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): **March 1, 2022**

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: **(617) 430-4680**

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 March 1, 2022, Xilio Therapeutics, Inc. announced its financial results for the quarter and year ended December 31, 2021 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 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 March 1, 2022
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: March 1, 2022

By: /s/ René Russo
René Russo
President and Chief Executive Officer

Exhibit 99.1

Xilio Therapeutics Reports Pipeline and Business Progress and Fourth Quarter and Full Year 2021 Financial Results

Initial Phase 1 Data Readouts from Clinical Trials of XTX101 and XTX202 Anticipated in 2022

On Track with Plans to Submit IND for XTX301 in Second Half of 2022

Continue to Anticipate Cash Runway into 2024 with $198.1 Million in Cash and Cash Equivalents at Year-End 2021

WALTHAM, Mass., March 1, 2022 – Xilio Therapeutics, Inc. (Nasdaq: XLO), a biotechnology company developing tumor-selective immuno-oncology therapies for people living with cancer, today announced pipeline and business progress and reported financial results for the fourth quarter and full year ended December 31, 2021.

"Xilio made significant pipeline and business progress in 2021, becoming a clinical-stage organization and transitioning to a publicly traded company through the successful completion of our IPO," said René Russo, Pharm.D., president and chief executive officer of Xilio. "As we look to 2022, I am excited about the many opportunities ahead of us, including anticipated initial clinical data readouts for XTX101, our tumor-selective anti-CTLA-4 monoclonal antibody, and XTX202, our tumor-selective IL-2. In addition, we plan to submit an IND for XTX301, our tumor-selective IL-12, in the second half of the year and continue to generate new research programs by leveraging our robust platform. With our exceptional team and strong financial position, we believe we have the resources in place to advance our vision of bringing transformative immuno-oncology therapies to people living with cancer."

Pipeline and Business Progress

Cytokine Programs

- Xilio continues to advance enrollment in the Phase 1 portion of its Phase 1/2 clinical trial evaluating XTX202 for the treatment of patients with solid tumors. XTX202, a modified form of interleukin-2 (IL-2), is 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. Xilio expects to report preliminary data from the Phase 1 portion of the trial in the second half of 2022.

- Xilio continues to progress preclinical studies for XTX301, a tumor-selective IL-12. The company plans to submit an investigational new drug application (IND) for XTX301 as a potential treatment for patients with solid tumors in the second half of 2022.

Checkpoint Inhibitor Program

- Xilio continues to advance enrollment in the Phase 1 portion of its Phase 1/2 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. Xilio expects to report preliminary data from the monotherapy cohort of the Phase 1 portion of the trial in the middle of 2022 and preliminary data from the combination cohort of the Phase 1 portion of the trial in the second half of 2022.

Recent Business Highlights

- In January 2022, Xilio appointed Yuan Xu, Ph.D., to its board of directors.

Fourth Quarter and Full Year 2021 Financial Results

- **Cash Position:** Cash and cash equivalents were $198.1 million as of December 31, 2021, compared to $19.2 million as of December 31, 2020. The increase was primarily related to $144.9 million in net proceeds received from convertible preferred stock financings in the first quarter of 2021 and $116.4 million in net proceeds received from Xilio's initial public offering in the fourth quarter of 2021. Net cash proceeds from financings were partially offset by operating uses of cash for the year ended December 31, 2021.

- **Research & Development (R&D) Expenses:** R&D expenses were $11.4 million for the quarter ended December 31, 2021, compared to $17.7 million for the quarter ended December 31, 2020. R&D expenses were $51.2 million for the year ended December 31, 2021, compared to $43.9 million for the year ended December 31, 2020. The year-over-year increase was primarily driven by higher personnel-related costs due to increased headcount and expenses associated with R&D programs.

- **General & Administrative (G&A) Expenses:** G&A expenses were $8.2 million for the quarter ended December 31, 2021, compared to $2.9 million for the quarter ended December 30, 2020. G&A expenses were $23.9 million for the year ended December 31, 2021, compared to $10.7 million for the year ended December 31, 2020. The year-over-year increase was primarily driven by higher personnel-related costs due to increased headcount and professional and consulting fees related to transitioning to and operating as a publicly traded company.

- **Net Loss:** Net loss was $19.7 million for the quarter ended December 31, 2021 and $75.8 million for the year ended December 31, 2021.

Financial Guidance

Xilio continues to believe that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into 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, and XTX401, a tumor-selective IL-15. For more information, please visit www.xiliotx.com.

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 the presentation of preliminary Phase 1 clinical data for XTX101 and XTX202 and the submission of an IND for XTX301; Xilio's ability to generate new research programs by leveraging its platform; 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 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.

For Investor Inquiries:
Sal Giovine, CFO
investors@xiliotx.com

For Media Inquiries:
Dan Budwick
dan@1abmedia.com

XILIO THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(In thousands)
(Unaudited)

	December 31, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 198,053	$ 19,238
Other assets	20,007	17,079
Total assets	$ 218,060	$ 36,317
Liabilities and Stockholders' Equity (Deficit)		
Liabilities	$ 32,631	$ 41,602
Convertible preferred stock	—	78,002
Stockholders' equity (deficit)	185,429	(83,287)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 218,060	$ 36,317

XILIO THERAPEUTICS, INC.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Operating expenses [1]				
Research and development	$ 11,352	$ 17,667	$ 51,188	$ 43,910
General and administrative	8,204	2,928	23,856	10,653
Total operating expenses	19,556	20,595	75,044	54,563
Loss from operations	(19,556)	(20,595)	(75,044)	(54,563)
Other income (expense), net				
Other expense, net	(145)	(177)	(756)	(656)
Total other income (expense), net	(145)	(177)	(756)	(656)
Net loss and comprehensive loss	$ (19,701)	$ (20,772)	$ (75,800)	$ (55,219)
Net loss per share, basic and diluted	$ (0.98)	$ (31.51)	$ (13.52)	$ (105.42)
Weighted average common shares outstanding, basic and diluted	20,057,208	659,277	5,606,308	523,786

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

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Research and development expense	$ 426	$ 92	$ 1,290	$ 332
General and administrative expense	1,645	274	3,668	964
Total equity-based compensation expense	$ 2,071	$ 366	$ 4,958	$ 1,296