

**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 7, 2019

XENON PHARMACEUTICALS INC.

(Exact name of Registrant as Specified in Its Charter)

Canada
(State or Other Jurisdiction
of Incorporation)

001-36687

(Commission File Number)

98-0661854
(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))

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.

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 Global Market |

Item 2.02 Results of Operations and Financial Condition

On May 7, 2019, Xenon Pharmaceuticals Inc. (the “Company”) announced via press release the Company’s financial results for the three months ended March 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 May 7, 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: May 7, 2019

By: _____ */s/ Ian Mortimer*

Ian Mortimer
President & Chief Financial Officer

Xenon Pharmaceuticals Reports First Quarter 2019 Financial Results and Provides Corporate Update***Company Reports Advancements in Neurology-Focused Pipeline and Anticipates Multiple Products in Phase 2 or Later Stage Development this Year******Conference Call at 4:30 pm ET Today***

BURNABY, British Columbia, May 7, 2019 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today reported its financial results for the first quarter ended March 31, 2019 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "We continue to make significant progress advancing our robust, novel pipeline comprised of neurology-focused product candidates, including XEN496, XEN1101, XEN901, and XEN007. Supported by a strong balance sheet, we are executing our clinical development plans with the goal of having multiple products in Phase 2 or later stage development this year. Some important anticipated milestone events include: initiating a Phase 3 clinical trial for XEN496 for the treatment of KCNQ2 epilepsy; further advancing our ongoing XEN1101 Phase 2b clinical trial in adult focal epilepsy; and initiating a Phase 2 clinical trial for XEN901 in either a pediatric or adult epilepsy indication depending on regulatory feedback. In addition, we expect to initiate a Phase 2, or later stage, clinical trial for XEN007 in an orphan neurological indication."

Achievements and Anticipated Milestones

- XEN496 (active ingredient ezogabine) is a Kv7 potassium channel modulator being developed by Xenon. The FDA has granted orphan drug designation (ODD) for XEN496 as a treatment of KCNQ2 epileptic encephalopathy (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 is planning to test the XEN496 pediatric formulation in a study of healthy adult volunteers, which is expected to be initiated in the third quarter of 2019. Xenon expects to file an Investigational New Drug (IND) application in the fourth quarter of 2019 to initiate a Phase 3 clinical trial in KCNQ2-EE. The FDA has indicated that it is 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.
 - XEN1101 is a differentiated Kv7 potassium channel modulator being developed for the treatment of epilepsy and potentially other neurological disorders. Xenon has initiated a Phase 2b clinical trial, which 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 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. 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. Results from a XEN901 Phase 1 clinical trial and related pilot TMS study were announced in December 2018. The next steps for XEN901 include continued planning for Phase 2 or later clinical development to evaluate XEN901 as a treatment for rare, pediatric forms of epilepsy, including SCN8A epileptic encephalopathy (SCN8A-EE) or adult focal seizures, depending on feedback from regulatory agencies. Xenon expects to receive feedback on the requirements to advance XEN901 into pediatric SCN8A-EE patients in the second quarter of 2019. In order to support future pediatric development plans, juvenile toxicology studies and pediatric formulation work are underway.
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- 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. Available in certain countries outside of the United States, flunarizine 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 an adjunctive treatment in certain epilepsies, including childhood absence epilepsy. The FDA granted a rare pediatric disease designation for the treatment of AHC with XEN007, and previously granted ODD for XEN007 as a treatment of both AHC and HM. To support the advanced clinical development of XEN007, Xenon has entered into key licensing and manufacturing agreements. 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.

First Quarter 2019 Financial Results

Cash and cash equivalents and marketable securities as of March 31, 2019 were \$110.4 million, compared to \$119.3 million as of December 31, 2018. There were 25,771,954 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, 2019.

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 quarter ended March 31, 2019 were \$9.1 million, compared to \$5.6 million for the same period in 2018. The increase of \$3.6 million was primarily attributable to increased spending on the XEN1101, XEN901, and XEN496 product candidates. These increases were partially offset by decreased spending on pre-clinical, discovery and other internal program expenses.

General and administrative expenses for the quarter ended March 31, 2019 were \$2.6 million, compared to \$2.2 million for the same period in 2018. The increase of \$0.4 million was primarily attributable to increased legal expenses for intellectual property protection and business development expenses.

Other income for the quarter ended March 31, 2019 was \$0.5 million, compared to \$4.1 million for the same period in 2018. The decrease of \$3.6 million was primarily driven by a one-time gain of \$4.4 million recognized in March 2018 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 an increase in interest income 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 quarter ended March 31, 2019 was \$11.3 million, compared to \$3.8 million for the same period in 2018. The change was primarily attributable to the decrease in other income and higher 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 first quarter 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 7268384. 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” and the Xenon logo are registered trademarks or trademarks of Xenon Pharmaceuticals Inc. in various jurisdictions. All other trademarks belong to their respective owner.

XENON PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheets
(Expressed in thousands of U.S. dollars)

| | March 31, 2019 | December 31, 2018 |
|---|-------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents and marketable securities | \$ 110,429 | \$ 119,306 |
| Other current assets | 1,618 | 2,026 |
| Other assets | 2,503 | 1,096 |
| Total assets | \$ 114,550 | \$ 122,428 |
| Liabilities | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | 5,794 | 4,119 |
| Other current liabilities | 582 | — |
| Other liabilities | 15,861 | 15,014 |
| Total liabilities | \$ 22,237 | \$ 19,133 |
| Shareholders' equity | \$ 92,313 | \$ 103,295 |
| Total liabilities and shareholders' equity | \$ 114,550 | \$ 122,428 |

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, | |
|---|------------------------------|------------|
| | 2019 | 2018 |
| Operating expenses: | | |
| Research and development | \$ 9,137 | \$ 5,568 |
| General and administrative | 2,621 | 2,238 |
| Total operating expenses | 11,758 | 7,806 |
| Loss from operations | (11,758) | (7,806) |
| Other income | 454 | 4,063 |
| Loss before income taxes | (11,304) | (3,743) |
| Income tax expense | (37) | (12) |
| Net loss and comprehensive loss | (11,341) | (3,755) |
| Net loss attributable to preferred shareholders | (430) | (33) |
| Net loss attributable to common shareholders | \$ (10,911) | \$ (3,722) |
| Net loss per common share: | | |
| Basic | \$ (0.42) | \$ (0.21) |
| Diluted | \$ (0.42) | \$ (0.21) |
| Weighted-average common shares outstanding: | | |
| Basic | 25,753,836 | 17,804,421 |
| Diluted | 25,753,836 | 17,804,421 |

Investor/Media Contact:

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