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

May 12, 2026

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

Presented new preclinical data for XTX601, a potential first-in-class masked T cell engager targeting CLDN18.2, at the AACR annual meeting

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

Achieved development milestone under AbbVie collaboration and extended cash runway into early 2028

WALTHAM, Mass., May 12, 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 first quarter ended March 31, 2026.

"We ended the first quarter of 2026 with strong momentum across our pipeline of highly differentiated I-O therapies leveraging our best-in-class masking technology," said René Russo, Pharm.D., president and chief executive officer of Xilio. "XTX501 has the potential to be a foundational backbone therapy for combination regimens across a broad range of solid tumors, and we are on track to advance this program into the clinic this year. In addition, our recent data for our CLDN18.2 program presented at AACR further demonstrate the power of our masking technology to unlock the potential of T cell engagers. This progress, together with the recent achievement of another financial milestone under our AbbVie collaboration, highlights the productivity of our pipeline and underscores our ability to maximize the value of our clinically-validated masking technology."

Pipeline Progress and Business Updates

XTX501: bispecific PD-1 / masked IL-2

XTX501 is a novel bispecific PD-1 / masked IL-2 that has the potential to be a foundational "backbone" therapy for combination treatment with other agents. XTX501 is designed to selectively stimulate PD-1 positive, antigen-experienced T cells and enhance their function while overcoming 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 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 patients with metastatic non-small cell lung cancer in the second half of 2027, subject to clearance of the IND by the U.S. Food and Drug Administration.

Masked T Cell Engager Programs

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

Xilio's masked TCEs include a masked CD3 targeting domain and one or more tumor-associated antigen (TAA) binding domains (which may be masked) as part of the core molecule design. Depending on the desired properties that Xilio is seeking to achieve for a particular molecule, Xilio's modular architecture enables the ability to incorporate a co-stimulatory domain designed to further enhance potency and durability of T cell response, include multiple TAA binding domains and/or also mask the TAA binding domain(s) and/or co-stimulatory signaling domain. Upon tumor-selective activation, Xilio's TCE molecules are designed to release a potent, short half-life TCE in the tumor microenvironment.

- Xilio is advancing XTX601, a potential first-in-class masked TCE targeting CLDN18.2, a TAA expressed in gastrointestinal cancers (gastric, pancreatic and esophageal). In parallel, Xilio is leveraging its modular design architecture to evaluate designs that incorporate masking of the CLDN18.2 binding domain and/or the addition of a co-stimulatory domain. Xilio initiated IND-enabling activities for its CLDN18.2 program in the first quarter of 2026.
- In April 2026, Xilio presented new preclinical data for XTX601 at the American Association for Cancer Research (AACR) Annual Meeting demonstrating protease-dependent, tumor-selective activation and potent anti-tumor activity in multiple preclinical models. In addition, XTX601 was well-tolerated in non-human primates with a favorable therapeutic index. For more information, read the press release here.

- Xilio is also advancing a potential first-in-class multi-specific, masked TCE program targeting PSMA and STEAP1 with built-in co-stimulatory signaling. PSMA and STEAP1 are expressed in most prostate cancer tumors, and targeting both TAAs with a single molecule has the potential to address tumor heterogeneity while minimizing the potential for resistance due to antigen escape. Xilio anticipates initiating IND-enabling activities for its PSMA+STEAP1 program in the second quarter of 2026.
- Xilio plans to submit IND applications for its CLDN18.2 and PSMA+STEAP1 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

- Xilio strengthened its board of directors with the appointment of Cheryl R. Blanchard, Ph.D., a renowned biopharmaceutical leader, in April 2026. Dr. Blanchard brings more than 30 years of leadership experience to Xilio, with deep scientific, operational and commercial leadership in life science companies.
- In the second quarter of 2026, Xilio achieved a $6.0 million development milestone related to the masked antibody-based immunotherapy program under the company's collaboration, license and option agreement with AbbVie.

First Quarter 2026 Financial Results

- **Cash Position:** Cash and cash equivalents were $150.3 million as of March 31, 2026, compared to $137.5 million as of December 31, 2025. The increase was primarily driven by $37.3 million in net proceeds from a follow-on offering in February 2026.
- **Collaboration and License Revenue:** Collaboration and license revenue was $12.6 million for the quarter ended March 31, 2026, compared to $2.9 million for the quarter ended March 31, 2025. The increase was primarily driven by an increase in collaboration and license revenue recognized under the collaboration and license agreements with AbbVie and Gilead.
- **Research & Development (R&D) Expenses:** R&D expenses were $19.8 million for the quarter ended March 31, 2026, compared to $8.3 million for the quarter ended March 31, 2025. The increase was primarily driven by manufacturing activities related to IND-enabling studies and preclinical development activities for XTX501, increased costs related to masked TCE programs and indirect research and development, increased clinical development activities related to efarindodekin alfa and increased personnel-related costs.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.9 million for the quarter ended March 31, 2026, compared to $8.5 million for the quarter ended March 31, 2025. The decrease was primarily driven by a decrease in professional and consulting fees, including legal fees and other professional costs and a decrease in personnel-related costs.
- **Net Loss:** Net loss was $9.5 million for the quarter ended March 31, 2026, compared to a net loss of $13.3 million for the quarter ended March 31, 2025.

Cash Runway

Based on its current operating plans, Xilio anticipates that its cash and cash equivalents as of March 31, 2026, together with the development milestone achieved under the AbbVie collaboration in the second quarter of 2026, will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into early 2028.

This estimate excludes any potential additional milestone payments, option-related fees or other contingent payments under Xilio's collaboration and license 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.

Xilio has the potential to achieve up to $31.0 million in additional near-term milestones and option extension fees under the existing 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; 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 best-in-class potential of XTX501 and the potential for XTX501 to be a foundational "backbone" therapy for combination treatment with other agents and the first-in-class potential of Xilio's masked TCE programs targeting CLDN18.2 and PSMA+STEAP1; 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 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 Annual Report on Form 10-K 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)

	March 31, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 150,333	$ 137,531
Other assets	13,154	17,154
Total assets	$ 163,487	$ 154,685
Liabilities and Stockholders' Equity		
Liabilities		
Deferred revenue	$ 48,010	$ 60,658
Common stock warrant liabilities	26,260	29,560
Other liabilities	16,672	29,194
Total liabilities	$ 90,942	$ 119,412
Stockholders' equity	72,545	35,273
Total liabilities and stockholders' equity	$ 163,487	$ 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 March 31,	
	2026	2025
Collaboration and license revenue	$ 12,648	$ 2,930
Operating expenses[2]		
Research and development	$ 19,832	$ 8,266
General and administrative	6,928	8,515
Total operating expenses	26,760	16,781
Loss from operations	(14,112)	(13,851)
Other income, net		
Change in fair value of common stock warrant liabilities	3,300	—
Other income, net	1,283	586
Total other income, net	4,583	586
Net loss and comprehensive loss	$ (9,529)	$ (13,265)
Net loss per share, basic and diluted	$ (0.58)	$ (2.49)
Weighted average common shares outstanding, basic and diluted[3]	16,347,538	5,335,740

(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 March 31,	
	2026	2025
Research and development expense	$ 792	$ 389
General and administrative expense	1,419	1,146
Total stock-based compensation expense	$ 2,211	$ 1,535

(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.