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 8, 2022

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** **(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 8, 2022, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the six and nine months ended September 30, 2022. 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 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 8, 2022.
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 8, 2022

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

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports Third Quarter 2022 Financial Results and Provides Corporate Update

XEN1101 Phase 3 program launched with initiation of X-TOLE2 clinical trial

Strong financial position of approximately $752 million to fully support XEN1101 Phase 3 program development and expected cash runway into 2026

Conference call at 4:30 pm ET today

BURNABY, British Columbia, November 8, 2022 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer, stated, "We have made significant progress during the past quarter to support the initiation of our XEN1101 Phase 3 program. XEN1101 represents the most advanced potassium channel modulator in clinical development, with substantial clinical efficacy data supporting its advancement for the treatment of epilepsy. Backed by a strong scientific rationale, we have ambitious development plans for XEN1101, including the X-TOLE2 and X-TOLE3 clinical trials in focal onset seizures and the Phase 3 X-ACKT clinical trial in primary generalized tonic clonic seizures to be conducted in parallel. We continue to hear from key opinion leaders and prescribing physicians that novel mechanisms are needed to provide new therapeutic options that are clearly differentiated from the currently approved anti-seizure medications. Based on the strength of our Phase 2b efficacy data, our team is committed to advancing our Phase 3 XEN1101 epilepsy program through clinical development and towards commercialization, with the goal of improving the lives of epilepsy patients."

Mr. Mortimer continued, "Looking ahead, in parallel with the important ongoing activities to support our XEN1101 Phase 3 program, 2023 represents another key year for clinical inflection points within our pipeline. As a result of the advancements of our XEN1101 MDD study, we have further refined our guidance with topline data expected in the third quarter of next year. In addition, our partners at Neurocrine expect to have a clinical read-out from their Phase 2 study in adult patients with focal onset seizures in 2023."

Highlights and Anticipated Milestones

Proprietary Programs
XEN1101 is a differentiated Kv7 potassium channel opener being developed for the treatment of epilepsy and major depressive disorder (MDD).

XEN1101 for Epilepsy (Focal Onset Seizures)
In October 2021, Xenon announced positive results from its Phase 2b X-TOLE clinical trial, which evaluated the clinical efficacy, safety and tolerability of XEN1101 administered as an adjunctive treatment for adult patients with focal epilepsy. In June 2022, Xenon announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food & Drug Administration (FDA). Based on the EOP2 meeting, Xenon and the FDA aligned on key elements of the Phase 3 program to support a New Drug Application (NDA) submission. Xenon plans to submit an NDA upon completion of the first XEN1101 Phase 3 clinical trial (X-TOLE2), if successful, and use the existing data package from the Phase 2b X-TOLE clinical trial along with additional safety data from other clinical trials to meet regulatory requirements.

In November 2022, Xenon initiated its XEN1101 Phase 3 development program, which includes two identical Phase 3 clinical trials to be run in parallel, called 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 will evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered as adjunctive treatment in approximately 360 patients per study with focal onset seizures (FOS). The primary efficacy endpoint is the median percent change (MPC) in monthly seizure frequency from baseline through the double-blind period (DBP) of XEN1101 compared to placebo. On completion of the DBP in X-TOLE2 and X-TOLE3, eligible patients may enter an open-label extension (OLE) study for up to three years. In addition, the ongoing X-TOLE OLE also continues to generate important long-term data for XEN1101 in FOS.

XEN1101 for Epilepsy (Primary Generalized Tonic Clonic Seizures)
Alignment was obtained with the FDA at the EOP2 meeting on key elements of a single Phase 3 clinical trial to pursue an additional epilepsy indication of primary generalized tonic clonic seizures (PGTCS). Xenon intends to initiate a Phase 3 clinical trial, called X-ACKT, to support potential regulatory submissions in PGTCS. This multicenter, randomized, double-blind, placebo-controlled study will evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered 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 XEN1101 compared to placebo. On completion of the DBP in X-ACKT, eligible patients may enter an OLE study for up to three years.

XEN1101 for Major Depressive Disorder
Based on promising pre-clinical data with XEN1101 and published clinical data generated from both an open-label study and a randomized, placebo-controlled clinical trial that explored the targeting of KCNQ channels as a treatment for MDD using ezogabine, Xenon is evaluating the clinical efficacy, safety and tolerability of XEN1101 administered as monotherapy in approximately 150 patients with MDD in a Phase 2 clinical trial called X-NOVA. Designed as a randomized, double-blind, placebo-controlled, multicenter clinical study, the primary objective is to assess the efficacy of XEN1101 compared to placebo on improvement of depressive symptoms in subjects diagnosed with moderate to severe MDD, using the Montgomery-Åsberg Depression Rating Scale (MADRS) score change through week six. Topline results from the X-NOVA study are anticipated in the third quarter of 2023.

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 XEN1101 for the treatment of MDD in approximately 60 subjects. The primary objective of the study is to investigate the effect of XEN1101 on the brain reward circuit as measured by the change in bilateral ventral striatum activity as assessed by functional MRI (fMRI). The secondary objectives are to test the effect of XEN1101 compared to placebo on clinical measures of depression and anhedonia using the MADRS and SHAPS scales.

XEN496
XEN496, a Kv7 potassium channel opener, is a proprietary pediatric formulation of the active ingredient ezogabine being developed for the treatment of KCNQ2 developmental and epileptic encephalopathy (KCNQ2-DEE). A Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter clinical trial, called EPIK, is ongoing to evaluate the efficacy, safety, and tolerability of XEN496 administered as adjunctive treatment in approximately 40 pediatric patients aged one month to less than six years with KCNQ2-DEE. Based on current patient enrollment rates, Xenon now anticipates that the EPIK study will be completed in 2024.

Partnered Programs

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. Neurocrine Biosciences is conducting a Phase 2 clinical trial evaluating NBI-921352 in adult patients with focal onset seizures, with data expected in 2023. In addition, a Phase 2 clinical trial is underway evaluating NBI-921352 in patients aged between 2 and 21 years with SCN8A developmental and epileptic encephalopathy (SCN8A-DEE). Pursuant to the terms of the agreement, Xenon has the potential to receive certain clinical, regulatory, and commercial milestone payments, as well as future sales royalties.

Third Quarter 2022 Financial Results

Cash and cash equivalents and marketable securities were $752.2 million as of September 30, 2022, compared to $551.8 million as of December 31, 2021. The increase was primarily the result of the completion of the Company’s public offering in June 2022. As of September 30, 2022, there were 62,542,542 common shares and 3,103,864 pre-funded warrants outstanding.

Based on current assumptions, which include supporting the XEN1101 clinical development program including the completion of the planned Phase 3 epilepsy studies, XEN496, and pre-clinical and discovery programs, Xenon anticipates having sufficient cash to fund operations into 2026, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

For the quarter ended September 30, 2022, Xenon reported total revenue of $0.1 million, compared to $8.1 million for the same period in 2021. The decrease of $8.0 million was primarily attributable to the recognition of a $5.3 million milestone under the license and collaboration agreement with Neurocrine Biosciences in the third quarter of 2021, whereas no milestones were recognized in the third quarter of 2022. In addition, the research collaboration with Neurocrine Biosciences ended in June 2022, resulting in a decrease in research and development services revenue.

Research and development expenses for the quarter ended September 30, 2022 were $29.4 million, compared to $18.9 million for the same period in 2021. The increase of $10.5 million was primarily attributable to increased expenses related our XEN1101 program to support the initiation of the Phase 3 epilepsy program as well as the X-NOVA Phase 2 MDD clinical trial and increased investment in pre-clinical, discovery and other internal programs.

General and administrative expenses for the quarter ended September 30, 2022 were $8.8 million compared to $4.8 million for the same period in 2021. The increase of $4.0 million was primarily attributable to increased stock-based compensation expense, salaries and benefits due to an increase in employee headcount, recruitment fees, insurance premiums and expenses supporting intellectual property.

Other income for the quarter ended September 30, 2022 was $0.4 million compared to other expense of $0.1 million for the same period in 2021. The change was primarily attributable to increased interest income due to a higher balance of marketable securities and market yields, partially offset by increased foreign exchange losses due to a higher balance of cash and cash equivalents and marketable securities denominated in Canadian dollars and a decline in the value of the Canadian dollar.

Net loss for the quarter ended September 30, 2022 was $37.2 million, compared to $15.4 million for the same period in 2021. The change was primarily attributable to an increase in research and development and general and administrative expenses, lower revenue and higher foreign exchange losses, partially offset by an increase in interest income.

Conference Call Information

Xenon will host a conference call and audio webcast today at 4:30 pm Eastern Time (1:30 pm Pacific Time) to discuss its third quarter results and to provide a corporate update. The listen-only audio webcast will be broadcast live on the Investors section of the Xenon website. To participate in the live call, please register using the following link to receive dial-in details and a unique PIN code: Register and receive dial-in details.

About Xenon Pharmaceuticals Inc.

Xenon Pharmaceuticals (NASDAQ:XENE) is a clinical stage biopharmaceutical company committed to developing innovative therapeutics to improve the lives of patients with neurological disorders. We are advancing a novel product pipeline of neurology therapies to address areas of high unmet medical need, with a focus on epilepsy. 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, 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 XEN1101 and other development programs; the timing and results of our interactions with regulators; our ability to successfully develop and obtain regulatory approval of XEN1101 and our other product candidates; anticipated enrollment in our clinical trials and the timing thereof; and our expectation that we will have sufficient cash to fund operations into 2026. 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 XEN1101 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 the ongoing COVID-19 pandemic 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, may be more severe and more prolonged than currently anticipated; the impact of the COVID-19 pandemic on our business; 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 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 PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheets
(Expressed in thousands of U.S. dollars)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 638,185	$ 551,774
Other current assets	10,991	7,246
Marketable securities, long term	113,989	—
Other assets	12,648	12,987
Total assets	$ 775,813	$ 572,007
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 15,537	$ 13,717
Other current liabilities	—	605
Other liabilities	7,157	7,652
Total liabilities	$ 22,694	$ 21,974
Shareholders' equity	$ 753,119	$ 550,033
Total liabilities and shareholders' equity	$ 775,813	$ 572,007

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,	
	2022	2021	2022	2021
Revenue	$ 132	$ 8,124	$ 9,434	$ 14,700
Operating expenses:				
Research and development	29,431	18,891	70,937	53,576
General and administrative	8,829	4,831	24,309	15,279
Total operating expenses	38,260	23,722	95,246	68,855
Loss from operations	(38,128)	(15,598)	(85,812)	(54,155)
Other (expense) income	391	(52)	(3,187)	347
Loss before income taxes	(37,737)	(15,650)	(88,999)	(53,808)
Income tax recovery	587	205	1,021	490
Net loss	(37,150)	(15,445)	(87,978)	(53,318)
Net loss attributable to preferred shareholders	—	(362)	(420)	(1,308)
Net loss attributable to common shareholders	$ (37,150)	$ (15,083)	$ (87,558)	$ (52,010)
Other comprehensive loss:				
Unrealized losses on available-for-sale securities	$ (1,965)	$ —	$ (1,965)	$ —
Comprehensive loss	$ (39,115)	$ (15,445)	$ (89,943)	$ (53,318)
Net loss per common share:				
Basic and diluted	$ (0.57)	$ (0.36)	$ (1.49)	$ (1.29)
Weighted-average common shares outstanding:				
Basic and diluted	65,465,069	42,274,348	58,836,928	40,396,391

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