Xilio Therapeutics Announces Pipeline and Business Updates and Second Quarter 2024 Financial Results

August 8, 2024

Initiated enrollment in Phase 2 clinical trial of XTX101, a tumor-activated, Fc-enhanced anti-CTLA-4, in combination with atezolizumab in patients with microsatellite stable colorectal cancer (MSS CRC)

Initiated enrollment in Phase 1B monotherapy dose expansion for XTX301, a tumor-activated IL-12, in patients with advanced solid tumors; Phase 1A monotherapy dose escalation ongoing with no dose-limiting toxicities observed to date

Expect to report clinical data for XTX101 and XTX301 in the fourth quarter of 2024

Ended second quarter of 2024 with $74.9 million in cash and cash equivalents and continue to anticipate cash runway into the second quarter of 2025

WALTHAM, Mass., Aug. 08, 2024 (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, 2024.

“This quarter, we continued to make meaningful progress advancing our clinical-stage pipeline toward key data milestones and potential value drivers anticipated later this year,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “We recently initiated enrollment in our Phase 2 trial of XTX101 in combination with atezolizumab in patients with MSS CRC and our Phase 1 monotherapy dose expansion for XTX301 in patients with advanced solid tumors, and we look forward to reporting clinical data for each of these programs in the fourth quarter. Beyond our clinical-stage pipeline, we are also advancing multiple research-stage programs leveraging our tumor-activated approach for masked immune cell engagers.”

Dr. Russo continued, “I am excited to announce the promotion of Chris Frankenfield to chief financial officer of Xilio. Chris’ strategic, financial and operational expertise, together with his collaborative approach and experience building companies, will be instrumental in advancing our pipeline of novel tumor-activated immuno-oncology therapies.”

Pipeline and Business Updates

XTX101: tumor-activated anti-CTLA-4

XTX101 is an investigational tumor-activated, Fc-enhanced, high affinity binding anti-CTLA-4 designed to block CTLA-4 and deplete regulatory T cells when activated (unmasked) in the tumor microenvironment (TME).

- Xilio today announced the initiation of enrollment in its Phase 2 clinical trial of XTX101 in combination with atezolizumab in patients with MSS CRC, including patients with and without liver metastases. The trial will evaluate the safety and efficacy of XTX101 at 100 mg every six weeks (Q6W) in combination with atezolizumab at 1200 mg every three weeks (Q3W).
- Xilio expects to report initial Phase 2 data for XTX101 in combination with atezolizumab in approximately 20 patients with MSS CRC in the fourth quarter of 2024 and in approximately 20 additional patients (40 patients total) in the first quarter of 2025.

XTX301: tumor-activated, engineered IL-12

XTX301 is an investigational tumor-activated, engineered IL-12 molecule designed to potently stimulate anti-tumor immunity and reprogram the TME of poorly immunogenic “cold” tumors towards an inflamed, or “hot,” state.

- Xilio today announced the initiation of enrollment in Phase 1B monotherapy dose expansion of its ongoing Phase 1 clinical trial of XTX301 in patients with advanced solid tumors. In addition, enrollment in monotherapy dose escalation for XTX301 is ongoing, with XTX301 currently being evaluated at a dose level of 60 ug/kg Q6W (preceded by a single priming dose of 15 ug/kg). To date, XTX301 has been generally well-tolerated, with no dose-limiting toxicities observed in patients.
- Xilio expects to report safety, pharmacokinetic and pharmacodynamic data from the ongoing Phase 1 clinical trial for XTX301 in the fourth quarter of 2024.

Tumor-activated bispecific and immune cell engager programs

- Xilio is advancing a pipeline of research-stage tumor-activated bispecifics and immune cell engagers, including tumor-activated cell engagers and tumor-activated effector-enhanced cell engagers, leveraging the company’s masking technology.

Corporate Updates

- Xilio today announced the promotion of Chris Frankenfield to chief financial officer. Mr. Frankenfield will also continue to serve in his current role as chief operating officer.
- In June 2024, Xilio announced the appointments of Aoife Brennan, M.D., and James Shannon, M.D., to its board of directors.

Second Quarter 2024 Financial Results

- **Cash Position:** Cash and cash equivalents were $74.9 million as of June 30, 2024, compared to $44.7 million as of December 31, 2023. Cash and cash equivalents as of June 30, 2024 included the $30.0 million upfront payment under the company's license agreement with Gilead Sciences, Inc. (Gilead) for XTX301, approximately $28.1 million in gross proceeds from the sale and issuance of common stock and prefunded warrants to certain existing accredited investors and Gilead in private placements and $7.0 million in gross proceeds from the sale and issuance of common stock under the company's at-the-market offering program.
- **License Revenue:** License revenue was $2.4 million for the quarter ended June 30, 2024, which was associated with revenue recognized under the license agreement and stock purchase agreement with Gilead. No license revenue was recognized prior to the quarter ended June 30, 2024.
- **Research & Development (R&D) Expenses:** R&D expenses were $11.2 million for the quarter ended June 30, 2024, compared to $13.2 million for the quarter ended June 30, 2023. The decrease was primarily driven by decreased manufacturing activities for XTX301, decreased clinical development activities for XTX202, decreased spending related to early-stage programs and indirect research and development costs and decreased personnel-related costs, partially offset by a $1.0 million development milestone payment to WuXi Biologics (Hong Kong) Limited under the company's CTLA-4 monoclonal antibody license agreement, and increased clinical development activities for XTX101 and XTX301.
- **General & Administrative (G&A) Expenses:** G&A expenses were $5.8 million for the quarter ended June 30, 2024, compared to $6.9 million for the quarter ended June 30, 2023. The decrease was primarily driven by decreased personnel-related costs, decreased professional and consulting fees, lower costs related to directors' and officers' liability insurance and a reduction in other general and administrative expenses.
- **Net Loss:** Net loss was $13.9 million for the quarter ended June 30, 2024, compared to $19.4 million for the quarter ended June 30, 2023.

Financial Guidance

Based on its current operating plans, Xilio anticipates that its existing cash and cash equivalents as of June 30, 2024 will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2025.

About XTX101 (anti-CTLA-4) and the Phase 1/2 Combination Clinical Trial

XTX101 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 (unmasked) in the tumor microenvironment. In the third quarter of 2023, Xilio entered into a co-funded clinical trial collaboration with Roche to evaluate XTX101 in combination with atezolizumab (Tecentriq®) in a multi-center, open-label Phase 1/2 clinical trial. Xilio is currently evaluating the safety and efficacy of the combination in a Phase 2 clinical trial in patients with microsatellite stable colorectal cancer. Please refer to NCT04896697 on www.clinicaltrials.gov for additional details.

About XTX301 (IL-12) and the Phase 1 Clinical Trial

XTX301 is an investigational tumor-activated IL-12 designed to potently stimulate anti-tumor immunity and reprogram the tumor microenvironment 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 currently evaluating the safety and tolerability of XTX301 as a monotherapy in patients with advanced solid tumors in a first-in-human, multi-center, open-label Phase 1 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 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 using its proprietary platform to advance a pipeline of novel, tumor-activated clinical and preclinical I-O molecules that are designed to optimize the therapeutic index by localizing anti-tumor activity within the tumor microenvironment, including tumor-activated cytokines and antibodies (including bispecifics) and immune cell engagers (including tumor-activated cell engagers and tumor-activated effector-enhanced cell engagers). Learn more by visiting http://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 and anticipated milestones for XTX101 and XTX301, including plans and timing for reporting clinical data for each of these programs; the potential for Xilio to leverage its research platform to develop masked immune cell engager molecules; the potential benefits of any of Xilio's current or future product candidates in treating patients as a monotherapy or combination therapy; Xilio's estimated cash and cash equivalents and the period in which Xilio expects to have cash to fund its operations; 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, general market conditions; 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 advancement of multiple early-stage immune cell engager programs, including tumor-activated cell engagers and tumor-activated effector-enhanced cell engagers; interim or preliminary preclinical or clinical data or results, which 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, which may not support further development of such product candidates; actions of regulatory agencies, which 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 ability to obtain and maintain sufficient cash resources to fund its operations; the impact of international trade policies on Xilio’s business, including U.S. and China trade policies; Xilio’s ability to maintain its clinical trial collaboration with Roche to develop XTX101 in combination with atezolizumab; and Xilio’s ability to maintain its license agreement with Gilead to develop and commercialize XTX301. 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, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 74,949	$ 44,704
Other assets	14,924	16,222
Total assets	89,873	60,926
Liabilities and Stockholders’ Equity		
Liabilities		
Deferred revenue	36,767	—
Other liabilities	19,690	24,099
Total liabilities	56,457	24,099
Stockholders’ equity	33,416	36,827
Total liabilities and stockholders’ equity	89,873	60,926

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,	
	2024	2023	2024	2023
License revenue	$ 2,357	$ —	$ 2,357	$ —
Operating expenses [1]				
Research and development	11,216	13,218	21,616	29,349
General and administrative	5,815	6,898	11,954	14,293
Restructuring	30	—	978	—
Total operating expenses	17,061	20,116	34,548	43,462
Loss from operations	(14,704)	(20,116)	(32,191)	(43,642)
Other income, net	779	761	1,063	1,641
Net loss and comprehensive loss	$ (13,925)	$ (19,355)	$ (31,128)	$ (42,001)
Net loss per share, basic and diluted	$ (0.24)	$ (0.70)	$ (0.73)	$ (1.53)
Weighted average common shares outstanding, basic and diluted	57,760,178	27,468,668	42,836,381	27,451,058

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development expense	$ 385	$ 549	$ 891	$ 1,122
General and administrative expense	1,126	1,251	2,453	2,469
Total stock-based compensation expense	$ 1,511	$ 1,800	$ 3,344	$ 3,591