Xilio Therapeutics Announces Pipeline and Business Updates and Fourth Quarter and Full Year 2025 Financial Results

March 23, 2026

XTX501, a potential best-in-class bispecific PD-1 / masked IL-2, on track for planned IND submission in mid-2026 and Phase 1 initiation in the second half of 2026

Advancing potential first-in-class multi-specific, masked T cell engager targeting PSMA and STEAP1

Plan to present new preclinical data at AACR for potential first-in-class masked T cell engager program targeting CLDN18.2

Extended cash runway through the end of 2027

WALTHAM, Mass., March 23, 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 fourth quarter and full year ended December 31, 2025.

“As we enter 2026, we are well-positioned to leverage our clinically validated masking technology to continue advancing our next generation of multi-specific I-O therapies toward the clinic,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “We are encouraged by the progress the field has recently made with masked T cell engagers for prostate cancer, and we are excited to be advancing a potential first-in-class multi-specific masked T cell engager targeting both PSMA and STEAP1 with built-in co-stimulatory signaling designed to enhance potency and durability of response. We believe that targeting both PSMA and STEAP1, which are the most prevalent tumor-associated antigens expressed in prostate cancer, will minimize resistance due to antigen escape. In addition, this quarter we continued to make strong progress advancing XTX501, our potential best-in-class bispecific PD-1 / masked IL-2, toward a planned IND submission mid-year.”

Pipeline Progress and Business Updates

XTX501: bispecific PD-1 / masked IL-2

XTX501 is a novel bispecific PD-1 / masked IL-2 designed to selectively stimulate PD-1 positive, antigen-experienced T cells and enhance their function. XTX501 incorporates masking and is designed to overcome IL-2 receptor-mediated clearance, peripheral activity and tolerability issues associated with non-masked IL-2 agents. In preclinical studies, XTX501 demonstrated robust monotherapy activity (including in settings insensitive to PD-1 therapy) and tumor-selective pharmacodynamics consistent with its intended mechanism of action.

- Xilio is currently advancing XTX501 through investigational new drug (IND)-enabling studies and plans to submit an IND application for XTX501 in the middle of 2026.
- Xilio plans to initiate a Phase 1 trial for XTX501 in the second half of 2026 and report initial Phase 1 data in the second half of 2027, subject to clearance of the IND by the U.S. Food and Drug Administration.
- Xilio plans to initially evaluate XTX501 in patients with metastatic non-small cell lung cancer before expanding development to other solid tumor types, including tumors that are insensitive to PD-1 therapy. The company believes XTX501 also has the potential to be a foundational “backbone” therapy for combination treatment with other agents.

Masked T Cell Engager Programs

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

Xilio’s masked T cell engagers include molecules with one or more tumor-associated antigen (TAA) binding domains and a CD3 targeting domain, which are designed to release a potent, short half-life T cell engager upon tumor-selective activation (ATACR format), and molecules that include a co-stimulatory domain designed to further enhance potency and durability of the T cell response (SEECR format). Depending on the desired properties that Xilio is seeking to achieve for a particular molecule and TAA(s), Xilio’s modular architecture for its masked T cell engagers enables optionality to: include multiple TAA binding domains; add a co-stimulatory domain; and/or mask the CD3 targeting domain, TAA binding domain(s) and/or the co-stimulatory signaling domain.

- Xilio is advancing a wholly-owned masked T cell engager program targeting CLDN18.2 (ATACR format). Xilio’s modular design architecture for T cell engagers also enables flexibility to evaluate designs that incorporate masking of the CLDN18.2 binding domain and/or add a co-stimulatory domain (SEECR format) in parallel with advancing the current molecule design. CLDN18.2 is expressed in gastrointestinal cancers (including gastric, pancreatic and esophageal) and lung cancer.

- Xilio plans to present new preclinical data for its CLDN18.2 program in a poster presentation at the American Association for Cancer Research (AACR) Annual Meeting taking place from April 17-22, 2026 (abstract number: 1619).
- Xilio is advancing a wholly-owned multi-specific, masked T cell engager program targeting PSMA and STEAP1 with built-in co-stimulatory signaling (SEECR format). Xilio anticipates nominating a development candidate in the second quarter of 2026. PSMA and STEAP1 are expressed in most prostate cancer tumors, and targeting both of these TAAs has the potential to address tumor heterogeneity while minimizing the potential for resistance due to antigen escape.
- Xilio plans to advance these masked T cell engager programs into IND-enabling studies and submit IND applications for each of these programs in 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

- In January 2026, Xilio announced the appointment of Sara Bonstein as chair of the board of directors.
- In January 2026, Xilio announced the receipt of $35.8 million in gross proceeds from the exercise of Series B warrants, before deducting underwriting discounts and commissions and any offering expenses, including the full exercise of Series B warrants held by Coastlands Capital, Frazier Life Sciences and Gilead. The Series B warrants were issued in connection with a follow-on offering in June 2025.
- In January 2026, Xilio announced the achievement of a development milestone related to the masked antibody-based immunotherapy program under the company's collaboration, license and option agreement with AbbVie.
- In February 2026, Xilio closed a follow-on offering of prefunded warrants for $40.0 million in gross proceeds, before deducting underwriting discounts and commissions and any offering expenses. The offering was led by existing investor Coastlands Capital and included participation from OrbiMed, Perceptive Advisors and Gilead, as well as other new and existing institutional investors.

Year-End and Fourth Quarter 2025 Financial Results

- **Cash Position:** Cash and cash equivalents were $137.5 million as of December 31, 2025, compared to $55.3 million as of December 31, 2024. In the fourth quarter of 2025, Xilio received $35.8 million in gross proceeds from Series B warrant exercises and a $17.5 million development milestone payment under its license agreement with Gilead.
- **Collaboration and License Revenue:** Collaboration and license revenue was $13.7 million for the quarter ended December 31, 2025, compared to $1.7 million for the quarter ended December 31, 2024. Collaboration and license revenue was $43.8 million for the year ended December 31, 2025, compared to $6.3 million for the year ended December 31, 2024. The year-over-year increase was primarily driven by collaboration and license revenue recognized under the collaboration, license and option agreement and stock purchase agreement that Xilio entered into in February 2025 with AbbVie and an increase in collaboration and license revenue recognized under the license agreement with Gilead due to the achievement of a $17.5 million development milestone during the third quarter of 2025.
- **Research & Development (R&D) Expenses:** R&D expenses were $18.1 million for the quarter ended December 31, 2025, compared to $8.8 million for the quarter ended December 31, 2024. R&D expenses were $56.0 million for the year ended December 31, 2025, compared to $41.2 million for the year ended December 31, 2024. The year-over-year increase was primarily driven by manufacturing activities related to IND-enabling studies and preclinical development activities for XTX501, increased clinical development activities related to efarindodekin alfa, increased costs related to masked T cell engager programs and indirect research and development and increased personnel-related costs, which were partially offset by a decrease in costs related to vilastobart and XTX202.
- **General & Administrative (G&A) Expenses:** G&A expenses were $7.4 million for the quarter ended December 31, 2025, compared to $6.5 million for the quarter ended December 31, 2024. G&A expenses were $29.7 million for the year ended December 31, 2025, compared to $24.8 million for the year ended December 31, 2024. The year-over-year increase was primarily driven by an increase in professional and consulting fees, including legal fees and other professional costs, and an increase in personnel-related costs, which were partially offset by a decrease in costs related to directors' and officers' liability insurance.
- **Net Income (Loss):** Net income was $10.4 million for the quarter ended December 31, 2025, compared to a net loss of $13.1 million for the quarter ended December 31, 2024. Net loss was $35.0 million for the year ended December 31, 2025, compared to $58.2 million for the year ended December 31, 2024. The year-over-year decrease in net loss was primarily driven by increased collaboration and license revenue for the year ended December 31, 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 through the end of 2027.

This estimate excludes any potential future milestone payments, option-related fees or other contingent payments under Xilio's collaboration and partnership agreements with AbbVie and Gilead and excludes up to $36.2 million in additional gross proceeds in the second half of 2026 if all outstanding Series C warrants are exercised at their current exercise price.

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; the timing of clinical development, data releases, regulatory submissions, delivery of option data packages or other program updates; the promise or potential success of Xilio's programs, including the first-in-class potential of Xilio's masked T cell engager targeting PSMA and STEAP1, the best-in-class potential of XTX501 and the potential for XTX501 to be a foundational "backbone" therapy for combination treatment with other agents; 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 second half of 2026 if all of the 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, 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" 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 or partnership agreements with AbbVie, Gilead and Roche. 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.

Investor Contact
Alex Lobo, Precision AQ
alex.lobo@precisionaq.com

Media Contact
Josie Butler, 1AB
josie@1abmedia.com

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

	December 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 137,531	$ 55,291
Other assets	17,154	15,784
Total assets	$ 154,685	$ 71,075
Liabilities and Stockholders' Equity		
Liabilities		
Deferred revenue	$ 60,658	$ 32,780
Common stock warrant liabilities	29,560	—
Other liabilities	29,194	20,697

Total liabilities	$ 119,412	$ 53,477
Stockholders' equity	35,273	17,598
Total liabilities and stockholders' equity	$ 154,685	$ 71,075

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

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
License revenue	$ 13,686	$ 1,724	$ 43,766	$ 6,344
Operating expenses [2]				
Research and development	18,122	8,836	56,039	41,211
General and administrative	7,400	6,517	29,709	24,778
Restructuring	—	—	—	937
Total operating expenses	25,522	15,353	85,748	66,926
Loss from operations	(11,836)	(13,629)	(41,982)	(60,582)
Other income, net				
Change in fair value of common stock warrant liabilities	21,275	—	5,845	—
Other income, net	921	536	1,101	2,341
Total other income, net	22,196	536	6,946	2,341
Net income (loss) and comprehensive income (loss)	$ 10,360	$ (13,093)	$ (35,036)	$ (58,241)
Net income (loss) per share, basic	$ 0.96	$ (2.83)	$ (4.19)	$ (15.24)
Basic weighted average common shares outstanding [3]	10,836,526	4,619,701	8,359,109	3,822,244
Net income (loss) per share, diluted [4]	$ 0.81	$ (2.83)	$ (4.19)	$ (15.24)
Diluted weighted average common shares outstanding	12,826,346	4,619,701	8,359,109	3,822,244

(1) On March 13, 2026, the company effected a 1-for-14 reverse 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 December 31,		Years Ended December 31,	
	2025	2024	2025	2024
Research and development expense	$ 1,013	$ 377	$ 2,066	$ 1,652
General and administrative expense	1,916	1,139	4,873	4,782
Total stock-based compensation expense	$ 2,929	$ 1,516	$ 6,939	$ 6,434

(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, and excludes shares of restricted common stock that were not vested as of the applicable period.

(4) Diluted earnings per share is the same as basic earnings per share in periods where the company is in a net loss position.