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 10, 2026**

Xilio Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-40925**	**85-1623397**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

828 Winter Street, Suite 300 **Waltham, Massachusetts**	**02451**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(857) 524-2466**

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 (*see* General Instruction A.2. below):

☐ 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, par value $0.0001 per share	**XLO**	**Nasdaq Capital 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 10, 2026, Xilio Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2026 and other business highlights. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Current Report on Form 8-K, including Exhibit 99.1, is intended to be 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 it be deemed incorporated by reference in any filing 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.

The following exhibit relating to Item 2.02 of this Current Report on Form 8-K shall be deemed to be furnished and not filed.

Exhibit No.	Description
99.1	Press release issued by Xilio Therapeutics, Inc. on November 10, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

XILIO THERAPEUTICS, INC.

Date: November 10, 2026

By: /s/ Ben Harshbarger
Ben Harshbarger
Chief Legal Officer

Exhibit 99.1

Xilio Therapeutics Reports Third Quarter 2026 Financial Results and Provides Pipeline and Business Updates

Dosed first patient in Phase 1/2 clinical trial for XTX501, a potential best-in-class PD-1/masked IL-2 bispecific, for patients with metastatic NSCLC, and plan to report initial Phase 1 data in the fourth quarter of 2027

Advancing XTX602, a dual-masked CLDN18.2-targeting multi-specific TCE with co-stimulation, and XTX701, a masked PSMAxSTEAP1-targeting multi-specific TCE with co-stimulation, toward planned IND applications in the fourth quarter of 2027

WALTHAM, Mass., November 10, 2026 (GLOBE NEWSWIRE) -- Xilio Therapeutics, Inc. (Nasdaq: XLO), a clinical-stage biotechnology company discovering and developing masked immuno-oncology therapies for people living with cancer, today announced pipeline progress and business updates and reported financial results for the third quarter ended September 30, 2026.

“In the third quarter, we initiated our Phase 1/2 clinical trial for XTX501, a PD-1/masked IL-2 bispecific that we believe has the potential to become a foundational backbone immunotherapy regimen for solid tumors,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “By incorporating masking and tumor-selective activation of a high potency, alpha-optimized IL-2 with inhibition of PD-1/PD-L1 in a single molecule, XTX501 is designed to simultaneously leverage these two validated mechanisms, while overcoming the toxicity and rapid clearance that have limited non-masked IL-2 therapies. We also continued to execute across our preclinical pipeline, advancing our programs for masked, multi-specific TCEs with built-in co-stimulation toward planned IND filings next year.”

Pipeline Progress and Business Updates

XTX501: PD-1/masked IL-2 bispecific

XTX501 is a novel, investigational PD-1/masked IL-2 (alpha-optimized) bispecific antibody fusion protein that combines two complementary mechanisms in a single molecule: selective inhibition of the PD-1/PD-L1 pathway and potent IL-2-driven expansion of T cells. The PD-1 binding arm is designed to selectively direct IL-2 activity to PD-1 positive, antigen-experienced T cells and enhance their function. The IL-2 binding arm incorporates a masked, high potency IL-2 variant with an alpha-optimized receptor binding profile. By leveraging Xilio’s proprietary masking technology, XTX501 aims to overcome IL-2 receptor-mediated clearance, peripheral activity and tolerability challenges associated with non-masked IL-2 therapies.

- Xilio recently dosed the first patient in the Phase 1 portion of the trial for XTX501 in patients with metastatic non-small cell lung cancer (NSCLC) and select advanced solid tumors. For more information, read the press release here.
- Xilio recently presented a trial-in-progress poster highlighting the design of the Phase 1/2 clinical trial of XTX501 at the Society for Immunotherapy of Cancer (SITC) 41st Annual Meeting.
- Xilio plans to report initial Phase 1 data in patients with metastatic NSCLC in the fourth quarter of 2027.

Masked T Cell Engager (TCE) Programs

Xilio is leveraging its proprietary, clinically-validated masking technology and modular TCE architecture to advance two wholly-owned masked TCE programs, as well as an additional masked TCE program in collaboration with AbbVie Group Holdings Limited (AbbVie).

As part of the core design, Xilio's TCEs incorporate a masked CD3 binding domain, a tumor-associated antigen (TAA) binding domain and built-in co-stimulation. The company's modular architecture enables the flexibility to incorporate additional TAA binding domains and mask the TAA binding domain(s) and/or co-stimulatory signaling domain. Upon tumor-selective activation, the molecules are designed to release the mask(s) and deliver a potent TCE with a short half-life in the tumor microenvironment.

XTX602: dual-masked CLDN18.2-targeting multi-specific TCE with co-stimulation

XTX602 is a potential first-in-class, dual-masked CLDN18.2-targeting multi-specific TCE with built-in CD2 co-stimulation. CLDN18.2 is a TAA expressed in gastrointestinal cancers (gastric, pancreatic and esophageal). By incorporating masks for both the CLDN18.2 and the CD3 binding domains, XTX602 is designed to overcome potential gastrointestinal toxicity associated with non-masked CLDN18.2-targeting molecules. In addition, the CD2 co-stimulatory domain is built directly into the molecule to enable enhanced T cell activation, expansion and durability of T cell response.

- Investigational new drug application (IND)-enabling studies for XTX602 are ongoing, and Xilio plans to submit an IND for XTX602 in the fourth quarter of 2027.

XTX701: masked PSMAxSTEAP1-targeting multi-specific TCE with co-stimulation

XTX701 is a potential first-in-class, masked PSMAxSTEAP1-targeting multi-specific TCE with built-in CD2 co-stimulation. PSMA and STEAP1 are TAAs collectively expressed in approximately 95% of metastatic castration-resistant prostate cancer. Targeting these two TAAs is intended to address heterogeneity of expression of PSMA and STEAP1 across prostate tumors and limit resistance and lack of durability of response due to antigen escape. By incorporating a mask for the CD3 binding domain, XTX701 is designed to minimize toxicity due to peripheral T cell activation and on-target, off-tumor engagement associated with non-masked molecules. In addition, the CD2 co-stimulatory domain is built directly into the molecule to enable enhanced T cell activation, expansion and durability of T cell response.

- IND-enabling studies for XTX701 are ongoing, and Xilio plans to submit an IND for XTX701 in the fourth quarter of 2027.

Efarindodekin alfa: masked IL-12

- Xilio is evaluating efarindodekin alfa as a monotherapy in an ongoing Phase 2 clinical trial in patients with advanced solid tumors and expects to deliver an option data package to Gilead Sciences, Inc. (Gilead) in the first half of 2027.

Recent Corporate Updates

- Xilio appointed Yariv Houvras, M.D., Ph.D., as its chief medical officer in September 2026. Dr. Houvras has over 20 years of executive leadership across premier industry and academic research institutions in clinical development, translational medicine and immuno-oncology. Read more here.

Third Quarter 2026 Financial Results

- **Cash Position:** Cash and cash equivalents were $122.2 million as of September 30, 2026, compared to $137.5 million as of December 31, 2025.
- **Collaboration and License Revenue:** Collaboration and license revenue was $10.0 million for the quarter ended September 30, 2026, compared to $19.1 million for the quarter ended September 30,

2025. The decrease was driven by a decrease in collaboration and license revenue recognized under the company's collaboration and license agreements with AbbVie and Gilead.

- **Research & Development (R&D) Expenses:** R&D expenses were $14.8 million for the quarter ended September 30, 2026, compared to $14.3 million for the quarter ended September 30, 2025. The increase was primarily driven by an increase in preclinical research and development activities related to the company's wholly-owned masked TCE programs, an increase in clinical trial startup activities related to the company's Phase 1/2 clinical trial for XTX501 and an increase in personnel-related costs due to higher research and development headcount, partially offset by a decrease in preclinical development activities and manufacturing activities related to IND-enabling studies for XTX501 and a decrease in clinical development activities for efarindodekin alfa and vilastobart.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.9 million for the quarter ended September 30, 2026, compared to $6.7 million for the quarter ended September 30, 2025. The increase was primarily driven by an increase in stock-based compensation expense.
- **Net Loss:** Net loss was $5.9 million for the quarter ended September 30, 2026, compared to a net loss of $16.3 million for the quarter ended September 30, 2025.

Cash Runway

Based on its current operating plans, Xilio anticipates that its existing cash and cash equivalents will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the first quarter of 2028.

This estimate excludes up to $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all outstanding Series C warrants are exercised at their current exercise price and any potential additional milestone payments, option-related fees or other contingent payments under Xilio's collaboration and license agreements with AbbVie and Gilead, including up to $31.0 million in near-term milestones and option extension fees that could be achieved under the AbbVie collaboration through the first half of 2027.

About Xilio Therapeutics

Xilio Therapeutics is a clinical-stage biotechnology company discovering and developing masked immuno-oncology (I-O) therapies with the goal of significantly improving outcomes for people living with cancer without the systemic side effects of current I-O treatments. Leveraging our clinically-validated masking technology and capabilities, Xilio is developing I-O therapies designed to selectively activate within the tumor microenvironment to achieve durable efficacy without the severe side effects associated with systemically active I-O agents. Learn more by visiting www.xiliotx.com and follow us on LinkedIn (Xilio Therapeutics, Inc.).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding plans, expectations, development timelines and anticipated milestones for Xilio's programs, including data releases, regulatory submissions, delivery of option data packages and other potential program milestones; the promise or potential success of Xilio's programs, including the best-in-class potential of XTX501 and the potential for XTX501 to be a foundational backbone I-O regimen for solid tumors and the first-in-class potential of Xilio's masked TCE programs targeting CLDN18.2 and PSMAxSTEAP1; the timing and receipt of future contingent payments under Xilio's collaboration and license agreements with AbbVie and Gilead; the potential receipt of up to $36.2 million in additional gross proceeds in the fourth quarter of 2026 if all outstanding Series C warrants are exercised at their current exercise price; the sufficiency of, and the period in which Xilio expects to have, cash to fund its operations and capital expenditure requirements; and

Xilio's strategy, goals and anticipated financial performance (including anticipated cash runway), milestones, business plans and focus. The words "aim," "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "seek," "target," "design," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of important risks, uncertainties and other factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks related to general market conditions and geopolitical uncertainties; risks and uncertainties related to ongoing and planned research and development activities, including initiating, conducting or completing preclinical studies and clinical trials and the timing and results of such preclinical studies or clinical trials; the delay of any current or planned preclinical studies or clinical trials or the development of Xilio's current or future product candidates; Xilio's ability to obtain and maintain sufficient preclinical and clinical supply of current or future product candidates; initial, preliminary, interim or retrospective preclinical or clinical data or results may not be replicated in or predictive of future preclinical or clinical data or results; Xilio's ability to successfully demonstrate the safety and efficacy of its product candidates and gain approval of its product candidates on a timely basis, if at all; results from preclinical studies or clinical trials for Xilio's product candidates may not support further development of such product candidates; actions of regulatory agencies may affect the initiation, timing and progress of current or future clinical trials; Xilio's ability to obtain, maintain and enforce patent and other intellectual property protection for current or future product candidates; Xilio's need to obtain additional cash resources to advance its pipeline of masked I-O molecules; the impact of international trade policies on Xilio's business, including U.S. and China trade policies; and Xilio's ability to maintain its collaboration and license agreements with AbbVie and Gilead. These and other risks and uncertainties are described in greater detail in the sections entitled "Risk Factor Summary" and "Risk Factors" in Xilio's filings with the U.S. Securities and Exchange Commission (SEC), including Xilio's most recent Quarterly Report on Form 10-Q and any other filings that Xilio has made or may make with the SEC in the future. Any forward-looking statements contained in this press release represent Xilio's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Xilio explicitly disclaims any obligation to update any forward-looking statements.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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XILIO THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 122,182	$ 137,531
Other assets	12,650	17,154
Total assets	$ 134,832	$ 154,685
Liabilities and Stockholders' Equity		
Liabilities		
Deferred revenue	$ 25,334	$ 60,658
Common stock warrant liabilities	25,380	29,560
Other liabilities	15,884	29,194
Total liabilities	$ 66,598	$ 119,412
Stockholders' equity	68,234	35,273
Total liabilities and stockholders' equity	$ 134,832	$ 154,685

XILIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data) [1]
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Collaboration and license revenue	$ 9,984	$ 19,066	$ 41,324	$ 30,080
Operating expenses [2]				
Research and development	$ 14,805	$ 14,321	$ 49,196	$ 37,917
General and administrative	6,928	6,674	21,480	22,309
Total operating expenses	21,733	20,995	70,676	60,226
Loss from operations	(11,749)	(1,929)	(29,352)	(30,146)
Other income (expense), net				
Change in fair value of common stock warrant liabilities	4,820	(15,380)	4,180	(15,430)
Other income, net	981	1,022	3,322	180
Total other income (expense), net	5,801	(14,358)	7,502	(15,250)
Net loss and comprehensive loss	$ (5,948)	$ (16,287)	$ (21,850)	$ (45,396)
Net loss per share, basic and diluted	$ (0.30)	(1.58)	$ (1.18)	$ (6.03)
Weighted average common shares outstanding, basic and diluted [3]	19,687,818	10,293,347	18,492,240	7,524,228

(1) On March 13, 2026, the company effected a 1-for-14 reverse stock split of its common stock. All share amounts and per share amounts in this press release have been adjusted retroactively to reflect the reverse stock split for the periods presented.

(2) Operating expenses include the following amounts of non-cash stock-based compensation expense:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 632	$ 319	$ 1,947	$ 1,054
General and administrative	1,286	804	3,780	2,955
Total stock-based compensation expense	$ 1,918	$ 1,123	$ 5,727	$ 4,009

(3) Weighted average common shares outstanding, basic and diluted, includes prefunded warrants to purchase common stock, as the prefunded warrants are exercisable at any time for nominal cash consideration.