Xilio Therapeutics Reports Pipeline and Business Highlights and First Quarter 2022 Financial Results

May 12, 2022

Clinical programs for XTX202, a tumor-selective IL-2, and XTX101, a tumor-selective anti-CTLA-4, continue to advance with preliminary data anticipated in 2022

On track with plans to submit IND for XTX301, a tumor-selective IL-12, in second half of 2022

Strong financial position with $177 million in cash and cash equivalents as of March 31, 2022, with cash runway anticipated into first half of 2024

WALTHAM, Mass., May 12, 2022 (GLOBE NEWSWIRE) -- Xilio Therapeutics, Inc. (Nasdaq: XLO), a biotechnology company developing tumor-selective immuno-oncology therapies for people living with cancer, today announced pipeline and business highlights and reported financial results for the first quarter ended March 31, 2022.

“Leveraging our geographically precise solutions (GPS) platform, we are developing a pipeline of tumor-selective immunotherapies that have the potential to achieve meaningful anti-tumor activity while minimizing serious, systemic effects,” said René Russo, Pharm.D., president and chief executive officer of Xilio. “We continue to progress enrollment in our Phase 1 clinical programs, XTX101 and XTX202, with planned preliminary data readouts later this year, and we remain on track with our plans to submit an IND application for XTX301 in the second half of 2022. With our strong financial position and an outstanding team in place, we believe we are well-positioned to advance our pipeline of tumor-selective immuno-oncology programs with the goal of transforming the lives of people living with cancer.”

Pipeline and Business Progress

Cytokine Programs

- Enrollment is ongoing in the Phase 1 clinical trial evaluating XTX202 for the treatment of patients with solid tumors, with preliminary data anticipated to be reported in the second half of 2022. XTX202 is a tumor-selective interleukin-2 (IL-2) designed to localize activity in the tumor microenvironment, with the goal of overcoming the known tolerability challenges of existing IL-2 therapies while achieving enhanced anti-tumor activity as monotherapy and in combination with standard of care agents.
- Preclinical data from the XTX301 program was presented at the New York Academy of Sciences Frontiers in Cancer Immunotherapy 2022 conference on May 10, 2022. XTX301 demonstrated tumor-selective activation in patient-derived tumor explants, and a murine surrogate of XTX301 (mXTX301) induced significant tumor growth inhibition in a mouse model and improved tolerability compared to a non-tumor-selective version of mXTX301. View the poster online here.
- Xilio continues to anticipate submitting an investigational new drug application (IND) for XTX301, a tumor-selective interleukin-12 (IL-12), in the second half of 2022 for evaluation in patients with solid tumors.

Upcoming Presentations

- A trials-in-progress poster outlining details of the ongoing Phase 1/2 clinical trial for XTX202 will be presented at the American Society of Clinical Oncology (ASCO) 2022 Annual Meeting:

  Presentation title: A first-in-human, multicenter, phase 1/2, open-label study of XTX202, a masked and tumor-selective recombinant human interleukin-2 (IL-2) protein, in patients with advanced solid tumors
  Session date and time: Sunday, June 5, 2022, 8:00-11:00 AM CDT
  Abstract number: TPS2697

Checkpoint Inhibitor Program

- Enrollment is ongoing in the Phase 1 clinical trial evaluating XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody, as a monotherapy and in combination with pembrolizumab, an anti-PD-1, for the treatment of patients with advanced solid tumors.
- Preliminary data for the Phase 1 clinical trial for XTX101 is anticipated to be reported from the monotherapy cohort in the middle of 2022 and from the combination cohort in the second half of 2022.

First Quarter 2022 Financial Results

- **Cash Position:** Cash and cash equivalents were $177.0 million as of March 31, 2022, as compared to $198.1 million as of December 31, 2021. The decrease was primarily driven by cash used in operations for the three months ended March 31, 2022.
- **Research & Development (R&D) Expenses:** R&D expenses were $14.9 million for the first quarter of 2022, compared to $11.6 million for the first quarter of 2021. The increase was primarily driven by increased costs associated with XTX301 and other preclinical programs, as well as higher personnel-related costs due to increased headcount.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.3 million for the first quarter of 2022, compared to $4.9 million for the first quarter of 2021. The increase was primarily driven by higher personnel-related costs due to increased headcount and other costs related to operating as a publicly traded company.
- **Net Loss:** Net loss was $21.4 million for the first quarter of 2022, compared to $16.7 million for the first quarter of 2021.

Financial Guidance

As a result of prioritization within the company's preclinical portfolio, Xilio now anticipates that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the first half of 2024.

About Xilio Therapeutics

Xilio Therapeutics is a clinical-stage biotechnology company focused on harnessing the immune system to achieve deep and durable clinical responses to improve the lives of patients with cancer. The company is using its proprietary geographically precise solutions (GPS) platform to rapidly engineer novel molecules, including cytokines and other biologics, that are designed to optimize their therapeutic index. These molecules are designed to localize activity within the tumor microenvironment without systemic effect, resulting in the potential to achieve enhanced anti-tumor activity. Xilio is building a pipeline of wholly owned, tumor-selective, GPS-enabled cytokine and checkpoint inhibitor product candidates, including its clinical-stage programs, XTX101, a tumor-selective anti-CTLA-4 monoclonal antibody, and XTX202, a tumor-selective IL-2, as well as its earlier pipeline, including XTX301, a tumor-selective IL-12. For more information, please visit www.xiliotx.com and follow us on Twitter (@xiliotx) and 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 and timing related to reporting preliminary Phase 1 clinical data for XTX101 and XTX202 and the submission of an IND for XTX301; the potential benefits of any of Xilio's current or future product candidates in treating patients; Xilio's ability to fund its operating expenses and capital expenditure requirements with its existing cash and cash equivalents; 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," "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 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 programs; 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 current or future operating expenses and capital expenditure requirements; the impact of international trade policies on Xilio's business, including U.S. and China trade policies; and the impact of the COVID-19 pandemic on Xilio's business, operations, strategy, goals and anticipated milestones. 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, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 176,959	$ 198,053
Other assets	19,393	20,007
Total assets	$ 196,352	$ 218,060
Liabilities and Stockholders' Equity		
Liabilities	$ 30,231	$ 32,631
Stockholders' equity	166,121	185,429
Total liabilities and stockholders' equity	$ 196,352	$ 218,060

XILIO THERAPEUTICS, INC.

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

	Three Months Ended March 31,	
	2022	2021
Operating expenses [1]		
Research and development	$ 14,920	$ 11,621
General and administrative	6,304	4,899
Total operating expenses	21,224	16,520
Loss from operations	(21,224)	(16,520)
Other expense, net		
Other expense, net	(129)	(147)
Total other expense, net	(129)	(147)
Net loss and comprehensive loss	$ (21,353)	$ (16,667)
Net loss per share, basic and diluted	$ (0.78)	$ (23.53)
Weighted average common shares outstanding, basic and diluted	27,367,377	708,264

[1] Operating expenses include the following amounts of non-cash equity-based compensation expense:

	Three Months Ended March 31,	
	2022	2021
Research and development expense	$ 596	$ 135
General and administrative expense	1,433	659
Total equity-based compensation expense	$ 2,029	$ 794