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 6, 2019

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 Instructions 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))

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 6, 2019, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the year ended December 31, 2018. 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 6, 2019.

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 6, 2019

By: /s/ *Ian Mortimer*

Ian Mortimer
President & Chief Financial Officer

Exhibit 99.1

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports 2018 Financial Results and Provides Corporate Update

Multiple Neurology-Focused Products Anticipated to be in Phase 2 or Later Stage Development in 2019

Global XEN1101 Phase 2b Clinical Trial Underway with Data Anticipated in Second Half of 2020

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, March 6, 2019 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today reported its financial results for the year ended December 31, 2018 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "2018 was a pivotal year for Xenon as we built out our neurology pipeline and advanced multiple CNS product candidates using a variety of development strategies, including a 'precision medicine' approach to address rare pediatric disorders. This foundational work has resulted in four distinct therapeutic candidates – XEN496, XEN1101, XEN901 and XEN007 – that are expected to be in Phase 2 or later stage development this year."

Dr. Pimstone continued, "We have taken great care to create a diverse portfolio of therapeutic candidates, with a common focus on addressing neurological disorders. In 2019, we anticipate initiating a Phase 3 clinical trial for XEN496 for the treatment of KCNQ2 epilepsy; advancing our ongoing XEN1101 Phase 2b clinical trial in adult focal epilepsy; initiating a Phase 2 clinical trial for XEN901 in either a pediatric or adult epilepsy indication depending on regulatory feedback; and initiating a Phase 2 clinical trial for XEN007 in an orphan neurological indication. We intend to achieve these development milestones with the support of a strong balance sheet that funds our portfolio into 2021."

Achievements and Anticipated Milestones

- XEN496 (active ingredient ezogabine) is a Kv7 potassium channel modulator being developed for the treatment of KCNQ2 epileptic encephalopathy (KCNQ2-EE). Ezogabine was previously approved by the U.S. Food and Drug Administration (FDA), as an anti-epileptic drug (AED) as an adjunctive treatment for adults with focal seizures with or without secondary generalization. Xenon received orphan drug designation (ODD) from the FDA for XEN496 as a treatment of KCNQ2-EE. A steering committee made up of key opinion leaders in the KCNQ2-EE and pediatric epilepsy fields has been established to help guide the clinical development of XEN496. In response to Xenon's pre-IND briefing package submission, the FDA indicated that it was acceptable to study XEN496 in infants and children up to 4 years old, and that a single pivotal trial in approximately 20 patients may be considered adequate in order to demonstrate XEN496's efficacy in KCNQ2-EE. Xenon is currently finalizing a pediatric-specific formulation to complete pre-clinical formulation testing with a final drug product expected in the second quarter of 2019. Xenon expects to file an Investigational New Drug (IND) application in the third quarter of 2019, and, based on regulatory feedback, Xenon expects to initiate a Phase 3 clinical trial thereafter. This timeline is based on the assumption that the testing of the new XEN496 pediatric formulation in healthy adult volunteers will not be a regulatory requirement prior to initiating a Phase 3 clinical trial.

- XEN1101 is a differentiated Kv7 potassium channel modulator being developed for the treatment of epilepsy and potentially other neurological disorders. Xenon announced final data from its XEN1101 Phase 1 clinical trial and the related transcranial magnetic stimulation (TMS) studies at the American Epilepsy Society (AES) Annual Meeting in December 2018. Based on the encouraging Phase 1 and Phase 1b TMS data, Xenon has initiated a Phase 2b clinical trial in adult patients with focal epilepsy. The Phase 2b clinical trial is designed as a randomized, double-blind, placebo-controlled, multicenter study to evaluate the clinical efficacy, safety and tolerability of XEN1101 administered as adjunctive treatment in adult patients with focal epilepsy. Approximately 300 patients will be randomized in a blinded manner to one of three active treatment groups or placebo in a 2:1:1:2 fashion (XEN1101 25 mg : 20 mg : 10 mg : Placebo). The primary endpoint is the median percent change in monthly focal seizure frequency from baseline compared to treatment period of active versus placebo. An IND application for XEN1101 has been accepted by the FDA, and site selection and patient enrollment are now underway for the XEN1101 Phase 2b clinical trial in the United States, Canada and Europe. Depending upon the rate of enrollment, top-line results from the XEN1101 Phase 2b clinical trial are anticipated in the second half of 2020.

- XEN901 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed for the treatment of epilepsy. Xenon announced results from its XEN901 Phase 1 clinical trial and the related pilot TMS study at the AES Annual Meeting in December 2018. The next steps for XEN901 include continued planning for Phase 2 or later stage clinical development to evaluate XEN901 as a treatment for adult focal seizures or for rare, pediatric forms of epilepsy, including SCN8A Epileptic Encephalopathy (SCN8A-EE) patients, depending on feedback from planned discussions with regulatory agencies. Xenon expects to receive feedback on the requirements to advance XEN901 into pediatric SCN8A-EE patients in the second quarter of 2019, and pediatric formulation development and juvenile toxicology studies are underway to support future pediatric development activities.

- 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. Flunarizine is available in certain countries outside of the United States, and has been reported to have clinical benefit in treating migraine and other neurological disorders, including hemiplegic migraine (HM), alternating hemiplegia of childhood (AHC), vertigo, and as adjunctive treatment in certain epilepsies. The FDA has granted a rare pediatric disease (RPD) designation for the treatment of AHC with XEN007. Xenon previously received ODD from the FDA for XEN007 for the treatment of both AHC and HM. In addition, Xenon has entered into key exclusive licensing agreements in order to access regulatory files and drug product manufacturing, both of which may enable advanced clinical development of XEN007. Various development strategies for XEN007 are under consideration, including the support of at least one Phase 2 (or later stage) clinical trial in an orphan neurological indication, with initiation anticipated in 2019.

2018 Financial Results

Cash and cash equivalents and marketable securities as of December 31, 2018 were $119.3 million, compared to $43.7 million as of December 31, 2017. There were 25,750,721 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, 2018.

Based on current assumptions, which include fully supporting the planned clinical development of XEN496, XEN1101, XEN901 and XEN007, Xenon anticipates having sufficient cash to fund operations into 2021, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

Research and development expenses for the year ended December 31, 2018 were $23.6 million, compared to $25.6 million for the same period in 2017. The decrease of $2.0 million was primarily attributable to decreased spending on pre-clinical, discovery and other internal program expenses, and XEN801, a product candidate which is no longer being developed. These decreases were partially offset by increased spending on the XEN1101, XEN496, and XEN901 product candidates as well as increased spending on pre-clinical and discovery expenses supporting the Nav1.6 program.

General and administrative expenses for the year ended December 31, 2018 were $8.4 million, compared to $7.3 million for the same period in 2017. The increase of $1.1 million was primarily attributable to increased stock-based compensation expense, salaries and benefits, legal expenses and recruitment fees.

Other operating expenses for the year ended December 31, 2018 were $6.0 million 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, 2018 was $3.5 million, compared to $1.9 million for the same period in 2017. The increase of $1.6 million was primarily driven by a one-time gain of $4.4 million on the termination of the collaboration agreement with Teva Pharmaceuticals International GmbH, along with Teva Canada Limited (together, Teva), resulting from the cancellation of 1,000,000 common shares of Xenon that were owned by Teva, partially offset by interest expense incurred on a term loan and a change in foreign exchange gains and losses arising largely from the translation of cash and cash equivalents and marketable securities denominated in Canadian dollars to U.S. dollars.

Net loss for the year ended December 31, 2018 was $34.5 million, compared to $30.7 million for the same period in 2017. The change was primarily attributable to the one-time payment to Bausch Health with respect to the XEN1101 program and higher general and administrative expenses, partially offset by an increase in other income and lower research and development expenses.

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 2018 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 1545448. 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, including rare central nervous system (CNS) conditions. 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 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. These forward-looking statements and supporting assumptions 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, XEN901, XEN1101, XEN007 and our other product candidates; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN901, XEN1101, XEN007 and our other product candidates; the anticipated timing of IND, or IND equivalent, submissions and the initiation of future clinical trials for XEN496, XEN901, XEN1101, XEN007 and our other product candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in the XEN496, XEN901, XEN1101, XEN007 and other 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; the progress and potential of our other ongoing development programs; the sufficiency of our cash to fund operations into 2021; 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 119,306	$ 43,667
Other current assets	2,131	1,154
Other assets	991	1,300
Total assets	$ 122,428	$ 46,121
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	4,119	3,383
Loan payable, current portion	—	700
Loan payable, long-term	15,014	6,104
Total liabilities	$ 19,133	$ 10,187
Shareholders' equity	$ 103,295	$ 35,934
Total liabilities and shareholders' equity	$ 122,428	$ 46,121

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, 2018	2017
Revenue:		
Collaboration revenue	$ —	$ 311
	—	311
Operating expenses:		
Research and development	23,634	25,573
General and administrative	8,382	7,313
Buy-out of future milestones and royalties	6,000	—
Total operating expenses	38,016	32,886
Loss from operations	(38,016)	(32,575)
Other income	3,519	1,871
Net loss	(34,497)	(30,704)
Net loss attributable to preferred shareholders	(2,881)	—
Net loss attributable to common shareholders	$ (31,616)	$ (30,704)
Net loss per common share:		
Basic	$ (1.63)	$ (1.71)
Diluted	$ (1.63)	$ (1.72)
Weighted-average common shares outstanding:		
Basic	19,425,711	17,985,061
Diluted	19,425,711	18,001,759

Investor/Media Contact:
Jodi Regts
Xenon Pharmaceuticals Inc.
Phone: 604.484.3353
Email: investors@xenon-pharma.com