UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **April 1, 2024**

Xilio Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-40925**	**85-1623397**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

828 Winter Street, Suite 300 **Waltham, Massachusetts** (Address of Principal Executive Offices)	**02451** (Zip Code)

Registrant's telephone number, including area code: **(857) 524-2466**

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**XLO**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On April 1, 2024, Xilio Therapeutics, Inc. (the "Company") announced its financial results for the quarter and year ended December 31, 2023 and other business highlights. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Current Report on Form 8-K, including Exhibit 99.1, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 2.02 of this Current Report on Form 8-K shall be deemed to be furnished and not filed:

Exhibit No.	Description
99.1	Press release issued by Xilio Therapeutics, Inc. on April 1, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

XILIO THERAPEUTICS, INC.

Date: April 1, 2024

By: /s/ Christopher Frankenfield
Christopher Frankenfield
Chief Operating Officer

Exhibit 99.1

Xilio Therapeutics Announces Pipeline and Business Updates and Fourth Quarter and Full Year 2023 Financial Results

On track with plans to initiate Phase 2 trial for XTX101, a tumor-activated, Fc-enhanced anti-CTLA-4, in combination with atezolizumab in patients with microsatellite stable colorectal cancer (MSS CRC) in the third quarter of 2024

Granted Gilead exclusive license to develop and commercialize XTX301, a tumor-activated IL-12

Anticipates cash runway into the second quarter of 2025

WALTHAM, Mass., April 1, 2024 -- 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 fourth quarter and full year ended December 31, 2023.

"With our recently announced partnership with Gilead for XTX301, our tumor-activated IL-12, and additional financing from existing investors, we believe we are well-positioned to continue to advance our differentiated pipeline of tumor-activated I-O therapies and achieve potential near-term clinical milestones and value-drivers," said René Russo, Pharm.D., president and chief executive officer of Xilio. "Looking ahead, we are focused on rapidly advancing clinical development for XTX301 and XTX101, our tumor-activated, Fc-enhanced anti-CTLA-4, with anticipated clinical data for each of these programs later this year, as well as continuing to leverage our novel research platform to design and develop tumor-activated bispecific and immune cell engager molecules."

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). XTX101 is currently being evaluated in combination with atezolizumab in an ongoing Phase 1 clinical trial in patients with advanced solid tumors.

Xilio today reaffirmed plans to:

- Select a recommended Phase 2 dose for XTX101 in combination with atezolizumab in the second quarter of 2024.
- Subject to the results of the Phase 1 combination dose escalation portion of the trial, initiate the Phase 2 portion of the trial for XTX101 in combination with atezolizumab in patients with microsatellite stable colorectal cancer (MSS CRC) in the third quarter of 2024.
- 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.

In March 2024, Xilio and Gilead Sciences, Inc. (Gilead) announced an exclusive license agreement for Xilio's tumor-activated IL-12 program, including XTX301. Under the terms of the agreement:

- Xilio is eligible to receive $43.5 million in upfront payments, including a cash payment of $30.0 million and an initial equity investment by Gilead of approximately $13.5 million in Xilio common stock. The initial equity investment closed on March 28, 2024, and the $30.0 million upfront cash payment is payable by Gilead within a specified time period promptly following signing of the license agreement.
- Xilio will be eligible to receive up to $604.0 million in additional contingent payments, including proceeds from up to three additional equity investments by Gilead, a $75.0 million transition fee and specified development, regulatory and sales-based milestones. Xilio will also be eligible to receive tiered royalties ranging from high single digits to mid-teens on annual global net product sales.
- Prior to the potential transition fee, Xilio is eligible to receive up to a total of $29.0 million in additional equity investments and a development milestone payment.
- Xilio will be responsible for conducting clinical development for XTX301 in the ongoing Phase 1 clinical trial through dose expansion. Following the delivery by Xilio of a specified clinical data package for XTX301, Gilead can elect to transition responsibilities for the development and commercialization of XTX301 to Gilead, subject to the terms of the agreement and payment by Gilead of the $75.0 million transition fee. If Gilead elects not to transition responsibilities for development and commercialization of the licensed products and pay the transition fee, then the license agreement will automatically terminate.

For more information, read the press release here.

XTX301 is currently being evaluated in Phase 1 dose escalation in patients with advanced solid tumors.

- In January 2024, Xilio reported encouraging preliminary safety data into the third dose level in the ongoing Phase 1 clinical trial. As of the data cutoff date of January 5, 2024, XTX301 had been administered at doses up to 45 ug/kg, which is nearly 100 times the maximum tolerated dose of recombinant human IL-12, and was generally well-tolerated with no dose-limiting toxicities observed.
- Xilio today reaffirmed plans to report Phase 1 safety, pharmacokinetic and pharmacodynamic data for XTX301 in patients with advanced solid tumors in the fourth quarter of 2024.

XTX202: tumor-activated, engineered IL-2

XTX202 is an investigational tumor-activated, beta-gamma biased IL-2 designed to potently stimulate CD8+ effector T cells and natural killer (NK) cells without concomitant stimulation of regulatory T cells when activated (unmasked) in the tumor microenvironment.

- In March 2024, Xilio announced additional data from its Phase 2 clinical trial evaluating XTX202 in patients with metastatic renal cell carcinoma or unresectable or metastatic melanoma. For more information, read the press release here.
- Together with previously reported data, Xilio believes these additional data further validate the company's tumor-activated approach and support the broad potential for XTX202 as a combination therapy. Xilio plans to explore strategic opportunities to continue to develop XTX202 in combination with other agents.

Tumor-Activated Bispecific and Immune Cell Engager Programs

In March 2024, Xilio announced plans to focus its research-stage development efforts on tumor-activated bispecifics and immune cell engagers, including tumor-activated cell engagers and tumor-activated effector-enhanced cell engagers.

Preclinical data from the company's first bispecific program, XTX501, a tumor-activated PD-1/IL-2 bispecific development candidate, will be featured at the American Association for Cancer Research (AACR) Annual Meeting 2024 in San Diego, California from April 5-10, 2024.

- **Presentation title:** A tumor-activated PD1/IL2 bispecific molecule, designed to overcome IL-2 receptor-mediated clearance, improve tolerability and stimulate antigen-experienced CD8+ T cells in the tumor microenvironment of murine models
- **Session date and time:** Sunday, April 7, 2024, at 1:30 pm to 5:00 pm P.T.
- **Abstract number:** 719
- **Poster board number:** 5

Corporate Updates

- In March 2024, Xilio announced a private placement equity financing with certain existing accredited investors, including Bain Capital Life Sciences and Rock Springs Capital. Xilio anticipates receiving aggregate gross proceeds from the private placement of approximately $11.3 million, before deducting placement agent fees and expenses payable by the company. The private placement is expected to close on April 2, 2024, subject to the satisfaction of customary closing conditions. Xilio expects to use the proceeds from the private placement to fund working capital and other general corporate purposes.
- In March 2024, Xilio announced plans to implement a strategic portfolio prioritization designed to focus its resources on rapidly advancing clinical development for XTX301 and XTX101 and leveraging the company's promising research platform to advance differentiated tumor-activated bispecific and immune cell engager molecules. As part of the strategic portfolio reprioritization, Xilio also announced plans to discontinue further investment in XTX202 as a monotherapy and implement an approximately 21% workforce reduction.

Year-End and Fourth Quarter 2023 Financial Results

- **Cash Position:** Cash and cash equivalents were $44.7 million as of December 31, 2023, compared to $120.4 million as of December 31, 2022.
- **Research & Development (R&D) Expenses:** R&D expenses were $11.7 million for the quarter ended December 31, 2023, compared to $15.0 million for the quarter ended December 31, 2022. R&D expenses were $52.1 million for the year ended December 31, 2023, compared to $59.2 million for the year ended December 31, 2022. The year-over-year decrease was primarily driven by decreases in manufacturing activities, XTX301 preclinical development activities, XTX101 clinical activities and personnel-related costs. These decreases were partially offset by increases in XTX301 and XTX202 clinical activities.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.4 million for the quarter ended December 31, 2023, compared to $8.2 million for the quarter ended December 31, 2022. G&A expenses were $27.0 million for the year ended December 31, 2023, compared to $29.9 million for the year ended December 31, 2022. The year-over-year decrease was primarily driven by decreases in professional and consulting fees, directors' and officers' liability insurance and stock-based compensation expenses.

- **Net Loss:** Net loss was $17.7 million for the quarter ended December 31, 2023, compared to $22.5 million for the quarter ended December 31, 2022. Net loss was $76.4 million for the year ended December 31, 2023, compared to $88.2 million for the year ended December 31, 2022.

Financial Guidance

Based on its current operating plans, Xilio anticipates that its cash and cash equivalents as of December 31, 2023, together with (i) the $30.0 million upfront payment under the license agreement with Gilead, (ii) the approximately $13.5 million in proceeds from the initial private placement with Gilead, which closed on March 28, 2024, and (iii) the approximately $11.3 million in proceeds from the private placement, which is expected to close on April 2, 2024 (subject to customary closing conditions), and after giving effect to (a) one-time costs and anticipated future cost savings associated with Xilio's strategic portfolio reprioritization and workforce reduction announced in March 2024 and (b) the repayment in the first quarter of 2024 of the outstanding loan balance under Xilio's loan and security agreement with Pacific Western Bank, 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 (TME). 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 tolerability of the combination in patients with advanced solid tumors in the Phase 1 dose escalation portion of the clinical trial. Subject to the results of Phase 1 combination dose escalation, Xilio plans to evaluate the safety and efficacy of the combination in the Phase 2 portion of the 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 (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 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 XTX202 (IL-2) and the Phase 2 Clinical Trial

XTX202 is an investigational tumor-activated, beta-gamma biased IL-2 designed to potently stimulate CD8+ effector T cells and natural killer (NK) cells without concomitant stimulation of regulatory T cells when activated (unmasked) in the TME. The Phase 2 clinical trial is a multi-center, open-label trial designed to evaluate the safety and efficacy of XTX202 as a monotherapy in patients with unresectable or metastatic melanoma and metastatic renal cell carcinoma who have progressed on standard-of-care treatment. Please refer to NCT05052268 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 and anticipated milestones for XTX101, XTX301 and XTX202; the expected closing of the private placement with existing accredited investors, as well as the anticipated use of proceeds from the private placement and whether the conditions for the closing of the private placement will be satisfied; the amount of proceeds expected from the transactions with Gilead; the timing and certainty of completion of the transactions with Gilead; the potential impact of the strategic portfolio reprioritization and workforce reduction on Xilio's operations and development timelines; Xilio's intent and ability to explore strategic opportunities to develop XTX202 in combination with other agents; the potential for Xilio to leverage its research platform to develop tumor-activated bispecific and 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; whether the conditions for the closing of the private placement will be satisfied; Xilio's ability to successfully achieve the benefits of the strategic portfolio reprioritization and workforce reduction; 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; 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.

TECENTRIQ is a registered trademark of Genentech USA, Inc., a member of the Roche Group.

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

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 44,704	$ 120,385
Other assets	16,222	18,780
Total assets	$ 60,926	$ 139,165
Liabilities and Stockholders' Equity		
Liabilities	$ 24,099	$ 35,518
Stockholders' equity	36,827	105,647
Total liabilities and stockholders' equity	$ 60,926	$ 139,165

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Operating expenses[1]				
Research and development	$ 11,736	$ 14,997	$ 52,136	$ 59,201
General and administrative	6,394	8,170	26,997	29,948
Total operating expenses	18,130	23,167	79,133	89,149
Loss from operations	(18,130)	(23,167)	(79,133)	(89,149)
Other income, net				
Other income, net	475	701	2,729	927
Total other income, net	475	701	2,729	927
Net loss and comprehensive loss	$ (17,655)	$ (22,466)	$ (76,404)	$ (88,222)
Net loss per share, basic and diluted	$ (0.64)	$ (0.82)	$ (2.78)	$ (3.22)
Weighted average common shares outstanding, basic and diluted	27,557,021	27,415,832	27,496,107	27,392,087

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Research and development expense	$ 519	$ 600	$ 2,189	$ 2,427
General and administrative expense	1,411	1,215	5,193	5,997
Total stock-based compensation expense	$ 1,930	$ 1,815	$ 7,382	$ 8,424