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

August 12, 2026

Received FDA clearance of IND application for XTX501, a potential best-in-class bispecific PD-1 / masked IL-2

Advancing IND-enabling studies for potential first-in-class multi-specific, masked T cell engager programs targeting CLDN18.2 and PSMA+STEAP1; IND applications anticipated in the second half of 2027

Cash runway into the first quarter of 2028 expected to support key milestones across pipeline of next generation multi-specific I-O therapies

WALTHAM, Mass., Aug. 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 second quarter ended June 30, 2026.

“In the second quarter, we remained focused on disciplined execution across our pipeline as we continued to advance our next generation of masked immuno-oncology therapies toward the clinic. Today, we are excited to announce FDA clearance of our IND for XTX501, a bispecific PD-1 / masked IL-2 that we believe has the potential to become a foundational backbone therapy for solid tumors,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “At the same time, we are advancing IND-enabling studies for our multi-specific, masked T cell engagers targeting CLDN18.2 and PSMA+STEAP1. Together, these programs highlight the potential to leverage our masking technology to unlock the next generation of sophisticated, multi-specific I-O therapies for people living with cancer.”

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 solid tumors, including in combination 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.

- Xilio received clearance from the U.S. Food and Drug Administration (FDA) for the company’s investigational new drug application (IND) to proceed to a Phase 1/2 clinical trial for XTX501.
- Xilio expects to initiate dosing in the Phase 1 portion of the trial in patients with metastatic non-small cell lung cancer (NSCLC) and select advanced solid tumors in the second half of 2026. Xilio plans to report initial Phase 1 data in patients with metastatic NSCLC in the second half of 2027.

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).

The company’s masked TCEs are designed with a masked CD3 targeting domain and one or more tumor-associated antigen (TAA) binding domains as part of the core molecule design. In addition, the company’s modular architecture enables the incorporation of a co-stimulatory domain designed to further enhance potency and durability of T cell response, as well as the potential to mask the TAA binding domain(s) and/or mask the 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 IND-enabling studies for a potential first-in-class masked TCE program targeting CLDN18.2 and a potential first-in-class multi-specific, masked TCE program targeting PSMA and STEAP1 with built-in co-stimulatory signaling. CLDN18.2 is a TAA expressed in gastrointestinal cancers (gastric, pancreatic and esophageal), and PSMA and STEAP1 are TAAs expressed in prostate cancer.
- Xilio plans to submit INDs for its CLDN18.2 and PSMA+STEAP1 programs in the second half 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 Ben Harshbarger as its chief legal officer in June 2026. Ben has over 20 years of executive leadership and legal expertise within the biopharmaceutical industry. Read more here.

Second Quarter 2026 Financial Results

- **Cash Position:** Cash and cash equivalents were $136.0 million as of June 30, 2026, compared to $137.5 million as of December 31, 2025.
- **Collaboration and License Revenue:** Collaboration and license revenue was $18.7 million for the quarter ended June 30, 2026, compared to $8.1 million for the quarter ended June 30, 2025. The increase was 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 $14.6 million for the quarter ended June 30, 2026, compared to $15.3 million for the quarter ended June 30, 2025. The decrease was primarily driven by decreased clinical development activities related to vilastobart and decreased manufacturing activities for XTX501, partially offset by increased costs related to masked TCE programs and indirect research and development and increased personnel-related costs.
- **General & Administrative (G&A) Expenses:** G&A expenses were $7.6 million for the quarter ended June 30, 2026, compared to $7.1 million for the quarter ended June 30, 2025. The increase was primarily driven by an increase in personnel-related costs.
- **Net Loss:** Net loss was $6.4 million for the quarter ended June 30, 2026, compared to a net loss of $15.8 million for the quarter ended June 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 second half 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 XTX501 and the Phase 1/2 Clinical Trial

XTX501 is an investigational bispecific PD-1 / masked IL-2 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. Xilio is evaluating the safety and tolerability of XTX501 as a monotherapy in patients with metastatic non-small cell lung cancer (NSCLC) and select advanced solid tumors in the Phase 1 portion of a first-in-human, multi-center, open-label Phase 1/2 clinical trial at multiple sites in the United States. Please refer to NCT07688577 on www.clinicaltrials.gov for additional details.

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 solid tumors 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 (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" 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)

	June 30, 2026	December 31, 2025
Assets		
Cash and cash equivalents	$ 136,040	$ 137,531
Other assets	18,214	17,154
Total assets	$ 154,254	$ 154,685
Liabilities and Stockholders' Equity		
Liabilities		
Deferred revenue	$ 35,318	$ 60,658
Common stock warrant liabilities	30,200	29,560
Other liabilities	16,472	29,194
Total liabilities	$ 81,990	$ 119,412
Stockholders' equity	72,264	35,273
Total liabilities and stockholders' equity	$ 154,254	$ 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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Collaboration and license revenue	$ 18,692	$ 8,084	$ 31,340	$ 11,014
Operating expenses[2]				
Research and development	$ 14,559	$ 15,330	$ 34,391	$ 23,596
General and administrative	7,624	7,120	14,552	15,635
Total operating expenses	22,183	22,450	48,943	39,231
Loss from operations	(3,491)	(14,366)	(17,603)	(28,217)
Other income (expense), net				
Change in fair value of common stock warrant liabilities	(3,940)	(50)	(640)	(50)

Other income (expense), net	1,058	(1,428)	2,341	(842)
Total other income (expense), net	(2,882)	(1,478)	1,701	(892)
Net loss and comprehensive loss	$ (6,373)	$ (15,844)	$ (15,902)	$ (29,109)
Net loss per share, basic and diluted	$ (0.33)	(2.30)	$ (0.89)	$ (4.76)
Weighted average common shares outstanding, basic and diluted[3]	19,404,688	6,889,119	17,884,542	6,116,721

(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 June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Research and development	$ 524	$ 346	$ 1,316	$ 735
General and administrative	1,074	1,005	2,493	2,151
Total stock-based compensation expense	$ 1,598	$ 1,351	$ 3,809	$ 2,886

(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.