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): September 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 8.01 Other Events.

On September 29, 2022, Amylyx Pharmaceuticals, Inc. (the "Company") announced that the U.S. Food and Drug Administration (FDA) has approved RELYVRIO™ (sodium phenylbutyrate and taurursodiol) for the treatment of adults with amyotrophic lateral sclerosis (ALS). RELYVRIO (previously known as AMX0035 in the U.S.) significantly slowed the loss of physical function in people living with ALS in a randomized, placebo-controlled clinical trial. RELYVRIO can be taken as a monotherapy or with existing approved treatments.

ALS is a relentlessly progressive and fatal neurodegenerative disorder caused by motor neuron death in the brain and spinal cord. Motor neuron loss in ALS leads to deteriorating muscle function, the inability to move and speak, respiratory paralysis and eventually, death. More than 90% of people with ALS have sporadic disease, showing no clear family history. ALS affects approximately 29,000 people in the U.S.

The approval of RELYVRIO is based on data from CENTAUR, a multicenter Phase 2 clinical trial in 137 participants with ALS encompassing a 6-month randomized, placebo-controlled phase and an open-label extension (OLE) long-term follow-up phase. Detailed data from CENTAUR were published in the New England Journal of Medicine, Muscle & Nerve, and the Journal of Neurology, Neurosurgery, and Psychiatry.

The most common adverse events occurring with RELYVRIO (at least 15% and at least 5% greater than placebo) 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 three weeks of treatment.

A copy of the press release announcing the approval of RELYVRIO, attached as Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the filings of the Company under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, statements regarding the potential of AMX0035 as a treatment for ALS and the Company's plans to explore the use of AMX0035 for other neurodegenerative diseases; the potential market acceptance and market opportunity for RELYVRIO™; the Company's ability to make RELYVRIO available commercially in the United States, as well as access to and coverage for RELYVRIO; and expectations regarding our longer-term strategy.

Statements using words such as "expect", "anticipate", "believe", "may", "will" and similar terms are also forward-looking statements. Such statements are subject to numerous risks and uncertainties, including, but not limited to, risks associated with general economic and market conditions and the other important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022 and the Company's other filings with the Securities and Exchange Commission. Except as required by law, we undertake no obligations to make any revisions to the forward-looking statements contained in this Current Report on Form 8-K or to update them to reflect events or circumstances occurring after the date of this Current Report on Form 8-K, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of the Company, dated September 29, 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: September 30, 2022

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

Exhibit 99.1

Amylyx Pharmaceuticals Announces FDA Approval of RELYVRIO™ for the Treatment of ALS

- RELYVRIO (previously known as AMX0035 in the U.S.) is an oral, fixed-dose combination therapy for the treatment of adults with ALS
- RELYVRIO significantly slowed loss of physical function in a randomized, placebo-controlled clinical trial in ALS
- Detailed data from the CENTAUR clinical trial were published in the *New England Journal of Medicine*, *Muscle & Nerve*, and the *Journal of Neurology, Neurosurgery and Psychiatry*
- Amylyx to host investor conference call tomorrow, September 30 at 8:00 a.m. ET

CAMBRIDGE, Mass. September 29, 2022 — Amylyx Pharmaceuticals, Inc. (NASDAQ: AMLX) ("Amylyx" or the "Company") today announced that the U.S. Food and Drug Administration (FDA) has approved RELYVRIO™ (sodium phenylbutyrate and taurursodiol) for the treatment of adults with amyotrophic lateral sclerosis (ALS). RELYVRIO (previously known as AMX0035 in the U.S.) significantly slowed the loss of physical function in people living with ALS in a randomized, placebo-controlled clinical trial. RELYVRIO can be taken as a monotherapy or with existing approved treatments.

"Today's FDA approval of RELYVRIO is an exciting milestone for the ALS community and is a major step toward achieving our mission to one day end the suffering caused by neurodegenerative diseases," said Joshua Cohen and Justin Klee, Co-CEOs of Amylyx. "We want to give a heartfelt thank you to the broader ALS community, including healthcare professionals and those living with ALS, for their guidance, support of our clinical programs, and for sharing their experiences with us. Their stories inspired us and helped our team to better understand the ALS clock, instilling in us a deep sense of urgency that will continue to drive us forward. This is just the beginning and there is much more to be done."

ALS is a relentlessly progressive and fatal neurodegenerative disorder caused by motor neuron death in the brain and spinal cord. Motor neuron loss in ALS leads to deteriorating muscle function, the inability to move and speak, respiratory paralysis and eventually, death. More than 90% of people with ALS have sporadic disease, showing no clear family history. ALS affects approximately 29,000 people in the U.S.

Leading U.S. ALS advocacy organizations including The ALS Association, Answer ALS Foundation, I AM ALS, Les Turner ALS Foundation and Team Gleason said in a statement, "Our organizations have been on a mission to create a world free of ALS. With today's approval, we are encouraged that RELYVRIO can offer people living with ALS and their families the potential of more time with functional independence. This is especially important for a rapidly progressive disease with a median survival time from diagnosis of just two to three years. This is significant for people living with ALS, their loved ones, caregivers, clinicians, researchers, and advocacy, as we now have a new treatment option that could be a big step forward for the future of ALS care."

The approval of RELYVRIO is based on data from CENTAUR, a multicenter Phase 2 clinical trial in 137 participants with ALS encompassing a 6-month randomized, placebo-controlled phase and an open-label extension (OLE) long-term follow-up phase. Detailed data from CENTAUR were published in the *New England Journal of Medicine*, *Muscle & Nerve,* and the *Journal of Neurology, Neurosurgery, and Psychiatry*.

The most common adverse events occurring with RELYVRIO (at least 15% and at least 5% greater than placebo) 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 three weeks of treatment.

“Any time we have a new tool to slow the progression of this disease represents an important milestone in how we battle ALS. The published data on both function and survival in a randomized trial – and what this means for people living with ALS – are a step forward for the ALS community,” said Sabrina Paganoni, M.D., Ph.D., principal investigator of the CENTAUR trial, investigator at the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital, and Associate Professor of Physical Medicine and Rehabilitation at Harvard Medical School and Spaulding Rehabilitation Hospital.

“The approval of a new treatment that helps slow the progression of ALS, preserve physical function and potentially extend survival has the potential to greatly impact the hundreds of people living with ALS who I currently treat,” said Merit Cudkowicz, M.D., co-principal investigator of the CENTAUR trial and co-founder of the Northeast ALS Consortium, Chief of Neurology and the Director of the Healey & AMG Center for ALS and Chief of Neurology at Massachusetts General Hospital, and the Julieanne Dorn Professor of Neurology at Harvard Medical School. “There are too few options to target this uniformly fatal and rapid illness, and I am encouraged at this outcome and what it represents for my patients and their families.”

“Our priority now is to ensure that adults living with ALS in the U.S. whose doctors have prescribed RELYVRIO can access it as quickly as possible,” said Margaret Olinger, Global Head of Commercial and Chief Commercial Officer of Amylyx. “Physicians will be able to prescribe immediately, and we anticipate specialty pharmacies will be able to start to fill prescriptions and ship RELYVRIO to people with ALS in the next four to six weeks.”

After considering the input of many stakeholders throughout the ALS community in the U.S., Amylyx made the decision to price RELYVRIO below the latest FDA-approved product available to people with ALS. To ensure that every eligible person who can benefit from RELYVRIO will have access, Amylyx will provide support to healthcare professionals, people living with ALS, and their loved ones through the Amylyx Care Team (ACT) Support Program. ACT provides people living with ALS who have been prescribed RELYVRIO, and their loved ones, with a dedicated, single point of contact to guide their treatment journey. ACT works tirelessly to aid with navigating through insurance in an effort to overcome potential barriers to access. ACT helps confirm coverage and provides financial assistance options to eligible individuals with out-of-pocket costs. ACT also provides education, support, and resources to help adults living with ALS get started and continue with RELYVRIO treatment, as prescribed by their healthcare provider. People with ALS, their caregivers, and healthcare professionals in the U.S. can now call 1-866-318-2989 or email amylyxcareteam@amylyx.com to speak with an ACT team member.

Investor Conference Call Information

Amylyx’ management team will host a live conference call and webcast at 8:00 a.m. ET on September 30, 2022 to discuss the FDA approval of RELYVRIO. All interested parties are invited to access a live broadcast of the call via a webcast, which will be available on the “Events and Presentations” page in the “Investors” section of the Company’s website at investors.amylyx.com/news-events/events. An archived webcast will be available on the Company’s website approximately two hours after the conference call and will be available for 30 days following the call.

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 extension (OLE) long-term follow-up phase. The trial met its primary efficacy endpoint.

Detailed safety and functional efficacy data from CENTAUR were published in the *New England Journal of Medicine*. Data from additional analyses from the CENTAUR trial were published in *Muscle & Nerve* in 2020 and 2022, and the *Journal of Neurology, Neurosurgery and Psychiatry* in 2022.

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 RELYVRIO™ (previously known as AMX0035 in the U.S.)

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™ 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/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
- 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 may report side effects to FDA at 1-800-FDA-1088.

Please click here to read the full Prescribing Information for RELYVRIO™.

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 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 AMX0035 for the treatment of ALS in countries other than the United States and Canada; the potential of AMX0035 as a treatment for ALS and the Company’s plans to explore the use of AMX0035 for other neurodegenerative diseases; the potential market acceptance and market opportunity for RELYVRIO™; the Company’s ability to make RELYVRIO available commercially in the United States, as well as access to and coverage for RELYVRIO; and expectations regarding our 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 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, 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.

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