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 8.01. Other Events.

On August 18, 2026, Amylyx Pharmaceuticals, Inc. (the "Company") hosted a conference call with investors and analysts to discuss positive topline results from the LUCIDITY Phase 3 clinical trial evaluating the efficacy and safety of avexitide in participants with post-bariatric hypoglycemia following Roux-en-Y gastric bypass surgery. Selected slides from the investor presentation used during the conference call are attached as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Presentation 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

Exhibit 99.1

AMYLYX

Phase 3 LUCIDITY Trial of Avexitide in Post-Bariatric Hypoglycemia (PBH) Topline Data Conference Call

August 18, 2026

Maggie, a mom and advocate living with post-bariatric hypoglycemia (PBH).

Pancreatic islet cells

AMYLYX

Opening Remarks

Lindsey Allen

Vice President, Investor Relations & Communications at Amylyx

DISCLAIMER

Statements contained in this presentation 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 and preparedness for potential commercialization of avexitide, if approved. Any forward-looking statements in this presentation 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, including ongoing and planned clinical trials, Amylyx’s ability to execute on its development and regulatory strategy, regulatory developments, Amylyx’s cash runway and ability to fund 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 presentation 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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Phase 3 LUCIDITY Topline Data

Camille Bedrosian, MD
Chief Medical Officer of Amylyx

lucidity

LUCIDITY Met Its Primary and All Secondary Endpoints

Consistent, statistically significant, and clinically meaningful reductions in Level 2 and Level 3 hypoglycemic events vs. placebo

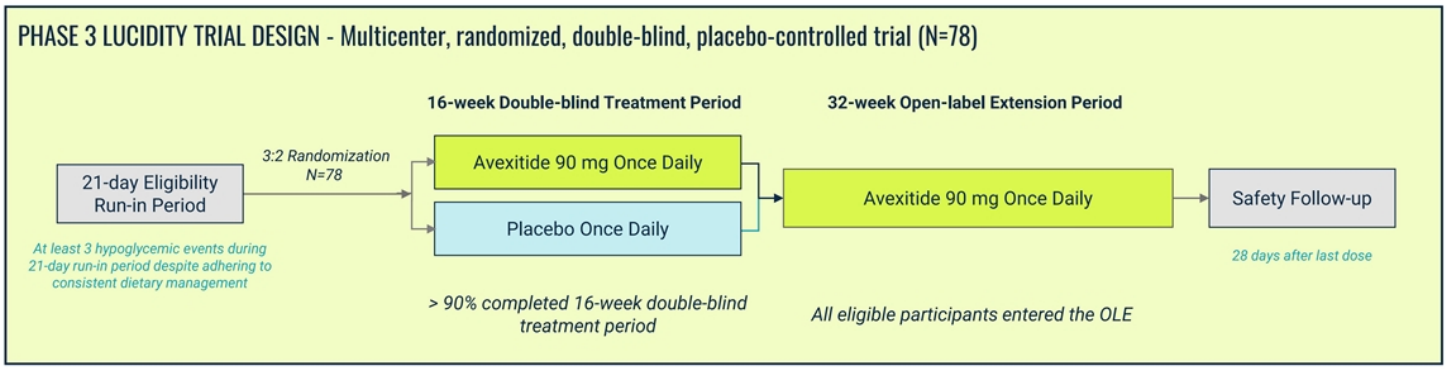
Avexitide An investigational, first-in-class GLP-1 receptor antagonist designed to reduce the exaggerated GLP-1 response in post-bariatric hypoglycemia (PBH) and restore activity to more physiological levels

- **FDA-Agreed Upon Primary Endpoint Met**
  55% reduction in the composite rate of Level 2 and Level 3 hypoglycemic events vs. placebo (p=0.000003)
- **All Secondary Endpoints Met**
  Significant reductions in Level 2 (SMBG and CGM) and Level 3 events vs. placebo
- **Generally Well-Tolerated**
  No treatment-related serious adverse events; most events mild or moderate

Potential to be the first FDA-approved therapy for PBH, a condition with a profound unmet medical need

SMBG: self-monitoring blood glucose; CGM: continuous glucose monitoring.

Phase 3 LUCIDITY Trial Design



Key Trial Entry Criteria

- Has undergone Roux-en-Y gastric bypass (RYGB) at least 12 months prior to screening visit
- Has a clinical diagnosis of PBH

Primary Endpoints

- Composite of Level 2 (SMBG) and Level 3 hypoglycemic events
- Safety and tolerability

Secondary Endpoints

- Level 2 hypoglycemic events (SMBG)
- Level 2 hypoglycemic events (CGM)
- Level 3 hypoglycemic events

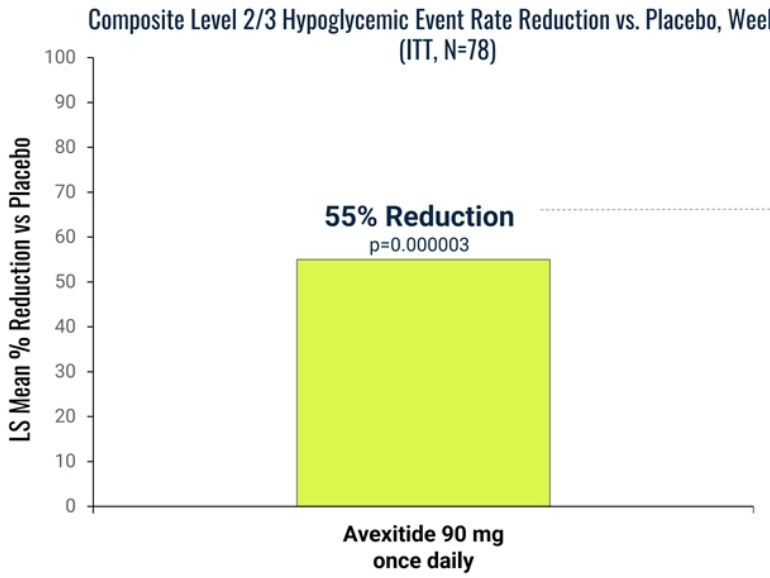
Hypoglycemic Events Definitions

- **Level 2:** glucose <54mg/dL
- **Level 3:** events characterized by altered mental and/or physical function requiring assistance

SMBG: self-monitoring blood glucose; CGM: continuous glucose monitoring.

LUCIDITY Met Primary Endpoint

Statistically significant 55% reduction in composite rate of Level 2 and Level 3 hypoglycemic events compared to placebo



Primary Analysis

Rate ratio: 0.45 (95% CI, 0.32, 0.63)
p=0.000003

LUCIDITY Met All Secondary Endpoints

Consistent, highly statistically significant, and clinically meaningful reductions

- Level 2 hypoglycemic events (SMBG)
- Level 2 hypoglycemic events (CGM)
- Level 3 hypoglycemic events

Avexitide was Generally Well-Tolerated with a Favorable Safety Profile Through 16 Weeks

- Adverse events were generally mild or moderate
- No treatment-related serious adverse events
- Most common adverse events were diarrhea, injection site erythema, and injection site bruising
- No changes in body weight with avexitide or placebo

Safety profile consistent with that observed across all PBH clinical trials completed to date

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The Burden of PBH

Marilyn Tan, MD, FACE

Principal Investigator of the LUCIDITY clinical trial and Clinical Professor of Medicine at Stanford University School of Medicine

Relevant Disclosures: Dr. Tan has received research payments from Amylyx Pharmaceuticals as primary investigator and received consulting payments.

Post-Bariatric Hypoglycemia (PBH): A Chronic, Debilitating Condition with High Unmet Need

~160,000 People Currently Living with PBH in the U.S.[1]

No approved treatment options

PBH Can be Dangerous and Life-Altering

Hypoglycemic events can cause cognitive impairment, loss of consciousness, and even seizures because the brain is not getting enough glucose (neuroglycopenia)

Can feel like a constant cycle of highs and lows with sudden and unpredictable crashes, with limited options to manage it

Can affect someone's ability to work, drive, function independently, care for others, or even be alone safely

In one study, over 90% of people with PBH described themselves as living with a disability, speaking to the incredible burden the condition can have on daily living[2]

Living with PBH

"It affected my ability to work and take care of my family."

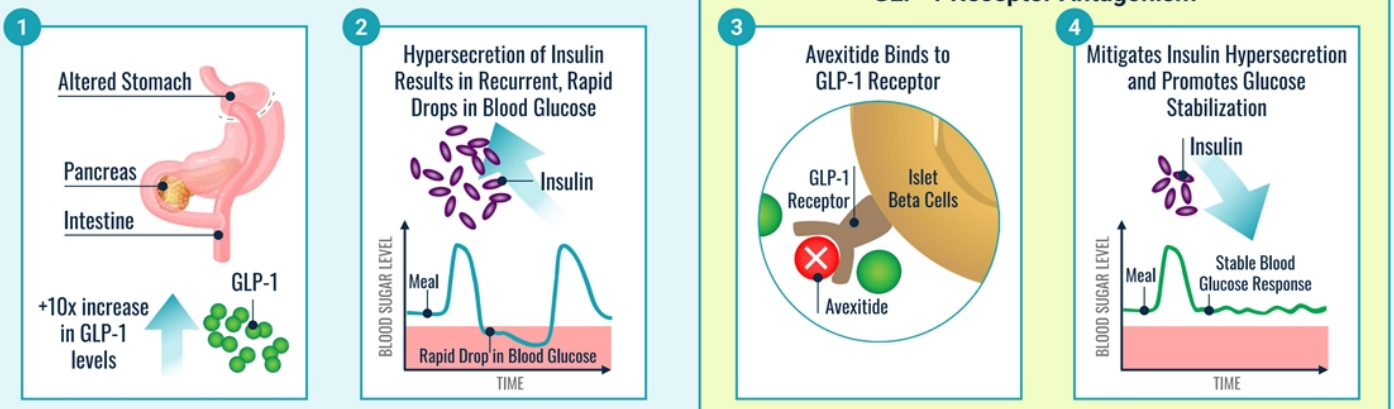
"I pass out multiple times a week. My lows are averaging 4-5 times a day."

"I lost my driver's license since I am unaware of my lows."

"I'm afraid to watch my own kids at the pool because I might pass out."

PBH=post-bariatric hypoglycemia; **1.** Craig CM, et al. *Surg Obes Relat Dis.* 2026;22(6):674-683. **2.** Craig CM and McLaughlin TL. *Surg Obes Relat Dis.* 2021 Nov;17(11):1865-1872.

Avexitide, an Investigational, First-in-Class GLP-1 Receptor Antagonist, Targets a Central Pathway of PBH Pathophysiology



Altered nutrient transit due to anatomical changes associated with bariatric surgery (e.g., Roux-en-Y gastric bypass) leads to **exaggerated GLP-1 secretion** in people with PBH

This exaggerated GLP-1 secretion leads to abnormally high insulin levels in the bloodstream, and subsequent hypoglycemia

Avexitide binds to the GLP-1 receptor on pancreatic islet beta cells to **reduce the effects of excessive GLP-1 signaling**

Decreased insulin secretion and stabilized glucose levels resulting from inhibition of the effect of exaggerated GLP-1

GLP-1=glucagon-like peptide-1; PBH=post-bariatric hypoglycemia; **1.** Sheehan A, Patti ME. *Diabetes Metab Syndr Obes*. 2020;13:4469-4482; **2.** Craig CM, et al. *Diabetes Obes Metab*. 2017; 1-10. **3.** Thorens B,. et al. *Diabetes*.1993;42(11):1678-1682. **4.** Craig CM, et al. *Diabetes Obes Metab*. 2018;20(2):352-361. **5.** Smith NK, et al. *Neurochem Int*. 2019;128:94-105. **6.** Meloni AR, et al. *Diabetes Obes Metab*. 2013;15(1):15-27. **7.** Craig CM, et al. *Diabetologia*. 2017;60(3):531-540. **8.** Craig C, et al. *J Endocr Soc*. 2022;6(Suppl 1):A349.

Avexitide has the Potential to be a First-in-Class Treatment for PBH

Phase 3 LUCIDITY Trial Topline Data Summary

Avexitide met primary and secondary endpoints demonstrating statistically significant and clinically meaningful reductions in both SMBG and CGM Level 2 and Level 3 hypoglycemic events

Avexitide was generally well-tolerated with a favorable safety profile across all PBH clinical trials to date

Builds on positive results of five prior clinical trials of avexitide in PBH, including statistically significant reductions in hypoglycemic events and stabilization of blood glucose

Patient Impact

Preventing a single Level 2 or Level 3 hypoglycemic event could enable someone to care for their child, function independently, and prevent potentially catastrophic consequences, such as a seizure, car accident, or loss of consciousness

High unmet need for an FDA-approved treatment for PBH, a disease with no approved therapies

~160K people living with PBH in the U.S. who require medical management despite the current standard of care, nutrition therapy

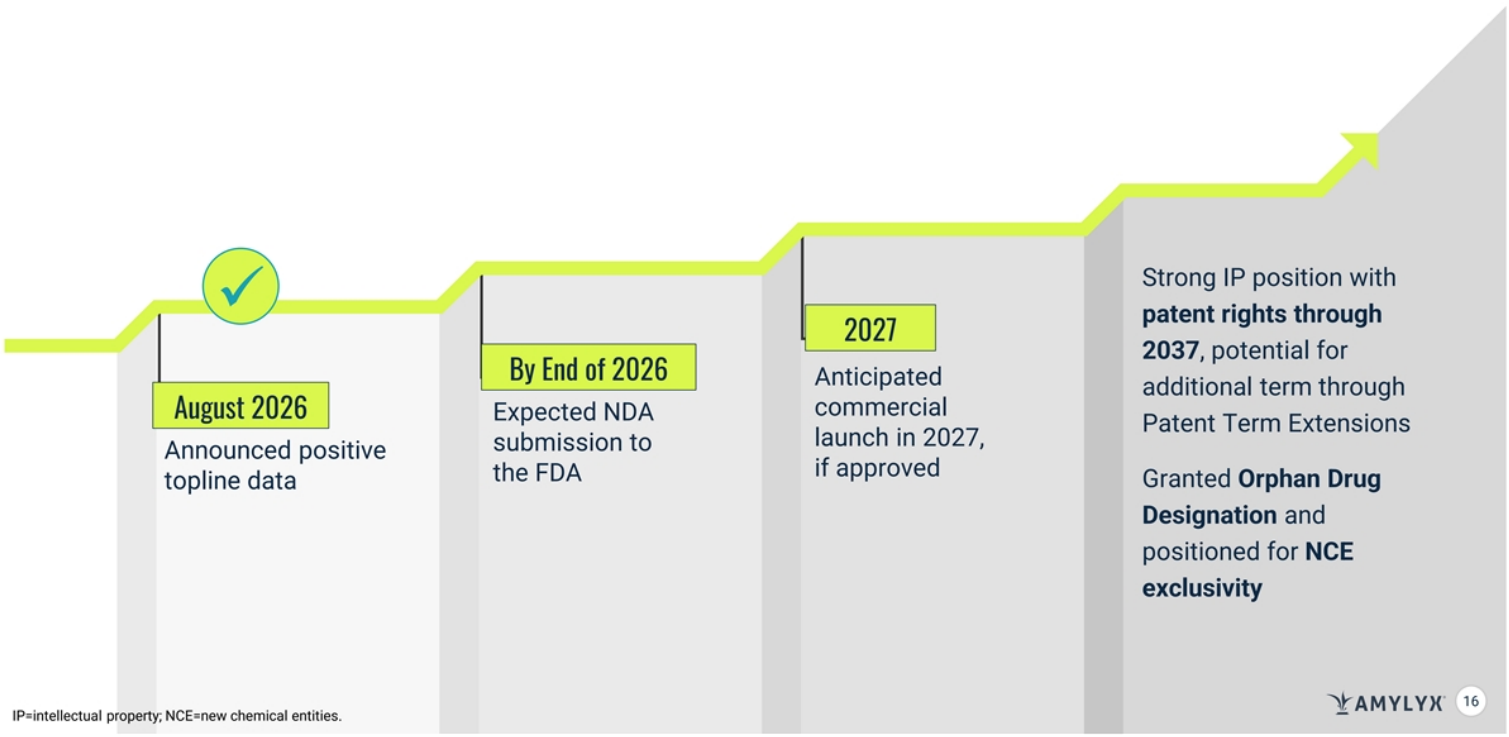

AMYLYX
Next Steps
Josh Cohen
Co-Chief Executive Officer & Co-Founder of Amylyx
Justin Klee
Co-Chief Executive Officer & Co-Founder of Amylyx

Preparing for NDA Submission and Potential Commercialization with Urgency

- Regulatory Submission Work Already Underway
- Continuing to Gain Key Insights into the PBH Market
- Building Medical Affairs and Commercial Organization with Key Hires
- Disease State Education Campaign Launched

Leadership team tenured in rare disease, global regulatory approval, and commercial launch experience

Avexitide Path to Potential Commercial Launch in 2027



IP=intellectual property; NCE=new chemical entities.

Q&A

AMYLYX®