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 10, 2021

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 November 10, 2021, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three and nine month periods ended September 30, 2021. 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 10, 2021.
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 10, 2021

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

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports Third Quarter 2021 Financial Results and Provides Corporate Update

XEN1101 X-TOLE Presentations Scheduled at AES 2021 with Planning Underway for Phase 3 Initiation in 2022

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, November 10, 2021 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported financial results for the third quarter ended September 30, 2021 and provided a corporate update.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer stated, "We were incredibly excited last month to announce positive topline results from our Phase 2b X-TOLE clinical trial, which demonstrated impressive efficacy for XEN1101 in 'difficult-to-treat' adult patients with focal epilepsy. With its differentiated potassium channel mechanism of action, strong efficacy data, and 'ease-of-use' attributes, including once-a-day dosing in the evening with no titration, we believe XEN1101 could play an important role in treating focal epilepsy. We look forward to presenting additional X-TOLE data in a late-breaking poster at the upcoming AES 2021 meeting, where we are also sponsoring a scientific symposium featuring a panel discussion with key opinion leaders in the adult focal epilepsy space."

Mr. Mortimer added, "Based on the positive outcome of the X-TOLE clinical trial, our efforts are focused on finalizing the clinical development plan for XEN1101, including a planned end-of-Phase 2 meeting with FDA anticipated in the second quarter of 2022 to be followed by the initiation of our Phase 3 program in adult focal epilepsy anticipated in the second half of 2022. Supported by the strength of the topline X-TOLE data, we are actively evaluating other potential epilepsy indications for XEN1101. In addition, an investigator-led study evaluating XEN1101 as a treatment for major depressive disorder is now underway, and we also plan to initiate a company-sponsored MDD study in the first half of 2022. In parallel to our XEN1101-related activities, patient enrollment continues in our Phase 3 'EPIK' pediatric clinical trial evaluating XEN496 as a treatment of KCNQ2 developmental and epileptic encephalopathy. New sites and jurisdictions continue to come online to support the EPIK study, which is expected to be completed in the first half of 2023."

Highlights and Anticipated Milestones

Proprietary Programs

XEN1101

XEN1101 is a differentiated Kv7 potassium channel opener being developed for the treatment of epilepsy and major depressive disorder (MDD). On October 4, 2021, Xenon announced positive topline data from the Phase 2b X-TOLE clinical trial, which was designed as a randomized, double-blind, placebo-controlled, multicenter study to evaluate the clinical efficacy, safety and tolerability of XEN1101 administered as an adjunctive treatment for adult patients with focal epilepsy. The trial met its primary efficacy endpoint with XEN1101 demonstrating a statistically significant and dose-dependent reduction from baseline in monthly (defined as 28 days) focal seizure frequency when compared to placebo (monotonic dose response; $p<0.001$). Additional primary and secondary measures included a pairwise comparison of each active dose to placebo and a responder analysis with the proportion of patients who achieved a 50% or greater reduction in monthly focal seizure frequency from baseline. These results are shown in the following table; all p-values are 2-sided comparing the active dose to placebo:

	XEN1101 25 mg (N=112)	**XEN1101 20 mg (N=51)**	**XEN1101 10 mg (N=46)**	**Placebo (N=114)**
Median Reduction from Baseline in Monthly Focal Seizure Frequency	52.8% (p<0.001)	46.4% (p<0.001)	33.2% (p=0.035)	18.2%
Patients with at least a 50% Reduction in Monthly Focal Seizure Frequency from Baseline	54.5% (p<0.001)	43.1% (p<0.001)	28.3% (p=0.037)	14.9%

Xenon anticipates participating in an “end-of-Phase 2” meeting with the U.S. Food and Drug Administration (FDA) in the second quarter of 2022 to support the initiation of its Phase 3 XEN1101 clinical program in adult patients with focal epilepsy, estimated in the second half of the year. In addition, the X-TOLE open-label extension, which has been extended to three years, is expected to continue to generate important long-term data for XEN1101. In parallel, based on the strength of the X-TOLE topline efficacy data, Xenon is evaluating other potential epilepsy indications for the future development of XEN1101. Xenon continues to execute on its strategy to expand the intellectual property portfolio that protects XEN1101. During the third quarter and subsequent to quarter-end, two U.S. patents were issued to Xenon with claims related to: (1) four distinct crystalline forms of XEN1101 drug substance (including the forms used in current and future clinical development) along with methods for their preparation; and (2) methods of enhancing the bioavailability of XEN1101 by administration with or close to a meal (consistent with the dosing of XEN1101 in clinical studies). These U.S. patents are expected to expire in 2039 and 2040, respectively, absent any extensions of patent term.

Based on its differentiated Kv7 mechanism of action, Xenon is expanding the development of XEN1101 to support proof-of-concept studies in MDD, which are supported by XEN1101 pre-clinical and clinical data, and previous ezogabine clinical data that explored the targeting of KCNQ channels as a treatment for MDD. Xenon is collaborating with the Icahn School of Medicine at Mount Sinai to conduct an investigator-sponsored Phase 2 proof-of-concept, multi-site, randomized, parallel-arm, placebo-controlled clinical trial of XEN1101 for the treatment of MDD, with patient enrollment underway. Approximately 60 patients with MDD will be randomized in a 1:1 fashion to XEN1101 (N=30) or matching placebo (N=30), with subjects taking 20 mg once a day of either XEN1101 or placebo for 8 weeks. The primary objective is to investigate the effect of XEN1101 on brain measures of reward using functional Magnetic Resonance Imaging (fMRI). Secondary endpoints include clinical measures of depression and anhedonia. In addition, Xenon is planning a larger company-sponsored clinical study in MDD with XEN1101, which is expected to be initiated in the first half of 2022.

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). Xenon received Fast Track designation and Orphan Drug Designation for XEN496 for the treatment of seizures associated with KCNQ2-DEE from the FDA as well as orphan medicinal product designation from the European Commission. A Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter clinical trial, called the “EPIK” study, is underway 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. Xenon anticipates that the EPIK study will be completed in the first half of 2023.

Other Updates

XEN007 (active ingredient flunarizine) is a CNS-acting Cav2.1 and T-type calcium channel modulator that is being studied in treatment-resistant absence seizures. To date, a total of eight subjects have been enrolled in an investigator-led Phase 2 proof-of-concept study examining the potential clinical efficacy, safety, and tolerability of XEN007 as an adjunctive treatment in pediatric patients diagnosed with treatment-resistant absence seizures, including childhood absence epilepsy and juvenile absence epilepsy. Given the prioritized focus on the development plans for XEN1101 and XEN496, Xenon is not planning any company-sponsored XEN007 development activities in 2022.

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 adolescent patients (aged 12 years and older) with SCN8A developmental and epileptic encephalopathy (SCN8A-DEE). In addition, a second Phase 2 clinical trial has recently been initiated evaluating NBI-921352 in adult patients with focal-onset seizures. Xenon received an aggregate milestone payment of $10.0 million in the form of cash and an equity investment in September 2021 based on the regulatory approval of a clinical trial application in Europe for NBI-921352 for focal-onset seizures in adults. Upon FDA acceptance of a protocol amendment for NBI-921352 in pediatric patients (aged 2-11 years) with SCN8A-DEE, Xenon is eligible to receive an aggregate payment of $15.0 million in the form of 45% cash and a 55% equity investment in Xenon’s common shares at a 15% premium to Xenon’s 30-day trailing volume weighted average price at that time.

FX301

Flexion acquired the global rights to develop and commercialize XEN402, a Nav1.7 inhibitor also known as funapide. Flexion's FX301 consists of XEN402 formulated for extended release from a thermosensitive hydrogel. The initial development of FX301 is intended to support administration as a peripheral nerve block for control of post-operative pain. Flexion is conducting a Phase 1b proof-of-concept trial evaluating the safety and tolerability of FX301 administered as a single-dose, popliteal fossa block (a commonly used nerve block in foot and ankle-related surgeries) in patients undergoing bunionectomy. Following the decision to expand the study with an additional cohort, Flexion now anticipates having data available in the first quarter of 2022. Pursuant to the terms of the agreement, Xenon is eligible to receive certain clinical, regulatory, and commercial milestone payments, as well as future sales royalties.

Third Quarter 2021 Financial Results

Cash and cash equivalents and marketable securities as of September 30, 2021 were $249.6 million, compared to $177.0 million as of December 31, 2020. As of September 30, 2021, there were 41,412,875 common shares, 1,081,081 pre-funded warrants and 1,016,000 Series 1 Preferred Shares, which are convertible into common shares on a one-for-one basis at the option of the holder, subject to certain limitations.

Subsequent to September 30, 2021, Xenon raised additional proceeds of approximately $324.3 million, net of underwriting discounts and commissions, but before offering expenses, from the sale of 10,000,000 common shares and pre-funded warrants to purchase 1,694,915 common shares under an underwritten public offering.

Based on current assumptions, which include fully supporting the planned XEN1101 clinical development program, XEN496, and pre-clinical and discovery programs, Xenon anticipates having sufficient cash to fund operations into at least 2024, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

For the quarter ended September 30, 2021, Xenon reported total revenue of $8.1 million, compared to $6.6 million for the same period in 2020. The increase of $1.6 million was primarily attributable to the recognition of $5.3 million of milestone revenue associated with the regulatory approval of a clinical trial application in Europe for NBI-921352 for focal-onset seizures in adults under the license and collaboration agreement with Neurocrine Biosciences and an increase in research and development services revenue. These increases were partially offset by deferred revenue related to the transfer of exclusive licenses and associated technology and know-how for certain compounds under the license and collaboration agreement with Neurocrine Biosciences being fully recognized by December 2020.

Research and development expenses for the quarter ended September 30, 2021 were $18.9 million, compared to $13.0 million for the same period in 2020. The increase of $5.8 million was primarily attributable to increased spending on Xenon's clinical development product candidates XEN1101 and XEN496 and increased spending on pre-clinical, discovery and other internal programs.

General and administrative expenses for the quarter ended September 30, 2021 were $4.8 million compared to $3.2 million for the same period in 2020. The increase of $1.6 million was primarily attributable to increased stock-based compensation expense, salaries and benefits from additional headcount, and market research costs.

Other expense for the quarter ended September 30, 2021 was $0.1 million compared to other income of $0.6 million for the same period in 2020. The decrease was primarily attributable to lower interest income and a foreign exchange loss recorded in the quarter ended September 30, 2021.

Net loss for the quarter ended September 30, 2021 was $15.4 million, compared to $8.9 million for the same period in 2020. The change was primarily attributable to higher research and development and general and administrative expenses, partially offset by higher revenue as compared to the same period in 2020.

Conference Call Information

Xenon will host a conference call and live audio webcast today at 4:30 pm Eastern Time (1:30 pm Pacific Time) to discuss the third quarter results and provide a corporate update. The webcast will be broadcast live on the Investors section of the Xenon website. To participate in the call, please dial (855) 779-9075, or (631) 485-4866 for international callers, and provide conference ID number 1244439.

About Xenon Pharmaceuticals Inc.

We are 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 results from clinical trials and pre-clinical development activities, including those related to XEN496, XEN1101, and other proprietary products, and those related to NBI-921352, FX301, and other partnered product candidates; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN1101 and other proprietary and partnered product candidates; the anticipated timing of IND, or IND-equivalent, submissions and the initiation of future clinical trials for XEN496, XEN1101, and other proprietary products, and those related to NBI-921352, FX301, and other partnered candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in the XEN496, XEN1101, and other proprietary development programs; the timing and results of our interactions with regulators; anticipated enrollment in our clinical trials and the timing thereof; the progress and potential of our other ongoing development programs; the potential receipt of milestone payments and royalties from our collaborators; our expectation of having sufficient cash to fund operations into at least 2024; our efforts to enhance our intellectual property portfolio and the timing of potential publication or presentation of future clinical data. 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: the impact of the COVID-19 pandemic on our business, research and clinical development plans and timelines and results of operations, including impact on our clinical trial sites, collaborators, and contractors who act for or on our behalf, may be more severe and more prolonged than currently anticipated; clinical trials may not demonstrate safety and efficacy of any of our or our collaborators' product candidates; 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 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; regulatory agencies may be delayed in reviewing, commenting on or approving any of our or our collaborators' clinical development plans as a result of the COVID-19 pandemic, which could further delay development timelines; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; impact of new or changing laws and regulations; adverse conditions in the general domestic and global economic markets; 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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 249,625	$ 176,997
Other current assets	6,689	4,786
Other assets	8,039	7,403
Total assets	$ 264,353	$ 189,186
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 9,968	$ 10,874
Deferred revenue	2,202	3,642
Other current liabilities	686	265
Other liabilities	2,558	3,050
Total liabilities	$ 15,414	$ 17,831
Shareholders' equity	$ 248,939	$ 171,355
Total liabilities and shareholders' equity	$ 264,353	$ 189,186

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 8,124	$ 6,554	$ 14,700	$ 27,016
Operating expenses:				
Research and development	18,891	13,045	53,576	35,556
General and administrative	4,831	3,208	15,279	9,838
Total operating expenses	23,722	16,253	68,855	45,394
Loss from operations	(15,598)	(9,699)	(54,155)	(18,378)
Other income (expense)	(52)	641	347	1,621
Loss before income taxes	(15,650)	(9,058)	(53,808)	(16,757)
Income tax recovery	205	203	490	243
Net loss and comprehensive loss	(15,445)	(8,855)	(53,318)	(16,514)
Net loss attributable to preferred shareholders	(362)	(250)	(1,308)	(474)
Net loss attributable to common shareholders	$ (15,083)	$ (8,605)	$ (52,010)	$ (16,040)
Net loss per common share:				
Basic and diluted	$ (0.36)	$ (0.25)	$ (1.29)	$ (0.47)
Weighted-average common shares outstanding:				
Basic and diluted	41,193,267	34,994,944	39,599,595	34,387,986

Investor/Media Contact:
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