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): August 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 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 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 August 6, 2019, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three and six month periods ended June 30, 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 August 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: August 6, 2019

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

XENON

NEWS RELEASE

Xenon Pharmaceuticals Reports Second Quarter 2019 Financial Results and Provides Corporate Update

Anticipate Testing of New Pediatric Formulations of XEN496 and XEN901 in Adults in Third Quarter, Followed by IND Submissions to Initiate Pediatric Clinical Trials in KCNQ2 and SCN8A Developmental and Epileptic Encephalopathies

Conference Call at 4:30 pm ET Today

BURNABY, British Columbia, August 6, 2019 – Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today reported its financial results for the second quarter ended June 30, 2019 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "Our neurology-focused product candidates, including XEN496, XEN1101, XEN901, and XEN007, continue to advance in development, supporting our goal to have multiple products in Phase 2 or later stage clinical trials this year. Site initiations and patient enrollment are underway in our XEN1101 Phase 2b clinical trial in adult focal epilepsy. We have completed development of a new, pediatric-specific formulation of ezogabine known as XEN496. We anticipate testing this new formulation in healthy adult volunteers, prior to filing an IND application in order to initiate a Phase 3 clinical trial in patients with KCNQ2 developmental and epileptic encephalopathy. Following a similar path as XEN496, we have also completed the development of a pediatric-specific formulation of XEN901 that we plan to test in healthy adults prior to filing an IND submission for a proposed Phase 2 or 3 clinical trial in patients with SCN8A epileptic encephalopathy."

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 developmental and epileptic encephalopathy (KCNQ2-DEE). Xenon has developed XEN496 as a pediatric-specific, granule formulation to be packaged as single-dose sachets, and plans to test XEN496 in healthy adult volunteers in a pharmacokinetic (PK) study that we expect to initiate in the third quarter of 2019. Xenon expects to file an Investigational New Drug (IND) application in the fourth quarter of 2019 in order to initiate a Phase 3 clinical trial in KCNQ2-DEE. The FDA has indicated that it is acceptable to study XEN496 in infants and children up to 4 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.

- 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 for this XEN1101 Phase 2b clinical trial are currently underway in the United States, Canada and Europe. Long term 6-and 9-month toxicology studies are underway and are expected to support the planned 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.

- XEN901 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed for the treatment of epilepsy. A XEN901 Phase 1 clinical trial has been completed. Xenon received important feedback from the FDA regarding the requirements for clinical development of our XEN901 program, including feedback to support advancing XEN901 directly into a pediatric clinical trial examining its efficacy in pediatric patients with SCN8A epileptic encephalopathy (SCN8A-EE). Xenon has recently completed the development of a pediatric-specific granule formulation of XEN901 and is in the process of completing juvenile toxicology studies to support pediatric development activities. Xenon intends to run a PK study in healthy adult volunteers with the new XEN901 pediatric formulation beginning in the third quarter of this year, followed by an IND submission to start a proposed Phase 2 or 3 clinical trial in SCN8A-EE patients.

- 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 (CAE). 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, and various development strategies for XEN007 are under consideration. In the near term, Xenon anticipates the initiation of a physician-led Phase 2 open label study examining the potential clinical efficacy, safety, and tolerability of XEN007 as an adjunctive treatment of CAE.

Second Quarter 2019 Financial Results

Cash and cash equivalents and marketable securities as of June 30, 2019 were $101.8 million, compared to $119.3 million as of December 31, 2018. There were 25,775,056 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 June 30, 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 June 30, 2019 were $8.2 million, compared to $5.4 million for the same period in 2018. The increase of $2.8 million was primarily attributable to increased spending on XEN1101 and XEN496 product candidates as well as increased spending on pre-clinical, discovery and other internal program expenses.

General and administrative expenses for the quarter ended June 30, 2019 were $2.3 million and did not change significantly as compared to $2.2 million for the same period in 2018.

Other income for the quarter ended June 30, 2019 was $0.5 million, compared to other expenses of $0.2 million for the same period in 2018. The change of $0.7 million was primarily driven 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 June 30, 2019 was $10.0 million, compared to $7.8 million for the same period in 2018. The change was primarily attributable to higher research and development expenses, partially offset by an increase in other income.

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 second 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 5946498. 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)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents and marketable securities	$ 101,801	$ 119,306
Other current assets	1,524	2,026
Other assets	2,567	1,096
Total assets	$ 105,892	$ 122,428
Liabilities		
Current liabilities:		
Accounts payable and accrued expenses	6,676	4,119
Other current liabilities	2,654	—
Other liabilities	13,775	15,014
Total liabilities	$ 23,105	$ 19,133
Shareholders' equity	$ 82,787	$ 103,295
Total liabilities and shareholders' equity	$ 105,892	$ 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 8,205	$ 5,416	$ 17,342	$ 10,984
General and administrative	2,307	2,178	4,928	4,416
Total operating expenses	10,512	7,594	22,270	15,400
Loss from operations	(10,512)	(7,594)	(22,270)	(15,400)
Other income (loss)	476	(215)	930	3,848
Loss before income taxes	(10,036)	(7,809)	(21,340)	(11,552)
Income tax (expense) recovery	29	8	(8)	(4)
Net loss and comprehensive loss	(10,007)	(7,801)	(21,348)	(11,556)
Net loss attributable to preferred shareholders	(380)	(1,303)	(810)	(996)
Net loss attributable to common shareholders	$ (9,627)	$ (6,498)	$ (20,538)	$ (10,560)
Net loss per common share:				
Basic and diluted	$ (0.37)	$ (0.45)	$ (0.80)	$ (0.66)
Weighted-average common shares outstanding:				
Basic	25,773,879	14,306,491	25,763,858	16,055,456
Diluted	25,775,559	14,306,491	25,763,858	16,055,456

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