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): August 18, 2026

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.)**

55 Cambridge Parkway, Suite 6W
Cambridge, Massachusetts **02142**
(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 7.01. Regulation FD Disclosure.

On August 18, 2026, Amylyx Pharmaceuticals, Inc. (the "Company") issued a press release titled "Amylyx Pharmaceuticals Announces Positive Topline Results from Phase 3 LUCIDITY Clinical Trial of Avexitide in Post-Bariatric Hypoglycemia." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report").

The information in Item 7.01 of this Current Report (including Exhibit 99.1 attached hereto) is being furnished and 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 they be deemed incorporated by reference into any filing by the Company, under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events

On August 18, 2026, the Company announced positive topline results from LUCIDITY, a 78-participant, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of avexitide, an investigational, first-in-class glucagon-like peptide-1 ("GLP-1") receptor antagonist, in participants with post-bariatric hypoglycemia ("PBH") following Roux-en-Y gastric bypass ("RYGB") surgery. LUCIDITY met the Food and Drug Administration (the "FDA")-agreed-upon primary endpoint demonstrating a 55% reduction in the composite rate of Level 2 and Level 3 hypoglycemic events compared to placebo (p=0.000003). In addition, LUCIDITY met all secondary endpoints demonstrating consistent, highly statistically significant, and clinically meaningful reductions in Level 2 hypoglycemic events by self-monitoring of blood glucose ("SMBG"), Level 2 hypoglycemic events by continuous glucose monitoring ("CGM"), and Level 3 hypoglycemic events.

The Phase 3 LUCIDITY trial enrolled 78 adult participants with PBH following RYGB surgery. Participants were randomized 3:2 to receive either 90 mg avexitide subcutaneously once daily or placebo. LUCIDITY met the primary endpoint demonstrating a 55% reduction (p=0.000003) in the composite rate of Level 2 and Level 3 hypoglycemic events compared to placebo through Week 16. LUCIDITY also met all secondary endpoints demonstrating consistent, highly statistically significant, and clinically meaningful reductions across SMBG-measured Level 2 events, CGM-measured Level 2 events, and independently adjudicated Level 3 events.

Avexitide was generally well-tolerated through the double-blind study period with a consistent and favorable safety profile replicated across all PBH clinical trials completed to date. The majority of adverse events in LUCIDITY were mild to moderate, and there were no serious adverse events related to avexitide treatment. The most common adverse events were diarrhea, injection site erythema, and injection site bruising. There were no changes in body weight observed in either the avexitide or placebo groups over the 16-week, double-blind period of the LUCIDITY trial.

The Company plans to submit a New Drug Application ("NDA") to the FDA by the end of 2026. The FDA previously granted avexitide Breakthrough Therapy Designation for PBH. LUCIDITY's 32-week open label extension remains ongoing. The avexitide expanded access program also remains ongoing. The Company plans to present the data from LUCIDITY at an upcoming medical meeting.

Forward Looking Statements

Statements contained in this Current Report on Form 8-K 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, Amylyx's expectations regarding: the therapeutic potential and safety of avexitide as a treatment for PBH; expectations regarding the timing for NDA submission with the FDA; the potential benefits of regulatory designations held with the FDA; the plan to present data from LUCIDITY at an upcoming medical meeting; and expectations regarding timing for potential commercialization of avexitide, if approved. Any forward-looking statements in this Current Report 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's program development activities; Amylyx's ability to execute on its regulatory development plans and expectations regarding the timing of results from its planned data announcements and initiation of clinical studies; the risk that early-stage results may not reflect later-stage results; Amylyx's ability to fund operations, and the impact that global macroeconomic uncertainty, geopolitical instability, and public health events will have on Amylyx's operations, as well as the risks and uncertainties set forth in Amylyx's United States Securities and Exchange Commission ("SEC") filings, including Amylyx's Annual Report on Form 10-K for the year ended December 31, 2025, and subsequent filings with the SEC. All forward-looking statements contained in this Current Report 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of the Company, dated August 18, 2026.
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 hereunto duly authorized.

AMYLYX PHARMACEUTICALS, INC.

Date: August 18, 2026

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

Amylyx Pharmaceuticals Announces Positive Topline Results from Phase 3 LUCIDITY Clinical Trial of Avexitide in Post-Bariatric Hypoglycemia

- *LUCIDITY met FDA-agreed-upon primary endpoint; avexitide demonstrated a 55% reduction in the composite rate of Level 2 and Level 3 hypoglycemic events compared to placebo (p=0.000003)*
- *LUCIDITY met all secondary endpoints showing consistent, highly statistically significant, and clinically meaningful reductions in Level 2 by self-monitoring of blood glucose (SMBG), Level 2 by CGM, and Level 3 hypoglycemic events*
- *Avexitide was generally well-tolerated with a favorable safety profile*
- *Amylyx plans to submit an NDA for avexitide with the FDA by year-end; avexitide has Breakthrough Therapy and Orphan Drug Designations by the FDA*
- *Company to host investor conference call today, August 18, 2026 at 8:00am ET*

CAMBRIDGE, Mass. August 18, 2026 — Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today announced positive topline results from LUCIDITY, a 78-participant, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of avexitide, an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist, in participants with post-bariatric hypoglycemia (PBH) following Roux-en-Y gastric bypass (RYGB) surgery. LUCIDITY met the FDA-agreed-upon primary endpoint demonstrating a 55% reduction in the composite rate of Level 2 and Level 3 hypoglycemic events compared to placebo (p=0.000003). In addition, LUCIDITY met all secondary endpoints demonstrating consistent, highly statistically significant, and clinically meaningful reductions in Level 2 hypoglycemic events by self-monitoring of blood glucose (SMBG), Level 2 hypoglycemic events by continuous glucose monitoring (CGM), and Level 3 hypoglycemic events.

"PBH is a chronic metabolic condition that causes recurrent and often debilitating hypoglycemia, which has a significant negative impact on patients' safety and quality of life," said Marilyn Tan, MD, FACE, Principal Investigator of the LUCIDITY clinical trial and Clinical Professor at the Stanford School of Medicine. "Level 2 and Level 3 hypoglycemic events can be medical emergencies that result in significant cognitive or physical impairment, loss of consciousness, seizures, and the need for assistance from others, underscoring the need for an FDA-approved treatment option. Preventing even one Level 2 or Level 3 event is medically meaningful. I am excited by the LUCIDITY results announced today and the potential to have the first treatment for patients with PBH."

"Today's results are a major milestone that demonstrate avexitide's potential to address a critical treatment gap for the PBH community and represent a meaningful step forward for people living with this condition," said Camille L. Bedrosian, MD, Chief Medical Officer at Amylyx. "Together with the positive data generated across five previous clinical trials of avexitide in PBH, we believe the LUCIDITY results bring us one step closer to potentially delivering the first approved treatment for people living with PBH. We are moving with urgency to submit an NDA to the FDA by the end of the year. In the meantime, the LUCIDITY open-label extension remains ongoing, and our avexitide expanded access program, which launched in May, will continue to provide access for eligible individuals."

The Phase 3 LUCIDITY trial enrolled 78 adult participants with PBH following RYGB surgery. Participants were randomized 3:2 to receive either 90 mg avexitide subcutaneously once daily or placebo. LUCIDITY met the primary endpoint demonstrating a 55% reduction (p=0.000003) in the composite rate of Level 2 and Level 3 hypoglycemic events compared to placebo through Week 16. LUCIDITY also met all secondary endpoints demonstrating consistent, highly statistically significant, and clinically meaningful reductions across SMBG-measured Level 2 events, CGM-measured Level 2 events, and independently adjudicated Level 3 events.

Avexitide was generally well-tolerated through the double-blind study period with a consistent and favorable safety profile replicated across all PBH clinical trials completed to date. The majority of adverse events in LUCIDITY were mild to moderate, and there were no serious adverse events related to avexitide treatment. The most common adverse events were diarrhea, injection site erythema, and injection site bruising. There were no changes in body weight observed in either the avexitide or placebo groups over the 16-week, double-blind period of the LUCIDITY trial.

“We are deeply grateful to the people living with PBH who participated in LUCIDITY, their families and care partners, trial investigators, and the broader PBH community who have made the trial possible and have been so open in sharing their experiences to build understanding and awareness of the everyday impact of this condition,” said Justin Klee and Joshua Cohen, Co-CEOs of Amylyx. “Today’s data represent an exciting outcome for the PBH community and mark an important milestone as we work toward what could be the first approved treatment option for this condition. Our NDA submission readiness is well underway, and we continue to advance our preparations for a potential commercial launch of avexitide in 2027, if approved.”

Amylyx plans to submit a New Drug Application (NDA) to the FDA by the end of 2026. The FDA previously granted avexitide Breakthrough Therapy Designation for PBH. LUCIDITY’s 32-week open label extension (OLE) remains ongoing. The avexitide expanded access program (EAP) also remains ongoing. The Company plans to present the data from LUCIDITY at an upcoming medical meeting.

Investor Conference Call Information

Amylyx’s management team will host a conference call today, August 18, 2026, at 8:00 a.m. ET to discuss the results of LUCIDITY. To access the conference call, please dial +1 (888) 880-3330 (U.S. & Canada) or +1 (646) 357-8766 (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/events-presentations. The webcast will be archived and available for replay for 90 days following the event.

About Avexitide

Avexitide is an investigational, first-in-class glucagon-like peptide-1 (GLP-1) receptor antagonist that has been evaluated in six clinical trials for post-bariatric hypoglycemia (PBH) and has also been studied in congenital hyperinsulinism (HI). The U.S. Food and Drug Administration (FDA) has granted avexitide Breakthrough Therapy Designation for both indications, Rare Pediatric Disease Designation in congenital HI, and Orphan Drug Designation for the treatment of hyperinsulinemic hypoglycemia (which includes PBH and congenital HI). In PBH, an exaggerated GLP-1 response leads to excessive insulin secretion, resulting in recurrent hypoglycemic events. Avexitide is a competitive GLP-1 receptor antagonist designed to bind to the GLP-1 receptor on pancreatic islet beta cells and inhibit the exaggerated GLP-1-driven insulin response characteristic of PBH, reducing inappropriate insulin secretion and stabilizing blood glucose levels. In two Phase 2 and the Phase 3 LUCIDITY clinical trials in PBH, avexitide demonstrated highly statistically significant reductions in hypoglycemic events.

About Post-Bariatric Hypoglycemia (PBH)

PBH is a chronic metabolic condition that is estimated to affect approximately 8% of people in the U.S. who have undergone the two most common types of bariatric surgery, sleeve gastrectomy and Roux-en-Y gastric bypass (approximately 160,000 people in the U.S.). PBH is thought to be driven by an exaggerated glucagon-like peptide-1 (GLP-1) response, primarily in response to food intake, leading to persistent, recurrent, and often debilitating rapid drops in blood glucose, known as hypoglycemia. The American Diabetes Association (ADA) recognizes hypoglycemia as a potential medical emergency because low blood glucose levels can compromise the body’s ability to maintain essential physiologic processes. In addition, hypoglycemia in the context of PBH may manifest as neuroglycopenia – an inadequate supply of glucose to the brain – which can cause confusion, cognitive dysfunction, loss of consciousness, and seizures. PBH can be associated with substantial disability, compromising safety, disrupting independent living, and affecting nutritional status and overall quality of life. Despite the substantial burden, there are currently no FDA-approved therapies for PBH.

About the LUCIDITY Trial

LUCIDITY (NCT06747468) is a 78-participant, multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating the efficacy and safety of avexitide in participants with PBH following RYGB surgery. The Phase 3 trial was conducted at 21 sites in the U.S. Participants were randomized 3:2 to receive either 90 mg of avexitide subcutaneously once daily or placebo. The trial includes an up to six-week screening period, including a three-week run-in period, a 16-week double-blind treatment period, and a 32-week open-label extension (OLE) period. The primary efficacy objective of LUCIDITY was to evaluate the FDA-agreed upon primary outcome of reduction in the composite of Level 2 and Level 3 hypoglycemic events through Week 16. Safety and tolerability were also evaluated.

About Amylyx Pharmaceuticals

At Amylyx, our mission is to usher in a new era of treating diseases with high unmet needs. Where others see challenges, we see opportunities that we pursue with urgency, rigorous science, and unwavering commitment to the communities we serve. We are currently focused on four investigational therapies across several endocrine conditions and neurodegenerative diseases in which we believe can make the greatest impact. For more information, visit amylyx.com and follow us on LinkedIn and X. 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, Amylyx’s expectations regarding: the therapeutic potential and safety of avexitide as a treatment for PBH; expectations regarding the timing for NDA submission with the U.S. Food and Drug Administration; the potential benefits of regulatory designations held with the FDA; the plan to present data from LUCIDITY at an upcoming medical meeting; and expectations regarding timing for potential commercialization of avexitide, if approved. 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’s program development activities; Amylyx’s ability to execute on its regulatory development plans and expectations regarding the timing of results from its planned data announcements and initiation of clinical studies; the risk that early-stage results may not reflect later-stage results; Amylyx’s ability to fund operations, and the impact that global macroeconomic uncertainty, geopolitical instability, and public health events will have on Amylyx’s operations, as well as the risks and uncertainties set forth in Amylyx’s United States Securities and Exchange Commission (SEC) filings, including Amylyx’s Annual Report on Form 10-K for the year ended December 31, 2025, 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, except as required by law.

Contacts

Media

Amylyx Media Team
+1 (857) 320-6244
amylyxmediateam@amylyx.com

Investors

Lindsey Allen
Amylyx Pharmaceuticals, Inc.
+1 (857) 320-6244
Investors@amylyx.com