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): November 5, 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** **(Address of Principal Executive Offices)**	**02142** **(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 November 5, 2026, Amylyx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2026. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "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 November 5, 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: November 5, 2026

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

Exhibit 99.1

Amylyx Pharmaceuticals Reports Third Quarter 2026 Financial Results

- *Reported positive topline results from Phase 3 LUCIDITY clinical trial of avexitide in post-bariatric hypoglycemia; New Drug Application submission planned by end of 2026 remains on track*
- *Results from LUCIDITY trial accepted as a late-breaking oral presentation at ObesityWeek® 2026 Annual Meeting on November 15*
- *Strengthened balance sheet through upsized public offering with net proceeds of approximately $545 million*
- *Management to host conference call and webcast today at 8:00 a.m. Eastern Time*

CAMBRIDGE, Mass., November 5, 2026 – Amylyx Pharmaceuticals, Inc. (Nasdaq: AMLX) ("Amylyx" or the "Company") today reported financial and business results for the third quarter ended September 30, 2026.

"The third quarter was a transformational period for Amylyx, as we reported positive topline results from the Phase 3 LUCIDITY trial of avexitide in post-bariatric hypoglycemia, bringing us one step closer to potentially delivering a first ever FDA-approved treatment to people living with PBH," said Joshua Cohen and Justin Klee, Co-CEOs of Amylyx. "Importantly, the enthusiastic response from the medical community to the strength and consistency of the data demonstrate the significant unmet need in PBH, and we look forward to building on this momentum with the upcoming presentation of LUCIDITY data at ObesityWeek this month. We remain on track to submit our NDA by year-end and are executing on our comprehensive commercial readiness plans ahead of a potential launch of avexitide in 2027, if approved. With a strengthened balance sheet following our recent equity financing, we believe we are well positioned to deliver on our commitment to bring meaningful new treatments to people living with diseases with high unmet needs."

Third Quarter and Recent Updates:

- **Amylyx reported positive topline results from Phase 3 LUCIDITY clinical trial of avexitide in participants with post-bariatric hypoglycemia (PBH) following Roux-en-Y gastric bypass (RYGB) surgery.** LUCIDITY met the prespecified primary endpoint demonstrating a 55% reduction in the composite rate of Level 2 and Level 3 hypoglycemic events compared to placebo (p=0.000003), and met all secondary endpoints demonstrating consistent, highly statistically significant, and clinically meaningful reductions across all endpoints. Avexitide was generally well-tolerated through the double-blind study period with a favorable safety profile. LUCIDITY's 32-week open label extension (OLE) and the avexitide Expanded Access Program for eligible adults with PBH following RYGB remain ongoing.
- **As Amylyx approaches a potential 2027 launch of avexitide, the Company is scaling its commercial organization and launch readiness capabilities.** During the third quarter, the Company solidified its full commercial leadership team and continues to invest in the capabilities and talent needed to support a successful launch. This includes key hiring across marketing, market access, patient services, and commercial operations. Furthermore, uncoverPBH.com, the PBH disease state education platform, continues to educate patients and healthcare professionals.
- **Amylyx recently completed enrollment of Cohort 3 (n=12) and began enrollment of Cohort 4 of the Phase 1 LUMINA clinical trial of AMX0114, an investigational antisense oligonucleotide targeting calpain-2 with FDA Fast Track Designation for the potential treatment of amyotrophic lateral sclerosis (ALS).** The LUMINA trial is a randomized, double-blind, placebo-controlled, multiple ascending dose clinical trial of AMX0114 in people living with ALS. LUMINA is evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of AMX0114 in people living with ALS and assessing both novel and broadly researched ALS biomarkers, including change from baseline in neurofilament light chain levels.

- **Amylyx recently presented data from the Phase 1 LUMINA clinical trial of AMX0114 at the Annual NEALS Meeting from the initial two dose cohorts.** The presentation is available on the "Presentations" tab of the Amylyx website.
- **Amylyx announced the closing of its underwritten public offering, with net proceeds to Amylyx of approximately $544.6 million.** The proceeds strengthen the Company's financial position, enabling Amylyx to enter 2027 well-funded to commercialize avexitide, if approved.

Upcoming Expected Milestones:

- **Amylyx plans to present results from the Phase 3 LUCIDITY clinical trial of avexitide in PBH in a late-breaking oral presentation on November 15, 2026, at the upcoming ObesityWeek® 2026 Annual Meeting, taking place in Washington, D.C.** The presentation will be made available on the "Presentations" tab of the Amylyx website.
- **Amylyx remains on track to submit a New Drug Application to the FDA by the end of 2026**. The FDA previously granted avexitide Breakthrough Therapy Designation for PBH.
- **Investigational New Drug (IND)-enabling studies for AMX0318, a novel GLP-1 receptor antagonist for long-acting administration to treat PBH and other rare diseases, are underway with an IND filing targeted for 2027.** AMX0318 was selected as a development candidate after demonstrating robust nonclinical and chemical properties, including a favorable pharmacokinetic profile that may support long-acting administration, a robust chemical stability profile, strong *in vitro* potency, evidence of *in vivo* activity and tolerability, and high solubility. AMX0318 was identified through a research collaboration with Gubra A/S, a company specializing in peptide-based drug discovery.

Financial Results for the Third Quarter Ended September 30, 2026

R&D Expenses: Research and development expenses for the third quarter of 2026 were $28.4 million, compared to $19.9 million for the same period in 2025. The increase was primarily due to an increase in spending related to the pivotal Phase 3 LUCIDITY clinical trial and other costs related to avexitide and other programs. The increase was partially offset by a decrease in spending related to AMX0035 for the treatment of progressive supranuclear palsy following its discontinuation. Research and development expenses include $3.2 million of stock-based compensation expense for the quarter ended September 30, 2026, compared to $1.6 million of stock-based compensation expense for the quarter ended September 30, 2025.

SG&A Expenses: Selling, general, and administrative expenses for the third quarter of 2026 were $21.3 million, compared to $16.2 million for the same period in 2025. This increase was primarily due to an increase in personnel-related costs to support our pre-commercialization activities and the vesting of PSU awards during the quarter. Selling, general, and administrative expenses include $7.2 million of stock-based compensation expense for the quarter ended September 30, 2026, compared to $5.4 million of stock-based compensation expense for the quarter ended September 30, 2025.

Net Loss: Net loss for the three months ended September 30, 2026 was $45.5 million, or $0.38 per share, compared to net loss of $34.4 million, or $0.37 per share, for the same period in 2025.

Cash Position: Cash, cash equivalents and marketable securities were $768.1 million at September 30, 2026, compared to $250.8 million at June 30, 2026. The Company's cash position reflects net proceeds of approximately $544.6 million following the Company's public offering in August 2026.

Investor Conference Call Information

Amylyx's management team will host a conference call today, November 5, 2026, at 8:00 a.m. ET. 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.

Available Information

Amylyx periodically provides other information for investors on the Company's corporate website, https://amylyx.com, and the Company's 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. Amylyx intends to use its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor Amylyx's website, in addition to following the Company's press releases, SEC filings, and public conference calls and webcasts.

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 Roux-en-Y gastric bypass 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 AMX0114

AMX0114 is an investigational antisense oligonucleotide (ASO) with U.S. Food and Drug Administration (FDA) Fast Track designation for the potential treatment of ALS. AMX0114 targets calpain-2 (*CAPN2*), a calcium-activated protease that is one of the fundamental drivers of axonal degeneration and consequent disease progression in ALS. In nonclinical studies, treatment with AMX0114 resulted in potent, dose-dependent, and durable reduction in *CAPN2* mRNA and calpain-2 protein levels in disease-relevant cell models of axonal degeneration. This translated to improved neuronal survival, including in a model of TDP-43 ALS, and reductions in extracellular neurofilament light (NfL) levels across multiple disease models and paradigms of neuronal injury. AMX0114 was

generally well-tolerated in LUMINA trial participants enrolled in Cohort 1 (n=12), with no treatment-related serious adverse events (SAEs).

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 of avexitide as a treatment for PBH; the timing for the submission of an NDA for avexitide in PBH; the timing for presentation of LUCIDITY data at an upcoming conference; Amylyx's commercial readiness plans; the timing for potential commercialization of avexitide, if approved; the therapeutic potential of AMX0114 as a treatment for ALS; the expected enrollment and progress of the LUMINA trial; the therapeutic potential of AMX0318 and the expected timeline for a potential IND submission; the potential benefits of expedited program and orphan designations held by Amylyx; the potential benefits of the research collaborations with Gubra A/S; and financial performance, cash runway, including the sufficiency of Amylyx's capital resources to support commercialization of avexitide, if approved, and 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'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; Amylyx's ability to obtain regulatory approval for, and successfully commercialize, avexitide; 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 and related comments in Amylyx's 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, except as required by law.

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

	September 30, 2026	December 31, 2025
Assets		
Cash, cash equivalents and marketable securities	$ 768,132	$ 316,979
Prepaid expenses and other current assets	10,726	6,692
Other assets	7,937	8,974
Total assets	$ 786,795	$ 332,645
Liabilities and Stockholders' Equity		
Accounts payable and accrued expenses	$ 28,116	$ 21,429
Other liabilities	4,943	5,957
Total liabilities	33,059	27,386
Stockholders' equity	753,736	305,259
Total liabilities and stockholders' equity	$ 786,795	$ 332,645

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 28,350	$ 19,855	$ 79,729	$ 69,191
Selling, general and administrative	21,308	16,172	59,400	47,495
Total operating expenses	49,658	36,027	139,129	116,686
Loss from operations	(49,658)	(36,027)	(139,129)	(116,686)
Other income, net	4,169	1,641	8,933	4,950
Net loss	$ (45,489)	$ (34,386)	$ (130,196)	$ (111,736)
Net loss per share — basic and diluted	$ (0.38)	$ (0.37)	$ (1.15)	$ (1.25)
Weighted-average shares used in computing net loss per share — basic and diluted	118,944,774	93,332,930	113,599,040	89,417,505

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