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): November 12, 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 November 12, 2024, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three and nine months ended September 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 November 12, 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: November 12, 2024

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

Exhibit 99.1

Xenon Reports Q3 2024 Financial Results and Business Update

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

– Long-term azetukalner results from X-TOLE open-label extension study in FOS to be presented at AES

– Phase 3 MDD program on track with X-NOVA2 study expected to initiate by year-end

– Expanding ion channel portfolio includes multiple candidates advancing towards IND filings in 2025

– Recent appointment of Matt Ronsheim, experienced pharmaceutical executive joining Xenon's senior executive team as Chief Operating Officer

– Conference call at 4:30 pm ET today

VANCOUVER, BC and BOSTON, MA, November 12, 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 business update and reported financial results for the third quarter ended September 30, 2024.

"Xenon's leadership in the Kv7 landscape is unmatched as our lead molecule, azetukalner, represents the only highly potent, selective Kv7 potassium channel opener in development for multiple indications that is backed by long-term efficacy and safety data with over 600-patient years of exposure in patients living with epilepsy. Importantly, we generated highly compelling double-blind efficacy data that we believe demonstrates the best placebo-adjusted results in focal onset seizure patients, and excitement around azetukalner is building as we continue to progress toward the X-TOLE2 topline data readout expected in the second half of 2025," stated Ian Mortimer, President and Chief Executive Officer of Xenon. "Within the X-TOLE open-label extension study, we are seeing patients – some who have been on azetukalner for more than 5 years – experience the long-term benefits of seizure freedom and improved quality of life, as well as a favorable tolerability profile and we are excited to present new 36-month data at the American Epilepsy Society annual meeting next month."

"Beyond epilepsy, we have a high degree of confidence in the broader applicability of azetukalner with our first Phase 3 trial in MDD expected to initiate by year-end, while continuing to increase the breadth of our pipeline as we progress our early-stage programs with the advancement of multiple candidates towards IND filings in 2025," added Mr. Mortimer.

Quarterly Business Highlights and Anticipated Milestones

Azetukalner Clinical Development

Azetukalner, a novel, highly potent, selective Kv7 potassium channel opener, represents the most advanced, clinically validated potassium channel modulator in late-stage clinical development for multiple indications. Xenon is currently developing azetukalner for the treatment of epilepsy, including focal onset seizures (FOS) and primary generalized tonic-clonic seizures (PGTCS), as well as major depressive disorder (MDD), while exploring applicability in other neuropsychiatric disorders.

Epilepsy Programs

- 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 study 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.
- Building upon the 600 patient-years of drug exposure to date, Xenon continues to generate long-term scientific evidence demonstrating azetukalner's compelling efficacy and safety profile in the ongoing X-TOLE open-label extension (OLE) study.
- The Company continues to present azetukalner data at leading medical conferences and congresses, including the recent 15th European Epilepsy Congress (EEC), Epilepsy Foundation Pipeline Conference, and AMCP Nexus 2024.
- Five abstracts were accepted for presentation at the upcoming American Epilepsy Society (AES 2024) annual meeting in Los Angeles, CA from December 6-10. The Company plans to showcase new data from the ongoing azetukalner OLE in FOS and anticipates presenting updated pre-clinical data from its Nav1.1 program.

MDD Program

- X-NOVA2, the first of three Phase 3 clinical trials evaluating azetukalner in patients with MDD, is expected to initiate before the end of the year.
- Xenon presented Phase 2 X-NOVA data at the Psych Congress, which took place from October 29- 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. Patient enrollment for this study is now complete and results are anticipated in the first half of 2025.

Early-Stage Pipeline: Next Generation Ion Channel Modulators

As leaders in the small molecule ion channel space, Xenon continues to expand its portfolio by leveraging its extensive expertise to discover and develop potassium and sodium channel therapeutics, including candidates targeting Kv7, Nav1.7, and Nav1.1 across various indications with the goal of filing multiple INDs, or equivalent, in 2025.

- IND-enabling work is underway with multiple Kv7 development candidates. Kv7 may have utility in a broad range of therapeutic indications including seizures, pain, and neuropsychiatric disorders, such as MDD.
- IND-enabling work is underway with a lead Nav1.7 development candidate. 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 candidate within its Nav1.1 program in 2025. Pre-clinical data suggests that targeting Nav1.1 could potentially address the underlying cause and symptoms of Dravet Syndrome.

Corporate

- Xenon continues to attract top talent with extensive biopharmaceutical experience, including the recent addition of Matthew D. Ronsheim, Ph.D. as Chief Operating Officer and a member of the Xenon senior executive team.

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 FOS.

Third Quarter Financial Results

- Cash and cash equivalents and marketable securities were $803.3 million as of September 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 September 30, 2024, there were 75,794,409 common shares and 2,173,081 pre-funded warrants outstanding.
- Research and development expenses for the quarter ended September 30, 2024 were $57.0 million, compared to $42.9 million for the same period in 2023. The increase of $14.1 million was primarily attributable to increased expenses related to the azetukalner Phase 3 epilepsy clinical trials and manufacturing activities, pre-clinical and discovery programs to advance multiple potential drug candidates targeting Kv7, Nav1.7, and Nav1.1, and increased personnel-related costs due to an increase in employee headcount and higher stock-based compensation expense.
- General and administrative expenses for the quarter ended September 30, 2024 were $16.7 million, compared to $12.8 million for the same period in 2023. The increase of $3.9 million was primarily attributable to personnel-related costs due to an increase in employee headcount and higher stock-based compensation expense.
- Other income for the quarter ended September 30, 2024 was $10.6 million, compared to $7.1 million for the same period in 2023. The increase of $3.5 million was primarily attributable to higher interest income.
- Net loss for the quarter ended September 30, 2024 was $62.8 million, compared to $48.5 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 and pre-clinical and discovery programs, as well as 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 third quarter results. A listen-only webcast can be accessed on the Investors section of the Xenon website, with a replay available following the event. Participants can access the conference call by dialing (800) 715-9871 or (646) 307-1963 for international callers and referencing conference ID 7128308.

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. 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.

About Xenon Pharmaceuticals Inc.

Xenon Pharmaceuticals (Nasdaq:XENE) is a neuroscience-focused biopharmaceutical company dedicated to discovering, developing, and delivering life-changing therapeutics. We are advancing an ion channel product portfolio to address areas of high unmet medical need, including epilepsy and depression. Azetukalner, a novel, highly potent, selective Kv7 potassium 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.

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; and our ability to successfully develop and obtain regulatory approval of azetukalner and our other product candidates. 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; 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)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 654,015	$ 638,082
Other current assets	5,624	6,880
Marketable securities, long-term	149,317	292,792
Other long-term assets	26,945	27,044
Total assets	$ 835,901	$ 964,798
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 28,308	$ 25,974
Other current liabilities	1,387	1,299
Other long-term liabilities	8,399	9,604
Total liabilities	$ 38,094	$ 36,877
Shareholders' equity	$ 797,807	$ 927,921
Total liabilities and shareholders' equity	$ 835,901	$ 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 56,970	$ 42,880	$ 150,922	$ 126,436
General and administrative	16,706	12,804	50,899	33,923
	73,676	55,684	201,821	160,359
Loss from operations	(73,676)	(55,684)	(201,821)	(160,359)
Other income	10,566	7,065	32,935	22,622
Loss before income taxes	(63,110)	(48,619)	(168,886)	(137,737)
Income tax recovery	320	157	241	87
Net loss	(62,790)	(48,462)	$ (168,645)	$ (137,650)
Other comprehensive income (loss):				
Unrealized gain on available-for-sale securities	$ 3,548	$ 346	$ 1,413	$ 47
Comprehensive loss	$ (59,242)	$ (48,116)	$ (167,232)	$ (137,603)
Net loss per common share:				
Basic and diluted	$ (0.81)	$ (0.73)	$ (2.17)	$ (2.09)
Weighted-average common shares outstanding:				
Basic and diluted	77,926,205	66,002,163	77,730,644	65,862,661