig-Maximilians-University in Munich, Germany and is the primary investigator for the Phase 3 ORION trial. A replay is available at https://investors.amylyx.com.
- **Marketing Authorisation Application (MAA) for AMX0035 for the treatment of ALS under review with the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP).** Amylyx received a negative opinion from the CHMP in June and requested a formal re-examination of the MAA in July. CHMP is re-examining its initial opinion on the current application for conditional marketing authorisation of AMX0035. The re-examination procedure is an approximately four-month process, which includes the appointment of a different rapporteur and co-rapporteur from the initial evaluation. At the end of the re-examination, the CHMP will adopt a final opinion, which is expected in fall 2023.

Financial Results for the Second Quarter Ended June 30, 2023

For the three months ended June 30, 2023, net product revenue was $98.2 million, and cost of sales were $5.6 million. Both net product revenue and cost of sales during the period were primarily attributable to sales of RELYVRIO in the U.S. and ALBRIOZA in Canada. There were no product revenues or cost of sales for the comparable period in 2022.

Research and development expenses were $29.0 million for the three months ended June 30, 2023, compared to $24.3 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 and an increase in spending on AMX0035 for the treatment of PSP to support the initiation of the Phase 3 ORION trial.

Selling, general and administrative expenses were $43.4 million for the three months ended June 30, 2023, compared to $30.0 million for the same period in 2022. The increase was primarily driven by higher personnel-related expenses due to added headcount to support our launch, commercialization initiatives, and operations as a public company.

Net income for the three months ended June 30, 2023 was $22.1 million, or $0.31 on a fully diluted per share basis, compared to a net loss of $54.1 million, or $0.93 on a fully diluted per share basis for the same period in 2022.

Cash, cash equivalents, and short-term investments were $357.3 million at June 30, 2023, compared to $345.7 million at March 31, 2023.

Investor Conference Call Information

Amylyx' management team will host a conference call and webcast today, August 10, 2023, at 4:30 p.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. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) is re-examining its initial opinion on the current application for conditional marketing authorisation of AMX0035, under the trade name ALBRIOZA®, for the treatment of ALS in the European Union. AMX0035 is being explored for the potential treatment of 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 the timing of review of its initial opinion and an anticipated final recommendation from the CHMP 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 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; 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; statements regarding coverage by insurance plans for ALBRIOZA and the timing of, and the Company's ability to, finalize and sign product listing agreements with the remaining public drug plans for ALBRIOZA in Canada; the potential continued market acceptance and market opportunity for RELYVRIO and ALBRIOZA and opportunities for growth; expectations regarding the speed of access to RELYVRIO; 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 a decision from the EMA 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 March 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)

	June 30, 2023	December 31, 2022
Assets		
Cash, cash equivalents and short-term investments	$ 357,276	$ 346,945
Accounts receivable, net	33,473	15,306
Inventories	42,587	9,769
Prepaid expenses and other current assets	11,787	10,113
Other assets	8,465	9,320
Total assets	$ 453,588	$ 391,453
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Accounts payable and accrued expenses	$ 61,936	$ 44,569
Other liabilities	5,287	6,277

Total liabilities	67,223	50,846
Stockholders' equity	386,365	340,607
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 453,588	$ 391,453

AMYLYX PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Product revenue, net	$ 98,216	$ —	$ 169,644	$ —
Operating expenses:				
Cost of sales	5,580	—	10,863	—
Research and development	29,044	24,259	53,236	45,723
Selling, general and administrative	43,391	29,994	87,397	56,344
Total operating expenses	78,015	54,253	151,496	102,067
Income (loss) from operations	20,201	(54,253)	18,148	(102,067)
Other income, net	3,806	360	7,262	472
Income (loss) before income taxes	24,007	(53,893)	25,410	(101,595)
Provision for income taxes	1,933	174	1,763	320
Net income (loss)	$ 22,074	$ (54,067)	$ 23,647	$ (101,915)
Net income (loss) per share attributable to common stockholders				
Basic	$ 0.33	$ (0.93)	$ 0.35	$ (1.85)
Diluted	$ 0.31	$ (0.93)	$ 0.34	$ (1.85)
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders				

Basic	67,233,617	58,275,903	66,976,871	54,958,537
Diluted	70,132,040	58,275,903	70,471,821	54,958,537

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