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 21, 2020

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 May 21, 2020, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three months ended March 31, 2020. A copy of the Company's press release is attached hereto as Exhibit 99.1. The information in 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 21, 2020.

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 21, 2020

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

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports First Quarter 2020 Financial Results and Provides Corporate Update

Progress Reported in Both Proprietary and Partnered Neurology Clinical Programs
Additional FDA Feedback Supports Commencement of XEN496 Phase 3 Clinical Trial in 2020

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, May 21, 2020 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today reported its financial results for first quarter ended March 31, 2020 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "Despite the global impacts of the COVID-19 pandemic, I am pleased to report exciting progress in both our proprietary and partnered neurology programs. Over the next 12 months, we anticipate a number of important clinical and regulatory milestone events from our pipeline of innovative epilepsy treatments, and we are fortunate to have the cash runway to support our business objectives."

Dr. Pimstone continued, "Looking specifically at our proprietary epilepsy programs, we anticipate top-line data in the first half of 2021 from the XEN1101 Phase 2b "X-TOLE" clinical trial currently underway in adult focal epilepsy, and we continue to analyze other potential clinical indications for this novel Kv7 potassium channel modulator. Importantly, over the past few months, we have also made great strides in advancing XEN496, which is our proprietary pediatric formulation of ezogabine being developed for the treatment of KCNQ2 developmental and epileptic encephalopathy. A recently completed pharmacokinetic study testing XEN496 in healthy adult volunteers demonstrates that XEN496 has similar absorption and elimination curves as the historical data for immediate release ezogabine tablets. Building on this encouraging PK data, we have also received recent FDA feedback on our XEN496 program and believe we have all the necessary input to initiate a double-blind, placebo-controlled Phase 3 clinical trial in approximately 40 pediatric patients with KCNQ2-DEE later this year."

Dr. Pimstone added, "I am proud that our partnered programs also continue to advance through development providing opportunities for milestone payments. Our collaborator, Neurocrine Biosciences, expects to file an IND in mid-2020 in order to start a Phase 2 clinical trial for NBI-921352 in SCN8A-DEE pediatric patients. In addition, Flexion Therapeutics recently announced positive pre-clinical data for FX301, a Nav1.7 inhibitor being developed in an injectable long acting formulation for control of post-operative pain, and advanced FX301 into GLP toxicology studies."

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, a Phase 2b clinical trial (called the X-TOLE study) is ongoing 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. Xenon continues to review blinded data from patients who have been treated to date in the X-TOLE trial in order to assess safety, tolerability, and discontinuations. To date, XEN1101 has been well-tolerated and the rate of discontinuations from the study are below what was modeled. In addition, more than 90% of subjects to date from the double-blind portion of the trial have rolled-over into the open-label extension phase. Therefore, based on analysis of the blinded safety data to date, Xenon does not expect the need to conduct an interim analysis, which was an option that would have allowed for re-sizing of lower dose groups or for other changes to the study if tolerability was different than modeled. In the context of the COVID-19 pandemic, Xenon is in close collaboration with each of the XEN1101 clinical sites in North America and Europe, taking specific direction from their respective clinical guidelines as they relate to new patient screening and randomization. Xenon's primary efforts are focused on patients currently enrolled in the study, either in the double-blind portion or in the open-label extension portion of the study, while making other necessary amendments in the study, including minimizing any in-person patient visits and making provisions for adequate study drug supplies to patients wherever possible, to ensure that data integrity is maintained. Xenon is expanding the X-TOLE clinical trial to include new sites in both existing and new jurisdictions to support enhanced patient screening as soon as the individual clinical trial sites deem it safe to do so. Topline data is anticipated in the first half of 2021, dependent upon patient enrollment rates, which may be impacted by the COVID-19 pandemic. Xenon also continues to explore the development of XEN1101 in other neurological indications.

- XEN496, a Kv7 potassium channel modulator, is a proprietary pediatric formulation of the active ingredient ezogabine being developed for the treatment of epilepsy. The U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) and Fast Track designation for the investigation of XEN496 for the treatment of seizures related to KCNQ2 developmental and epileptic encephalopathy (KCNQ2-DEE). Published case reports where physicians have used ezogabine in infants and young children with KCNQ2-DEE suggest that ezogabine may be efficacious in this often hard-to-treat pediatric patient population. To support a planned Phase 3 clinical trial of XEN496 in patients with KCNQ2-DEE, Xenon recently completed a pharmacokinetic (PK) study testing its proprietary pediatric formulation (XEN496) in 24 healthy adult volunteers. Subjects were given a single 400 mg dose of XEN496 in either the fed or the fasted state. While the study was not designed to determine bioequivalence – given ezogabine is not available to use as a comparator – the PK profile observed for XEN496 supports the Phase 3 plans and appears to be comparable to historical PK data for immediate-release ezogabine tablets, with XEN496 showing similar absorption and elimination curves. Xenon recently received additional feedback from FDA on its Phase 3 program for XEN496. The FDA has indicated that it is acceptable to study XEN496 in infants and children up to six years old, and that a single, small pivotal trial may be considered adequate in order to demonstrate XEN496's efficacy in KCNQ2-DEE, provided the study shows evidence of a clinically meaningful benefit in patients with the intended indication. Based on the FDA's feedback, Xenon anticipates initiating a randomized, double-blind, placebo-controlled Phase 3 clinical trial to evaluate the clinical efficacy, safety, and tolerability of XEN496 in approximately 40 pediatric patients with KCNQ2-DEE. The primary endpoint is expected to be the median percent change in seizure frequency from baseline compared to treatment period of active versus placebo. The XEN496 Phase 3 clinical trial is expected to be initiated in 2020.

- XEN007 (active ingredient flunarizine) is a CNS-acting calcium channel modulator that modulates Cav2.1 and T-type calcium channels. Other reported mechanisms include dopamine, histamine, and serotonin inhibition. A physician-led, Phase 2 proof-of-concept study is examining the potential clinical efficacy, safety, and tolerability of XEN007 as an adjunctive treatment in pediatric patients diagnosed with treatment-resistant childhood absence epilepsy, or CAE. Results from this Phase 2 study are expected in 2020, dependent upon patient enrollment rates given the ongoing COVID-19 pandemic. Depending on the final results, CAE may represent a potential orphan indication for future development of XEN007.

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. Neurocrine Biosciences has indicated that it anticipates filing an IND application with the FDA in mid-2020 in order to start a Phase 2 clinical trial in SCN8A-DEE patients in the second half of 2020. Xenon is eligible to receive up to $25 million upon the FDA acceptance of an IND for NBI-921352, with 55% of the amount in the form of an equity investment in Xenon at a 15% premium to Xenon's 30-day trailing volume weighted average price at that time.

- Flexion Therapeutics, Inc. acquired the global rights to develop and commercialize XEN402, a Nav1.7 inhibitor also known as funapide. Flexion's pre-clinical 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. In April 2020, Flexion presented new animal data in an ePoster presentation on the American Society of Regional Anesthesia and Acute Pain website that showed FX301 provided sustained, post-operative analgesic effect with no impairment in motor function compared to liposomal bupivacaine and placebo. In addition, high local concentrations of funapide, the active ingredient in FX301, were measured at the site of administration for the duration of the study which is consistent with the creation of a depot providing controlled drug release. A GLP toxicology study with FX301 commenced in April 2020, triggering a $0.5 million milestone payment to Xenon. Flexion anticipates initiating human clinical trials in 2021.

First Quarter 2020 Financial Results

Cash and cash equivalents and marketable securities as of March 31, 2020 were $229.7 million, compared to $141.4 million as of December 31, 2019. There were 34,956,272 common shares 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, outstanding as of March 31, 2020.

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 2022, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

For the quarter ended March 31, 2020, Xenon reported total revenue of $7.1 million related to recognition of $5.8 million of deferred revenue as well as $1.2 million for research and development services from the license and collaboration agreement with Neurocrine Biosciences. There was no revenue recognized for the same period in 2019.

Research and development expenses for the quarter ended March 31, 2020 were $11.8 million, compared to $9.1 million for the same period in 2019. The increase of $2.7 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 program expenses. This was partially offset by decreased spending on XEN901, now known as NBI-921352, as clinical development costs are borne by Neurocrine Biosciences.

General and administrative expenses for the quarter ended March 31, 2020 were $3.3 million, compared to $2.6 million for the same period in 2019. The increase of $0.7 million was primarily attributable to increased stock-based compensation expense, salaries and benefits, insurance premiums and business development expenses, partially offset by a decrease in legal fees for intellectual property protection.

Other income for the quarter ended March 31, 2020 was $0.5 million, consistent with $0.5 million for the same period in 2019.

Net loss for the quarter ended March 31, 2020 was $7.5 million, compared to $11.3 million for the same period in 2019. The change was primarily attributable to revenue recognized in the quarter ended March 31, 2020 pursuant to the agreement with Neurocrine Biosciences, partially offset by an increase in research and development and general and administrative expenses as compared to the same period in 2019.

Conference Call Information

Xenon will host a conference call and live audio webcast today at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss its first quarter 2020 financial results and to provide a business update. To participate in the call, please dial (855) 779-9075, or (631) 485-4866 for international callers, and provide conference ID number 8385218. The webcast will be broadcast live on the “Investors” section of Xenon's website at www.xenon-pharma.com and will be available for replay following the call for 30 days.

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 anticipated impact and timing of the COVID-19 pandemic on our business, research and clinical development plans and timelines and results of operations; 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, FX-301, 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, FX-301, 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 2022; 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 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 not permit certain of our product candidates to advance directly into a Phase 2 or later clinical trials, 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; 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, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 229,671	$ 141,358
Other current assets	4,199	3,508
Other assets	3,173	2,831
Total assets	$ 237,043	$ 147,697
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	8,084	8,818
Deferred revenue	24,608	29,743
Term loan	15,676	4,650
Other current liabilities	156	168
Other liabilities	541	12,341
Total liabilities	$ 49,065	$ 55,720
Shareholders' equity	$ 187,978	$ 91,977
Total liabilities and shareholders' equity	$ 237,043	$ 147,697

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, 2020	2019
Revenue	$ 7,078	—
Operating expenses:		
Research and development	$ 11,791	$ 9,137
General and administrative	3,320	2,621
Total operating expenses	15,111	11,758
Loss from operations	(8,033)	(11,758)
Other income	548	454
Loss before income taxes	(7,485)	(11,304)
Income tax (expense) recovery	1	(37)
Net loss and comprehensive loss	(7,484)	(11,341)
Net loss attributable to preferred shareholders	(222)	(430)
Net loss attributable to common shareholders	$ (7,262)	$ (10,911)
Net loss per common share:		
Basic and diluted	$ (0.22)	$ (0.42)
Weighted-average common shares outstanding:		
Basic and diluted	33,189,733	25,753,836

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