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): March 9, 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		**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 March 9, 2020, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the year ended December 31, 2019. 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 March 9, 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: March 9, 2020

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

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports 2019 Financial Results and Provides Corporate Update

Xenon's Robust Neurology Pipeline of Proprietary and Partnered Programs Advances with Multiple Important Milestone Opportunities Anticipated in 2020

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, March 9, 2020 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today reported its financial results for the year ended December 31, 2019 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "We are focused on developing multiple innovative products for the treatment of epilepsy and believe that Xenon has one of the most exciting epilepsy pipelines currently in development. Bolstered by a strong balance sheet, Xenon is entering a 'data-rich' period with the expectation that a number of our product candidates will either enter mid to late stage clinical trials or generate important clinical data in 2020."

Dr. Pimstone continued, "Within our proprietary programs, we anticipate top-line data from our ongoing XEN1101 Phase 2b clinical trial in adult focal epilepsy later this year, and we continue to analyze other potential clinical indications for this novel Kv7 potassium channel modulator. We expect FDA feedback on our Phase 3 protocol for XEN496 early within the second quarter, and expect to initiate a Phase 3 pivotal trial with XEN496 in patients with KCNQ2-DEE, a severe and rare form of pediatric epilepsy, in 2020. In addition, results from the physician-led Phase 2 study in treatment-resistant childhood absence epilepsy, also expected in 2020, will help shape our development strategy for XEN007."

Dr. Pimstone added, "Our partnered programs are also expected to make progress in the coming months, providing opportunities to earn milestone payments as they advance through development. Our collaborator, Neurocrine Biosciences, expects to file an IND in mid-2020 in order to start a Phase 2 clinical trial for NBI-921352 (formerly XEN901) in SCN8A-DEE pediatric patients, and Flexion continues its development planning for FX301 and anticipates initiating clinical trials in 2021."

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 underway 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 enrollment for this XEN1101 Phase 2b clinical trial is ongoing in the United States, Canada and Europe. Long term six-and nine-month toxicology studies have now been completed, providing support for the 12-month open label extension for patients enrolled in the Phase 2b clinical trial. Depending upon the rate of enrollment, top-line results are anticipated in the second half of 2020. Xenon continues to explore the development of XEN1101 in other neurological indications.

- XEN496 (active ingredient ezogabine) is a Kv7 potassium channel modulator being developed by Xenon. The U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) for XEN496 as a treatment of KCNQ2 developmental and epileptic encephalopathy (KCNQ2-DEE). The FDA previously indicated that it is acceptable to study XEN496 in infants and children up to four 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. In December 2019, Xenon filed an Investigational New Drug (IND) application with the FDA related to a pharmacokinetic (PK) study testing our proprietary pediatric formulation of ezogabine (XEN496) in healthy adult volunteers. In January 2020, Xenon received permission to proceed with the study, which is now ongoing and expected to be completed in the first quarter of 2020. In parallel, feedback from correspondence with the FDA regarding the Phase 3 clinical trial design is expected early in the second quarter of 2020. A Phase 3 clinical trial in KCNQ2-DEE is anticipated to start 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 ongoing to examine the potential clinical efficacy, safety, and tolerability of XEN007 as an adjunctive treatment in pediatric patients diagnosed with treatment-resistant childhood absence epilepsy. Results from this Phase 2 study are expected in 2020. Depending on the results from the study, CAE may represent a potential orphan indication for future development of XEN007.

Partnered Programs

- Xenon has an ongoing collaboration with Neurocrine Biosciences, Inc. 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 for epilepsy. In addition, Neurocrine Biosciences gained an exclusive license to pre-clinical compounds for development, including selective Nav1.6 inhibitors and dual Nav1.2/1.6 inhibitors. The agreement also included a multi-year research collaboration to discover, identify and develop additional novel Nav1.6 and Nav1.2/1.6 inhibitors. Neurocrine Biosciences anticipates filing an IND application with the FDA in mid-2020 in order to start a Phase 2 clinical trial in SCN8A developmental and epileptic encephalopathy (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., has acquired the global rights to develop and commercialize FX301 (formerly XEN402), a Nav1.7 inhibitor. Flexion's pre-clinical FX301 program 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 has indicated that it anticipates initiating FX301 clinical trials in 2021.

2019 Financial Results

Cash and cash equivalents and marketable securities as of December 31, 2019 were $141.4 million, compared to $119.3 million as of December 31, 2018. There were 28,139,228 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 December 31, 2019.

Included in cash and cash equivalents and marketable securities as of December 31, 2019, are net proceeds of $10.7 million from the sale of 805,643 common shares under Xenon's November 2019 at-the-market equity offering, or ATM, as well as an upfront fee of $50.0 million pursuant to the terms of Xenon's license and collaboration agreement with Neurocrine Biosciences which included a $30.0 million payment in cash and a $20.0 million equity investment in 1,408,847 common shares of Xenon. Subsequent to December 31, 2019, Xenon has raised additional net proceeds of approximately $102.8 million, net of underwriting discounts and commissions, but before offering expenses, from the sale of 6,759,187 common shares under its November 2019 ATM equity offering and an underwritten public offering.

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 year ended December 31, 2019, Xenon reported total revenue of $6.8 million, whereas no revenue was recognized for the same period in 2018. In 2019, revenue of $3.5 million was recognized in connection with the agreement entered into in September 2019 with Flexion for the global rights to develop and commercialize XEN402. In addition, revenue of $3.3 million was recognized for the transfer of licenses and related technology and know-how as well as for research and development services provided in 2019 under the license and collaboration agreement with Neurocrine Biosciences.

Research and development expenses for the year ended December 31, 2019 were $38.8 million, compared to $23.6 million for the same period in 2018. The increase of $15.2 million was primarily attributable to increased spending on Xenon's clinical development product candidates. Future clinical developments costs associated with the development of product candidates under the Neurocrine Biosciences collaboration including XEN901, now known as NBI-921352, will be borne by Neurocrine Biosciences.

General and administrative expenses for the year ended December 31, 2019 were $10.8 million, compared to $8.4 million for the same period in 2018. The increase of $2.4 million was primarily attributable to increased salaries and benefits, legal expenses for intellectual property protection, business development expenses and recruitment fees.

Other operating expenses were nil in the year ended December 31, 2019, compared to $6.0 million for the same period in 2018. The decrease is due to a one-time payment to Valeant Pharmaceuticals Luxembourg S.a.r.l. and Valeant Pharmaceuticals Ireland Limited, together, Bausch Health, for the buy-out of all future milestone payments and royalties owed to Bausch Health with respect to the XEN1101 program.

Other income for the year ended December 31, 2019 was $1.2 million, compared to $3.5 million for the same period in 2018. The decrease of $2.3 million was primarily driven by a $4.4 million gain on the termination of the collaboration agreement with Teva Pharmaceuticals International GmbH and Teva Canada Limited in March 2018, partially offset by a change in foreign exchange gains and losses and interest income earned on Xenon's cash and investment balances.

Net loss for the year ended December 31, 2019 was $41.6 million, compared to $34.5 million for the same period in 2018. The change was primarily attributable to higher research and development expenses as compared to the same period in 2018, partially offset by revenue recognized in the year pursuant to the agreements with Flexion and Neurocrine Biosciences and the one-time payment to Bausch Health with respect to the XEN1101 program which occurred in 2018.

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 2019 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 8487337. 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 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: 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; 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)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 141,358	$ 119,306
Other current assets	3,508	2,026
Other assets	2,831	1,096
Total assets	$ 147,697	$ 122,428
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	8,818	4,119
Deferred revenue	29,743	—
Term loan	4,650	—
Other current liabilities	168	—
Other liabilities	12,341	15,014
Total liabilities	$ 55,720	$ 19,133
Shareholders' equity	$ 91,977	$ 103,295
Total liabilities and shareholders' equity	$ 147,697	$ 122,428

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

	Year Ended December 31, 2019	2018
Revenue	$ 6,829	$ —
Operating expenses:		
Research and development	38,845	23,634
General and administrative	10,803	8,406
Buy-out of future milestones and royalties	—	6,000
Total operating expenses	49,648	38,040
Loss from operations	(42,819)	(38,040)
Other income	1,201	3,519
Loss before income taxes	(41,618)	(34,521)
Income tax recovery	23	24
Net loss and comprehensive loss	(41,595)	(34,497)
Net loss attributable to preferred shareholders	(1,568)	(2,881)
Net loss attributable to common shareholders	$ (40,027)	$ (31,616)
Net loss per common share:		
Basic and diluted	$ (1.54)	$ (1.63)
Weighted-average common shares outstanding:		
Basic and diluted	25,939,405	19,425,711

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