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): August 8, 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.)**
3650 Gilmore Way **Burnaby, British Columbia, Canada** **(Address of Principal Executive Offices)**		**V5G 4W8** **(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 August 8, 2024, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three and six months ended June 30, 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 August 8, 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: August 8, 2024

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

Exhibit 99.1

Xenon Reports Q2 2024 Financial Results and Business Update

– Phase 3 epilepsy program progressing with X-TOLE2 topline FOS data anticipated in H2 2025

– MDD program on track with Phase 3 study expected to initiate in H2 2024

– Multiple Kv7 and Nav1.7 candidates progressing towards development with INDs expected in 2025

– Conference call at 4:30 pm ET today

VANCOUVER, British Columbia, August 8, 2024 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neuroscience-focused biopharmaceutical company dedicated to discovering, developing, and delivering life-changing therapeutics for patients in need, today provided a corporate update and reported financial results for the second quarter ended June 30, 2024.

"We are proud to have the only Kv7 potassium channel opener in development with Phase 2b efficacy and long-term safety data in epilepsy patients. Today people living with epilepsy are still struggling to control seizures despite current medications, and we believe the compelling profile of azetukalner has the potential to be paradigm shifting in the future treatment of epilepsy," stated Ian Mortimer, President and Chief Executive Officer of Xenon. "We continue to progress our epilepsy program with plans to deliver X-TOLE2 topline data in the second half of 2025, in support of our expected NDA submission."

Mr. Mortimer continued, "Beyond azetukalner, we continue to build upon our Kv7 leadership with a broad portfolio of diverse chemistries to support our 'pipeline in a mechanism' approach. In parallel, we are advancing promising Nav1.7 candidates towards early human proof-of-concept in pain. We believe that the advancements in our azetukalner development programs in epilepsy and MDD, with our maturing pre-clinical pipeline, position Xenon with one of the most exciting CNS portfolios that exists today."

Quarterly Business Highlights and Anticipated Milestones

Azetukalner Clinical Development

Azetukalner (XEN1101) is a novel, potent Kv7 potassium channel opener being developed for the treatment of epilepsy, including focal onset seizures (FOS) and primary generalized tonic-clonic seizures (PGTCS), as well as major depressive disorder (MDD), with the Company exploring applicability in other neuropsychiatric disorders.

- Phase 3 FOS studies continue to advance, with the first topline data readout from X-TOLE2 anticipated in the second half of 2025. The Phase 3 FOS clinical trials are multicenter, randomized, double-blind, placebo-controlled studies evaluating the clinical efficacy, safety, and tolerability of azetukalner in patients with FOS.
- Phase 3 X-ACKT clinical trial is currently enrolling patients and is intended to support potential regulatory submissions in an additional epilepsy indication of PGTCS. This multicenter, randomized, double-blind, placebo-controlled trial is evaluating the clinical efficacy, safety and tolerability of azetukalner in patients with PGTCS.
- X-TOLE Phase 2b open-label extension (OLE) has been extended to seven years and continues to generate important long-term data for azetukalner beyond the 600 patient-years of exposure to date. Upon completion of the double-blind period in the Phase 3 epilepsy studies, eligible patients may enter an OLE study for up to three years.
- The Company presented Phase 2 X-NOVA data at the American Society of Clinical Psychopharmacology (ASCP) meeting in May. The X-NOVA study evaluated azetukalner in

patients with MDD. The first of three planned Phase 3 clinical trials is expected to initiate in the second half of 2024.

- Xenon will present three epilepsy related posters at the upcoming 15th European Epilepsy Congress in Rome, Italy from September 7 to 11. The Company will also present a poster on MDD at the Psych Congress in Boston, MA from October 29 to November 2.
- The Company continues to support the investigator-sponsored Phase 2 proof-of-concept study of azetukalner in MDD led by Icahn School of Medicine at Mount Sinai, with patient enrollment anticipated to complete this quarter.

Early-Stage Pipeline: Next Generation Ion Channel Modulators

As leaders in the small molecule ion channel space, Xenon continues to leverage its extensive expertise to discover and develop potassium and sodium channel therapeutics. The Company is evaluating multiple therapeutic candidates targeting Kv7, Nav1.7, and Nav1.1 across various indications with the goal of filing multiple INDs, or equivalent, in 2025.

- The Company has nominated multiple Kv7 development candidates, with a lead candidate in IND-enabling studies. Kv7 may have utility in a broad range of therapeutic indications including seizures, pain, and neuropsychiatric disorders, such as MDD.
- A lead Nav1.7 candidate is expected to enter IND-enabling studies in the near term. Nav1.7 is an important pain-related target, based on strong human genetic validation, that may represent a new class of medicines without the limitations of opioids.
- The Company expects to nominate a lead Nav1.1 candidate, as pre-clinical data suggests that targeting Nav1.1 could potentially address the underlying cause and symptoms of Dravet Syndrome.

Partnered Program

- As part of Xenon’s ongoing collaboration with Neurocrine Biosciences to develop treatments for epilepsy, a Phase 2 clinical trial is evaluating NBI-921352 (formerly XEN901) in an orphan pediatric epilepsy (SCN8A-DEE), and the next lead candidate, a Nav1.2/1.6 inhibitor, is in IND-enabling studies with the intent to progress into human clinical trials in 2025 as a potential treatment for focal onset seizures.

Second Quarter Financial Results

- Cash and cash equivalents and marketable securities were $850.6 million as of June 30, 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 June 30, 2024, there were 75,667,550 common shares and 2,173,081 pre-funded warrants outstanding.
- Research and development expenses for the quarter ended June 30, 2024 were $49.7 million, compared to $44.0 million for the same period in 2023. The increase of $5.7 million was primarily attributable to increased expenses related to our pre-clinical and discovery programs to advance multiple potential drug candidates targeting Kv7, Nav1.7, and Nav1.1, 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 for the quarter ended June 30, 2024 were $19.4 million, compared to $11.6 million for the same period in 2023. The increase of $7.8 million was primarily attributable to personnel-related costs due to an increase in employee headcount and higher stock-based compensation expense, and an increase in professional and consulting fees.

- Other income for the quarter ended June 30, 2024 was $10.8 million, compared to $7.9 million for the same period in 2023. The increase of $2.9 million was primarily attributable to higher interest income, partially offset by a decrease in the unrealized fair value gain on trading securities.
- Net loss for the quarter ended June 30, 2024 was $57.9 million, compared to $47.5 million for the same period in 2023. The increase in net loss was primarily attributable to higher research and development expenses driven by pre-clinical and discovery programs, 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 second quarter results. A listen-only webcast can be accessed on the Investors section of the Xenon website. Participants can access the conference call by dialing (800) 715-9871 or (646) 307-1963 for international callers and referencing conference ID 1631616. A replay of the webcast will be available on the website.

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. Azetukalner, our lead Kv7 channel opener, represents the most advanced, clinically validated potassium channel modulator in late-stage clinical development for multiple indications. For more information, please visit www.xenon-pharma.com.

About the Azetukalner Phase 3 Epilepsy Program

Xenon's Phase 3 epilepsy program includes three ongoing Phase 3 clinical trials in focal onset seizures (FOS) and primary generalized tonic-clonic seizures (PGTCS). Designed closely after the Phase 2b X-TOLE clinical trial, the Phase 3 X-TOLE clinical trials are multicenter, randomized, double-blind, placebo-controlled studies 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 with FOS per study. The primary efficacy endpoint is the median percent change (MPC) in monthly seizure frequency from baseline through the double-blind period (DBP) of azetukalner compared to placebo. X-ACKT is a multicenter, randomized, double-blind, placebo-controlled study evaluating the clinical efficacy, safety, and tolerability of 25 mg of azetukalner administered with food as adjunctive treatment in approximately 160 patients with PGTCS. The primary efficacy endpoint is the MPC in monthly PGTCS frequency from baseline through the DBP of azetukalner compared to placebo.

About the Azetukalner Phase 3 Major Depressive Disorder (MDD) Program

Xenon completed its Phase 2 proof-of-concept X-NOVA clinical trial, which evaluated the clinical efficacy, safety, and tolerability of 10 mg and 20 mg of azetukalner in 168 patients with moderate to severe MDD. The primary objective was to assess the efficacy of azetukalner compared to placebo on improvement of depressive symptoms using the Montgomery-Åsberg Depression Rating Scale (MADRS) score change through week 6. Based on X-NOVA results, Xenon plans on initiating the first of three Phase 3 clinical trials in MDD in the second half of 2024.

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 timing of topline data readout from our clinical trials of azetukalner; 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 market, industry, and regulatory conditions on clinical trial enrollment; 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.

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 721,535	$ 638,082
Other current assets	6,554	6,880
Marketable securities, long-term	129,062	292,792
Other long-term assets	26,860	27,044
Total assets	$ 884,011	$ 964,798
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 29,931	$ 25,974
Other current liabilities	1,354	1,299
Other long-term liabilities	8,679	9,604
Total liabilities	$ 39,964	$ 36,877
Shareholders' equity	$ 844,047	$ 927,921
Total liabilities and shareholders' equity	$ 884,011	$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 49,702	$ 44,040	$ 93,952	$ 83,556
General and administrative	19,402	11,584	34,193	21,119
	69,104	55,624	128,145	104,675
Loss from operations	(69,104)	(55,624)	(128,145)	(104,675)
Other income	10,847	7,943	22,369	15,557
Loss before income taxes	(58,257)	(47,681)	(105,776)	(89,118)
Income tax recovery (expense)	333	220	(79)	(70)
Net loss	(57,924)	(47,461)	$ (105,855)	$ (89,188)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	$ (443)	$ (1,479)	$ (2,135)	$ (299)
Comprehensive loss	$ (58,367)	$ (48,940)	$ (107,990)	$ (89,487)
Net loss per common share:				
Basic and diluted	$ (0.75)	$ (0.72)	$ (1.36)	$ (1.36)
Weighted-average common shares outstanding:				
Basic and diluted	77,671,128	65,861,138	77,632,864	65,792,910