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 11, 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 May 11, 2021, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three months ended March 31, 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 May 11, 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: May 11, 2021

By: /s/ Ian Mortimer
Ian Mortimer
President & Chief Financial Officer

XENON

NEWS RELEASE

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

Topline Data from XEN1101 Phase 2b "X-TOLE" Clinical Trial Anticipated by End of Third Quarter of 2021

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, May 11, 2021 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2021 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "We continue to make excellent progress across both our proprietary and partnered programs. In particular, I am pleased to report that we have completed patient screening in our Phase 2b 'X-TOLE' clinical trial evaluating XEN1101 as an adjunctive treatment of focal epilepsy. With the final patients currently in baseline, we anticipate randomization to be completed in June and the release of topline data by the end of the third quarter. Additionally, we continue to initiate new sites to support ongoing patient enrollment in our Phase 3 "EPIK" study, which is evaluating XEN496 as a treatment of KCNQ2 developmental and epileptic encephalopathy.

Mr. Ian Mortimer, Xenon's President and Chief Financial Officer added, "This quarter we successfully completed a public offering – resulting in approximately $115 million in gross proceeds to Xenon – to further fortify our balance sheet. We continue to prudently manage our resources and believe we have the team and capital in place to execute on our business and clinical development goals for this year. The additional capital will enable us to continue to expand our pipeline including a company sponsored clinical study of XEN1101 in major depressive disorder."

Highlights and Anticipated Milestones

Proprietary Programs

- XEN1101 is a differentiated Kv7 potassium channel modulator being developed for the treatment of epilepsy and potentially other neurological disorders. Designed as a randomized, double-blind, placebo-controlled, multicenter study, Xenon's "X-TOLE" study is an ongoing Phase 2b clinical trial to evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered as adjunctive treatment in approximately 300 adult patients with focal epilepsy. The primary endpoint is the median percent change in monthly focal seizure frequency from baseline compared to treatment period of active versus placebo. Patient screening has now been completed with the final patients currently in the baseline period. Patient randomization is expected to be complete in June, with topline data anticipated by the end of the third quarter of 2021.

- Xenon also continues to evaluate opportunities to develop XEN1101 in neurological indications outside of epilepsy that could be well-suited to its unique mechanism of action. On March 8, 2021, Xenon announced a collaboration with the Icahn School of Medicine at Mount Sinai to facilitate an investigator-sponsored Phase 2 proof-of-concept, randomized, parallel-arm, placebo-controlled clinical trial of XEN1101 for the treatment of major depressive disorder (MDD) and anhedonia, which is expected to be initiated in the coming months. In parallel, Xenon is planning a company-sponsored clinical study in MDD supported by promising pre-clinical data with XEN1101 and 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.

- XEN496, a Kv7 potassium channel modulator, is a proprietary pediatric formulation of the active ingredient ezogabine being developed for the treatment of KCNQ2 developmental and epileptic encephalopathy (KCNQ2-DEE). Xenon has received Fast Track designation and Orphan Drug Designation for XEN496 for the treatment of seizures associated with KCNQ2-DEE from the U.S. Food and Drug Administration (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 6 years with KCNQ2-DEE.

- XEN007 (active ingredient flunarizine) is a CNS-acting Cav2.1 and T-type calcium channel modulator that is being studied in treatment-resistant childhood absence epilepsy (CAE) and potentially other neurological disorders. An investigator-led Phase 2 proof-of-concept study is ongoing to examine the potential clinical efficacy, safety, and tolerability of XEN007 as an adjunctive treatment in pediatric patients diagnosed with treatment-resistant CAE. A presentation of promising interim data collected from a small number of patients was presented at the virtual annual meeting of the American Epilepsy Society in December 2020. Xenon continues to work with the lead investigator to include additional sites and expects that topline results from a larger data set will be available in the second half of 2021, which will inform Xenon's decision anticipated this year regarding the future development of XEN007 in CAE.

Partnered Programs

- 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 clinical stage selective Nav1.6 sodium channel inhibitor with potential in SCN8A developmental and epileptic encephalopathy (SCN8A-DEE) and other forms of epilepsy. The FDA has provided feedback on an Investigational New Drug (IND) application submitted by Neurocrine Biosciences in support of a Phase 2 clinical trial in SCN8A-DEE patients. Based on this feedback, Neurocrine Biosciences anticipates initiating a Phase 2 clinical trial in adolescent patients (aged 12 years and older) with SCN8A-DEE in the third quarter of 2021, and the trial protocol will be amended to include younger pediatric patients (aged 2-11 years) with SCN8A-DEE as soon as the FDA has reviewed and approved additional non-clinical information. In parallel, Neurocrine Biosciences is advancing clinical plans to develop NBI-921352 for the treatment of adult focal epilepsy and expects to initiate a Phase 2 clinical trial in 2021. Upon IND or equivalent regulatory acceptance for NBI-921352 in adult focal epilepsy, Xenon is eligible to receive a $10.0 million milestone payment; 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 a $25.0 million milestone payment, or a $15.0 million milestone payment if the IND acceptance for adult focal epilepsy occurs first. Both milestone payments are in the form of 45% cash and a 55% equity investment in Xenon at a 15% premium to Xenon's 30-day trailing volume weighted average price at that time.

- Flexion Therapeutics 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. On March 31, 2021, Flexion announced the treatment of the first patient in 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. Flexion anticipates data from the Phase 1b trial of FX301 in late 2021. 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.

First Quarter 2021 Financial Results

Cash and cash equivalents and marketable securities as of March 31, 2021 were $274.7 million, compared to $177.0 million as of December 31, 2020. As of March 31, 2021, there were 40,962,715 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.

Based on current assumptions, which include fully supporting the planned clinical development of XEN1101, XEN496 and XEN007, Xenon anticipates having sufficient cash to fund operations into 2023, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

For the quarter ended March 31, 2021, Xenon reported total revenue of $4.4 million, compared to $7.1 million for the same period in 2020. The decrease of $2.7 million was primarily attributable to deferred revenue associated with the license and collaboration agreement with Neurocrine Biosciences being fully recognized by December 2020, partially offset by $3.0 million in milestone revenue recognized in the quarter ended March 31, 2021 in connection with the agreement with Flexion.

Research and development expenses for the quarter ended March 31, 2021 were $16.3 million, compared to $11.8 million for the same period in 2020. The increase of $4.5 million was primarily attributable to increased spending on Xenon's clinical development product candidates XEN496 and XEN1101, and, to a lesser extent, increased spending on pre-clinical, discovery and other internal programs.

General and administrative expenses for the quarter ended March 31, 2021 were $4.1 million compared to $3.3 million for the same period in 2020. The increase of $0.8 million was primarily attributable to increased stock-based compensation expense and salaries and benefits, partially offset by a decrease in human resources costs due to the timing of recruitment fees.

Other income for the quarter ended March 31, 2021 was $0.2 million compared to $0.5 million for the same period in 2020. The decrease was primarily attributable to decreased interest income, partially offset by an increase in foreign exchange gains and a decrease in interest expense due to the repayment of a term loan in May 2020.

Net loss for the quarter ended March 31, 2021 was $15.8 million, compared to $7.5 million for the same period in 2020. The change was primarily attributable to lower revenue and interest income as well as higher research and development and general and administrative expenses 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 first 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 1496232.

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, XEN007, 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, XEN007 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, XEN007, 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, XEN007 and other proprietary development programs; the timing and results of our interactions with regulators; the potential to advance certain of our product candidates directly into Phase 2 or later stage clinical trials; 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 2023; 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)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 274,703	$ 176,997
Other current assets	8,557	4,786
Other assets	7,411	7,403
Total assets	$ 290,671	$ 189,186
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	$ 7,580	$ 10,874
Deferred revenue	3,642	3,642
Other current liabilities	270	265
Other liabilities	2,902	3,050
Total liabilities	$ 14,394	$ 17,831
Shareholders' equity	$ 276,277	$ 171,355
Total liabilities and shareholders' equity	$ 290,671	$ 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 March 31, 2021	2020
Revenue	$ 4,358	$ 7,078
Operating expenses:		
Research and development	16,308	11,791
General and administrative	4,109	3,320
Total operating expenses	20,417	15,111
Loss from operations	(16,059)	(8,033)
Other income	227	548
Loss before income taxes	(15,832)	(7,485)
Income tax recovery	68	1
Net loss and comprehensive loss	(15,764)	(7,484)
Net loss attributable to preferred shareholders	(423)	(222)
Net loss attributable to common shareholders	$ (15,341)	$ (7,262)
Net loss per common share:		
Basic and diluted	$ (0.42)	$ (0.22)
Weighted-average common shares outstanding:		
Basic and diluted	36,824,619	33,189,733

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