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): May 9, 2024

XENON PHARMACEUTICALS INC.

(Exact name of Registrant as Specified in Its Charter)

Canada	**001-36687**	**98-0661854**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
200-3650 Gilmore Way Burnaby, British Columbia, Canada		**V5G 4W8**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (604) 484-3300

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 Shares, without par value	XENE	The Nasdaq Stock Market LLC (The Nasdaq Global 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 May 9, 2024, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three months ended March 31, 2024. A copy of the Company's press release is attached hereto as Exhibit 99.1. The information in Item 2.02 of this Form 8-K and the attached exhibit are furnished to, but not filed with, the Securities and Exchange Commission.

Item 7.01 Regulation FD Disclosure

The Company announces material information to the public through a variety of means, including filings with the Securities and Exchange Commission, press releases, public conference calls, the Company's website (https://www.xenon-pharma.com), its investor relations website (https://investor.xenon-pharma.com), and its news site (https://investor.xenon-pharma.com/news-releases). The Company uses these channels, as well as social media, including its X (formerly known as Twitter) account (@XenonPharma), LinkedIn account (https://www.linkedin.com/company/xenonpharma/), and Facebook page (https://www.facebook.com/xenonpharma), to communicate with investors and the public about the Company, its product candidates, and other matters. Therefore, the Company encourages investors, the media, and others interested in the Company to review the information it makes public in these locations, as such information could be deemed to be material information.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Pursuant to the rules and regulations of the Securities and Exchange Commission, the attached exhibit is deemed to have been furnished to, but not filed with, the Securities and Exchange Commission:

Exhibit Number	Description
99.1	Press Release issued by Xenon Pharmaceuticals Inc. dated May 9, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

XENON PHARMACEUTICALS INC.

Date: May 9, 2024

By: /s/ Sherry Aulin
Sherry Aulin
Chief Financial Officer

Exhibit 99.1

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports First Quarter 2024 Financial Results and Provides Corporate Update

Phase 3 epilepsy program continues to progress with anticipated completion of patient enrollment in X-TOLE2 in late 2024 to early 2025

Successful "end-of-Phase 2" interactions with FDA in MDD; Phase 3 program on track to initiate in the second half of the year

Azetukalner now the international nonproprietary name (INN) and United States adopted name (USAN) for XEN1101

Conference call at 4:30 pm ET today

VANCOUVER, British Columbia, May 9, 2024 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neuroscience-focused biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2024 and provided a corporate update.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer, stated, "I am excited to announce that we have received approval for the use of 'azetukalner' as the nonproprietary, or generic, name for XEN1101, recognizing its novel Kv7 mechanism of action. This is an important milestone for Xenon, representing another step forward as we advance azetukalner towards commercialization."

Mr. Mortimer continued, "We have made significant advancements in our azetukalner MDD program over this past quarter, including reaching alignment with the FDA on key features of our Phase 3 program. Supported by the data generated from our Phase 2 proof-of-concept X-NOVA clinical trial demonstrating clinically meaningful drug activity in depression, we believe azetukalner has the potential to offer a differentiated and competitive profile in MDD based on its unique mechanism of action and a potential benefit on anhedonia, a key co-morbidity of depression. We look forward to initiating our Phase 3 program in the second half of this year, with the goal of potentially providing a new therapeutic option to address the unmet medical need that remains in major depressive disorder."

Mr. Mortimer added, "We recently hosted two oral presentations at the American Academy of Neurology annual meeting where we were met with neurologists and epileptologists who continue to express significant excitement about the unique mechanism of azetukalner and the compelling clinical data we have generated to date in both epilepsy and MDD. We look forward to continuing to showcase azetukalner at medical conferences throughout the remainder of this year."

Highlights and Anticipated Milestones

Azetukalner (XEN1101) Clinical Development Programs

Xenon announced that the United States Adopted Names (USAN) Council and the World Health Organization (WHO) International Nonproprietary Names (INN) expert committee have approved "azetukalner" as the nonproprietary, or generic, name for XEN1101. Azetukalner is a novel, potent Kv7 potassium channel opener being developed for the treatment of epilepsy, major depressive disorder, and potentially other neurological disorders.

Epilepsy (Focal Onset Seizures)

Xenon's Phase 3 epilepsy program in focal onset seizures, or FOS, includes two identical Phase 3 clinical trials, X-TOLE2 and X-TOLE3, that are designed closely after the Phase 2b X-TOLE clinical trial. These multicenter, randomized, double-blind, placebo-controlled trials are evaluating the clinical efficacy, safety, and tolerability of 15 mg or 25 mg of azetukalner administered with food as adjunctive treatment in approximately 360 patients per study with FOS. Xenon anticipates patient enrollment in X-TOLE2 will be completed in late 2024 to early 2025.

Epilepsy (Primary Generalized Tonic-Clonic Seizures)

Xenon's Phase 3 X-ACKT clinical trial is intended to support potential regulatory submissions in an additional epilepsy indication of primary generalized tonic-clonic seizures, or PGTCS. This multicenter, randomized, double-blind, placebo-controlled trial is evaluating the clinical efficacy, safety, and tolerability of 25 mg of azetukalner administered with food as adjunctive treatment in approximately 160 patients with PGTCS.

Epilepsy (Open-Label Extension)

Upon completion of the double-blind period in X-TOLE2, X-TOLE3, or X-ACKT, eligible patients may enter an open-label extension, or OLE, study for up to three years. In addition, the ongoing X-TOLE Phase 2b OLE has been extended from five to seven years and continues to generate important long-term data for azetukalner.

Major Depressive Disorder, or MDD

In November 2023, Xenon reported topline results from the Phase 2 proof-of-concept X-NOVA clinical trial, which evaluated the clinical efficacy, safety, and tolerability of 10 mg and 20 mg of XEN1101 in 168 patients with moderate to severe MDD. Xenon anticipates presenting the X-NOVA topline data at the annual meeting of the American Society of Clinical Psychopharmacology (ASCP) taking place May 28-31, 2024 in Miami, FL.

Based on “end-of-Phase 2” interactions with the U.S. Food and Drug Administration, Xenon continues to anticipate that the first of three Phase 3 clinical trials will be initiated in the second half of 2024.

In addition, Xenon is collaborating with the Icahn School of Medicine at Mount Sinai to support an ongoing investigator-sponsored Phase 2 proof-of-concept, randomized, parallel-arm, placebo-controlled multi-site study of azetukalner for the treatment of MDD in approximately 60 subjects.

Other Pipeline Opportunities

Xenon continues to leverage its extensive ion channel expertise and drug discovery capabilities to identify validated drug targets and develop new product candidates. The near-term focus is on developing Kv7 channel openers, Nav1.7 inhibitors and Nav1.1 openers, with the goal of advancing multiple candidates into IND-enabling studies in 2024 and 2025.

Partnered Program: NBI-921352

Xenon has an ongoing collaboration with Neurocrine Biosciences to develop treatments for epilepsy. Neurocrine Biosciences has an exclusive license to XEN901, now known as NBI-921352, a selective Nav1.6 sodium channel inhibitor. A Phase 2 clinical trial is ongoing evaluating NBI-921352 in patients aged between 2 and 21 years with SCN8A developmental and epileptic encephalopathy.

First Quarter Financial Results

Cash and cash equivalents and marketable securities were $885.4 million as of March 31, 2024, compared to $930.9 million as of December 31, 2023. Based on current operating plans, including the completion of the azetukalner Phase 3 epilepsy studies and fully supporting late-stage clinical development of azetukalner in MDD, Xenon anticipates having sufficient cash to fund operations into 2027. As of March 31, 2024, there were 75,459,681 common shares and 2,173,081 pre-funded warrants outstanding.

Research and development expenses were $44.3 million for the first quarter of 2024, compared to $39.5 million for the same period in 2023. The increase in research and development expenses was primarily attributable to manufacturing activities for the azetukalner program to support current and future clinical trials and a potential NDA submission, increased personnel-related costs due to an increase in employee headcount, and higher stock-based compensation expense. These increases were partially offset by a decrease in expenses for the XEN496 program as a result of Xenon's decision in early 2023 to no longer pursue the clinical development of XEN496.

General and administrative expenses were $14.8 million for the first quarter of 2024, compared to $9.5 million for the same period in 2023. The increase in general and administrative expenses was primarily attributable to personnel-related costs due to an increase in employee headcount and higher stock-based compensation expense, an increase in professional and consulting fees, and information technology costs related to ongoing business activities.

Other income was $11.5 million for the first quarter of 2024, compared to $7.6 million for the same period in 2023. The increase in other income was primarily attributable to higher interest income, partially offset by a decrease in the unrealized fair value gain on trading securities.

Net loss was $47.9 million for the first quarter of 2024, compared to $41.7 million for the same period in 2023. The increase in net loss was primarily attributable to higher research and development expenses driven by the azetukalner program, and increased personnel-related costs and stock-based compensation expense across the organization, partially offset by an increase in interest income.

Conference Call Information

Xenon will host a conference call and webcast today at 4:30 pm Eastern Time (1:30 pm Pacific Time) to discuss its first quarter results. The audio webcast can be accessed on the Investors section of the Xenon website. Participants are encouraged to pre-register for the conference call in order to obtain a conference passcode and unique PIN. Participants may pre-register at any time, including up to and after the call start time. Those without internet access, or unable to pre-register, may dial in toll-free to 1 (888) 500-3691, or 1 (646) 307-1951 for international callers. A replay of the webcast will be posted on the Xenon website approximately one hour after the conclusion of the event and will remain available for approximately one month.

About Xenon Pharmaceuticals Inc.

Xenon Pharmaceuticals (Nasdaq:XENE) is a neuroscience-focused biopharmaceutical company committed to discovering, developing, and commercializing innovative therapeutics to improve the lives of people living with neurological and psychiatric disorders. We are advancing a novel product pipeline to address areas of high unmet medical need, including epilepsy and depression. For more information, please visit www.xenon-pharma.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. These forward-looking statements are not based on historical fact, and include statements regarding the timing of and potential results from clinical trials; the potential efficacy, safety profile, future development plans in current and anticipated indications, addressable market, regulatory success and commercial potential of our and our partners' product candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in our azetukalner and other pipeline and development programs; the timing and results of our interactions with regulators; our ability to successfully develop and obtain regulatory approval of azetukalner and our other product candidates; anticipated enrollment in our clinical trials of azetukalner and the timing thereof; and our expectation that we will have sufficient cash to fund operations into 2027. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events, or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our or our collaborators' product candidates; promising results from pre-clinical development activities or early clinical trial results may not be replicated in later clinical trials; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our ongoing discovery and pre-clinical efforts may not yield additional product candidates; any of our or our collaborators' product candidates, including azetukalner, may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones in our proprietary or partnered programs; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; the impact of new or changing laws and regulations; the impact of pandemics, epidemics and other public health crises on our research and clinical development plans and timelines and results of operations, including impact on our clinical trial sites, collaborators, regulatory agencies and related review times, and contractors who act for or on our behalf; the impact of unstable economic conditions in the general domestic and global economic markets; adverse conditions from geopolitical events; as well as the other risks identified in our filings with the U.S. Securities and Exchange Commission and the securities commissions in British Columbia, Alberta, and Ontario. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

"Xenon" and the Xenon logo are registered trademarks or trademarks of Xenon Pharmaceuticals Inc. in various jurisdictions. All other trademarks belong to their respective owner.

XENON PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheets
(Expressed in thousands of U.S. dollars)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 699,602	$ 638,082
Other current assets	7,602	6,880
Marketable securities, long-term	185,836	292,792
Other long-term assets	25,983	27,044
Total assets	$ 919,023	$ 964,798
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 20,900	$ 25,974
Other current liabilities	1,323	1,299
Other long-term liabilities	9,102	9,604
Total liabilities	$ 31,325	$ 36,877
Shareholders' equity	$ 887,698	$ 927,921
Total liabilities and shareholders' equity	$ 919,023	$ 964,798

XENON PHARMACEUTICALS INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Expressed in thousands of U.S. dollars except share and per share amounts)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 44,250	$ 39,516
General and administrative	14,791	9,535
	59,041	49,051
Loss from operations	(59,041)	(49,051)
Other income	11,522	7,614
Loss before income taxes	(47,519)	(41,437)
Income tax expense	(412)	(290)
Net loss	$ (47,931)	$ (41,727)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	$ (1,692)	$ 1,180
Comprehensive loss	$ (49,623)	$ (40,547)
Net loss per common share:		
Basic and diluted	$ (0.62)	$ (0.63)
Weighted-average common shares outstanding:		
Basic and diluted	77,594,599	65,724,681

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