Xilio Therapeutics Announces Pipeline and Business Updates and Second Quarter 2025 Financial Results

August 14, 2025

Announced updated Phase 2 data at ASCO for vilastobart, a tumor-activated, Fc-enhanced, anti-CTLA-4, demonstrating deep and durable responses and a meaningfully differentiated safety and tolerability profile for an anti-CTLA-4 combination therapy

On track with plans to nominate first development candidates for wholly owned masked T cell engager programs in second half of 2025

$121.6 million in cash and cash equivalents as of June 30, 2025, with anticipated cash runway through end of third quarter of 2026

WALTHAM, Mass., Aug. 14, 2025 (GLOBE NEWSWIRE) -- Xilio Therapeutics, Inc. (Nasdaq: XLO), a clinical-stage biotechnology company discovering and developing tumor-activated 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, 2025.

“During the second quarter, we continued to make strong progress across our pipeline of novel tumor-activated immuno-oncology therapies, and with our recent financing, we believe that we are well-positioned to execute on our strategic goals,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “We believe our masked T cell engager molecules have the potential to be best-in-class, and we anticipate nominating our first development candidates for our wholly owned programs later this year. In addition, we are very encouraged by the clinical progress for XTX301, our tumor-activated IL-12 advancing in partnership with Gilead, and we look forward to providing a program update in the near-term. We also recently reported updated Phase 2 combination data for vilastobart at ASCO and believe these data not only highlight the significant opportunity for vilastobart across a range of I-O combinations and tumor types, but also provide further clinical validation for our proprietary masking technology and approach.”

Pipeline and Business Updates

Vilastobart: tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4

Vilastobart is an investigational tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4 monoclonal antibody designed to block CTLA-4 and deplete regulatory T cells when activated in the tumor microenvironment (TME). Vilastobart is currently being evaluated in combination with atezolizumab (Tecentriq®) in Phase 1C combination dose escalation in patients with advanced solid tumors and in a Phase 2 clinical trial in patients with metastatic microsatellite stable (MSS) colorectal cancer (CRC).

- In May 2025, Xilio announced promising updated Phase 2 data for vilastobart in combination with atezolizumab in patients with metastatic MSS CRC at the American Society of Clinical Oncology (ASCO) Annual Meeting. These data demonstrated a preliminary 26% objective response rate in heavily pre-treated metastatic MSS CRC patients without liver metastases, including deep and durable responses accompanied by substantial decreases in tumor biomarkers and improvements in clinical symptoms, as well as a differentiated and well-tolerated safety profile with a low incidence of colitis and other immune-related adverse events, which have historically limited the potential for anti-CTLA-4 therapies. For more information, read the press release here. Xilio anticipates reporting additional data from the Phase 2 trial in the first half of 2026.

- Based on the encouraging clinical data to date, Xilio believes vilastobart has the potential to be an I-O combination agent of choice and be combined with a range of existing and next-generation agents. Xilio continues to engage strategic partners on potential opportunities to accelerate and expand further development for vilastobart.

XTX301: tumor-activated IL-12

XTX301 is an investigational tumor-activated IL-12 designed to potently stimulate anti-tumor immunity and reprogram the TME of poorly immunogenic “cold” tumors towards an inflamed or “hot” state. In March 2024, Xilio entered into an exclusive license agreement with Gilead Sciences, Inc. (Gilead) related to Xilio’s tumor-activated IL-12 program, including XTX301. Xilio is evaluating XTX301 as a monotherapy in an ongoing Phase 1 clinical trial in patients with advanced solid tumors.

- Xilio recently completed enrollment in Phase 1A monotherapy dose escalation and evaluation of those patients is ongoing. In addition, Xilio continues to enroll patients in Phase 1B monotherapy dose expansion of the ongoing Phase 1 clinical trial of XTX301.

XTX501: masked PD-1/IL-2 bispecific

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

- Xilio is continuing to advance XTX501 in investigational new drug (IND)-enabling studies and plans to submit an IND application for XTX501 in the middle of 2026.

Masked T Cell Engager Programs

Xilio is leveraging its proprietary, clinically validated tumor-activation platform to advance multiple preclinical programs for masked T cell engagers, including wholly owned programs targeting the tumor-associated antigens for PSMA, CLDN18.2 and STEAP1 and an additional program in collaboration with AbbVie.

Xilio's masked T cell engager programs include bispecific molecules designed using its advanced tumor-activated cell engager (ATACR) format, which consists of a T cell engager with a masked CD3 targeting domain, and tri-specific molecules designed using its selective effector-enhanced cell engager (SEECR) format. The SEECR format builds upon the ATACR format by adding co-stimulatory signaling designed to further enhance potency and T cell activation.

- Xilio anticipates nominating development candidates for its PSMA program (ATACR format), CLDN18.2 program (ATACR format) and STEAP1 program (SEECR format) in the third quarter of 2025, fourth quarter of 2025 and first half of 2026, respectively.

- Xilio anticipates advancing at least two of these programs into initial IND-enabling studies and submitting IND applications for those programs in 2027.

Corporate Updates

- In June 2025, Xilio closed a follow-on public offering of prefunded warrants and accompanying common stock warrants and received initial gross proceeds of approximately $50.0 million before deducting underwriting discounts and commissions and offering expenses. In connection with the offering, Xilio issued Series B and Series C common stock warrants and will receive up to $100.0 million of additional gross proceeds by the second half of 2026 if all of those warrants are exercised in cash at their initial exercise price of $0.75 per warrant. The financing was co-led by new investors Coastlands Capital and Frazier Life Sciences and included participation from Gilead Sciences, Inc., Logos Capital, Samsara BioCapital and other new and existing institutional investors. For more information, read the press release here.

- In June 2025, Xilio announced the appointment of Akintunde (Tunde) Bello, Ph.D., to the company's board of directors. For more information, read the press release here.

Second Quarter 2025 Financial Results

- **Cash Position:** Cash and cash equivalents were $121.6 million as of June 30, 2025, compared to $55.3 million as of December 31, 2024. In the second quarter of 2025, Xilio received $47.0 million in net proceeds from its June 2025 follow-on public offering after deducting underwriting discounts and commissions and offering expenses payable by the company.

- **Collaboration and License Revenue:** Collaboration and license revenue was $8.1 million for the quarter ended June 30, 2025, compared to $2.4 million for the quarter ended June 30, 2024. Collaboration and license revenue for the quarter ended June 30, 2025 consisted of revenue recognized in connection with Xilio's collaborations with AbbVie and Gilead, and collaboration and license revenue for the quarter ended June 30, 2024 consisted of revenue recognized in connection with Xilio's collaboration with Gilead.

- **Research & Development (R&D) Expenses:** R&D expenses were $15.3 million for the quarter ended June 30, 2025, compared to $11.2 million for the quarter ended June 30, 2024. The increase was primarily driven by increased clinical development activities related to vilastobart, increased costs related to early-stage programs and indirect research and development and increased personnel-related costs, which were partially offset by decreased costs related to clinical development activities for XTX202, a tumor-activated IL-2, as a result of discontinuing further investment in that program. For the quarter ended June 30, 2025, R&D expenses also included manufacturing activities related to IND-enabling studies and preclinical development activities for XTX501, which were not separately tracked for the quarter ended June 30, 2024

as the company had not yet begun performing IND-enabling studies. For the quarter ended June 30, 2024, R&D expenses also included a $1.0 million development milestone under the CTLA-4 monoclonal antibody license agreement with WuXi Biologics (Hong Kong) Limited for which there was no comparable cost for the quarter ended June 30, 2025.

- **General & Administrative (G&A) Expenses:** G&A expenses were $7.1 million for the quarter ended June 30, 2025, compared to $5.8 million for the quarter ended June 30, 2024. The 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 Loss:** Net loss was $15.8 million for the quarter ended June 30, 2025, compared to $13.9 million for the quarter ended June 30, 2024.

Financial Guidance

Based on its current operating plans, Xilio anticipates that its cash and cash equivalents as of June 30, 2025 will be sufficient to enable it to fund its operating expenses and capital expenditure requirements through the end of the third quarter of 2026.

About Vilastobart

Vilastobart is an investigational tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4 monoclonal antibody designed to block CTLA-4 and deplete regulatory T cells when activated in the tumor microenvironment (TME). In 2023, Xilio entered into a co-funded clinical trial collaboration with Roche to evaluate vilastobart in combination with atezolizumab (Tecentriq®) in a multi-center, open-label Phase 1/2 clinical trial. Xilio is currently evaluating the safety and tolerability of the combination in Phase 1C dose escalation in patients with advanced solid tumors and the safety and efficacy of the combination in Phase 2 in patients with metastatic microsatellite stable colorectal cancer with and without liver metastases. Please refer to NCT04896697 on www.clinicaltrials.gov for additional details.

About XTX301

XTX301 is an investigational tumor-activated IL-12 designed to potently stimulate anti-tumor immunity and reprogram the tumor microenvironment (TME) of poorly immunogenic "cold" tumors towards an inflamed or "hot" state. In March 2024, Xilio entered into an exclusive license agreement with Gilead Sciences, Inc. for Xilio's tumor-activated IL-12 program, including XTX301. Xilio is evaluating the safety and tolerability of XTX301 as a monotherapy in patients with advanced solid tumors in the Phase 1 portion of a first-in-human, multi-center, open-label Phase 1/2 clinical trial. Please refer to NCT05684965 on www.clinicaltrials.gov for additional details.

About Xilio Therapeutics

Xilio Therapeutics is a clinical-stage biotechnology company discovering and developing tumor-activated, or 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. The company is leveraging its proprietary platform to advance a pipeline of novel, tumor-activated I-O molecules that are designed to optimize the therapeutic index by localizing anti-tumor activity within the tumor microenvironment. 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 data releases or program updates; the timing and potential receipt of cash proceeds upon the exercise of common stock warrants issued in connection with the June 2025 follow-on public offering; the receipt of future contingent payments under Xilio's collaboration or partnership agreements with AbbVie or Gilead; the ability to partner vilastobart and expand and accelerate further development; the potential benefits of any of Xilio's current or future product candidates in any indication; the sufficiency of, and the period in which Xilio expects to have, cash to fund its operations, capital expenditure requirements, and development plans and milestones; 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; Xilio's ability to advance multiple early stage masked T cell engager programs; initial, preliminary or interim 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 tumor-activated 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.

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

	June 30, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 121,551	$ 55,291
Other assets	12,262	15,784
Total assets	$ 133,813	$ 71,075
Liabilities and Stockholders' Equity		
Liabilities		
Deferred revenue	$ 70,910	$ 32,780
Common stock warrant liabilities	38,550	—
Other liabilities	17,284	20,697
Total liabilities	$ 126,744	$ 53,477
Stockholders' equity	7,069	17,598
Total liabilities and stockholders' equity	$ 133,813	$ 71,075

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Collaboration and license revenue	$ 8,084	$ 2,357	$ 11,014	$ 2,357
Operating expenses [1]				
Research and development	$ 15,330	$ 11,216	$ 23,596	$ 21,616
General and administrative	7,120	5,815	15,635	11,954
Restructuring	—	30	—	978
Total operating expenses	22,450	17,061	39,231	34,548
Loss from operations	(14,366)	(14,704)	(28,217)	(32,191)
Other income (expense), net				
Change in fair value of common stock warrant liabilities	(50)	—	(50)	—
Other income (expense), net	(1,428)	779	(842)	1,063
Total other income (expense), net	(1,478)	779	(892)	1,063
Net loss and comprehensive loss	$ (15,844)	$ (13,925)	$ (29,109)	$ (31,128)
Net loss per share, basic and diluted	$ (0.16)	(0.24)	$ (0.34)	$ (0.73)
Weighted average common shares outstanding, basic and diluted [2]	96,447,672	57,760,178	85,634,094	42,836,381

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development expense	$ 346	$ 385	$ 735	$ 891
General and administrative expense	1,005	1,126	2,151	2,453
Total stock-based compensation expense	$ 1,351	$ 1,511	$ 2,886	$ 3,344

(2) Weighted average common shares outstanding, basic and diluted, includes prefunded warrants to purchase common stock issued in connection with (i) the company's private placements with certain existing investors and Gilead and (ii) the company's June 2025 follow-on public offering, as the prefunded warrants are exercisable at any time for nominal cash consideration.