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 3, 2016

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 V5G 4W8 Canada

(Address of principal executive offices including zip code)

(604) 484-3300

(Registrant's telephone number, including area code)

(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))

Item 2.02 Results of Operations and Financial Condition

On August 3, 2016, Xenon Pharmaceuticals Inc. (the "Company") announced via press release the Company's financial results for the three and six month periods ended June 30, 2016. 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

<u>Number</u> <u>Description</u>

99.1 Press Release issued by Xenon Pharmaceuticals Inc. dated August 3, 2016.

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.

Date: August 3, 2016 XENON PHARMACEUTICALS INC.

By: <u>/s/ Ian Mortimer</u> Ian Mortimer Chief Financial Officer and Chief Operating Officer

EXHIBIT INDEX

Exhibit <u>Number</u> <u>Description</u>

99.1 Press Release issued by Xenon Pharmaceuticals Inc. dated August 3, 2016.



Xenon Pharmaceuticals Reports Second Quarter 2016 Financial Results and Provides Corporate Update

BURNABY, British Columbia, August 3, 2016 -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical-stage biopharmaceutical company, today reported its financial results for the quarter ended June 30, 2016 and provided a corporate update.

Dr. Simon Pimstone, Xenon's President and Chief Executive Officer, said, "Our proprietary programs continue to advance as we make strong progress towards our corporate milestones. We have now surpassed 50% enrollment in our XEN801 Phase 2 clinical trial in patients with moderate to severe acne, and based on updated projections, we anticipate a read out of top-line results in the first quarter of 2017. Within our preclinical Nav1.6 program, we are working with numerous potent, selective Nav1.6 inhibitors that have demonstrated efficacy for seizures in preclinical models, supporting the hypothesis that inhibiting the Nav1.6 channel could play a key role in treating rare and severe forms of childhood epilepsy. We expect to file an investigational new drug (IND) application in the first half of 2017."

Dr. Pimstone added, "Our pain-focused collaborations with Teva and Genentech also continue to progress well as we work to translate the therapeutic potential of the Nav1.7 target into novel pain therapeutics. These partnerships allow us to address large market opportunities, while at the same time enable us to pursue multiple therapeutic opportunities to build out our proprietary pipeline of novel therapies that address rare or orphan indications."

Achievements and Anticipated Milestones

Proprietary Pipeline

- XEN801 is a topical stearoyl Co-A desaturase-1, or SCD1 inhibitor, being developed for the treatment of moderate to severe acne. By targeting a reduction in the size and number of sebaceous glands, thereby reducing sebum production, Xenon believes XEN801 is a promising, novel treatment for acne, which could be better tolerated and without the serious side effects that often limit the use of currently approved retinoid treatments. We have currently enrolled approximately half of the patients in our ongoing XEN801 Phase 2 clinical trial, which is a randomized, double-blind, multi-center, vehicle-controlled, parallel-group study designed to evaluate the efficacy, safety, tolerability and systemic exposure of XEN801 for the treatment of moderate to severe facial acne. Xenon expects to enroll approximately 150 patients with moderate to severe acne, with topline results expected in the first quarter of 2017.
- Xenon presented data from the XEN801 Phase 1 clinical trial where 48 healthy volunteers were dosed for either a 14-day or 21-day treatment period. A number of different dose volumes of the 1% XEN801 drug product were evaluated in the Phase 1 clinical trial with dosing on the back and face of healthy volunteers to determine the maximum tolerated dose. As expected, the most common side effects were localized, generally mild skin reactions. No serious adverse events were observed. Maximal plasma concentrations of XEN801 were low, whereas skin biopsies from the back of subjects showed a concentration of approximately two orders of magnitude higher than the IC50 and higher than that required for 100% block of SCD1. It is expected that XEN801 could achieve even better penetration in the facial skin, as currently applied in the current Phase 2 clinical trial. A Phase 2 dose was selected based on favorable tolerability and skin drug concentrations.
- Xenon's development of a Nav1.6 sodium channel inhibitor for the treatment of rare infantile epileptic encephalopathies such as Dravet Syndrome and SCN8A (Nav1.6 gain-of-function) Epilepsy – continues to progress well. Xenon has identified potent, selective Nav1.6 inhibitors, and encouraging results from *in vivo* animal studies indicate that selective Nav1.6 inhibitors have demonstrated efficacy for seizures in a model of Nav1.6 gain-of-function SCN8A epilepsy, supporting the hypothesis that SCN8A epilepsies can be treated with potent, selective Nav1.6 inhibitors. Xenon expects to identify a development candidate in 2016 and file an investigational new drug (IND) application in the first half of 2017.
- Xenon continues to leverage its drug discovery platform to identify validated drug targets and develop new product candidates, and expects to provide updates as new drug discovery programs advance in 2016.

Partnered Programs

- TV-45070 is a product candidate being developed in collaboration with Xenon's partner, Teva Pharmaceutical Industries Ltd., for the treatment of pain. Teva is currently conducting a randomized, double-blind, placebo-controlled Phase 2b clinical trial for TV-45070 in patients with post-herpetic neuralgia, with results expected in the first half of 2017.
- Xenon's partner Genentech, a member of the Roche Group, is currently conducting two Phase 1 clinical trials for GDC-0276 and GDC-0310, which are both oral, selective Nav1.7 small-molecule inhibitors being developed for the potential treatment of pain. Both Phase 1 clinical trials are ongoing, and pending a full assessment of the results, Genentech intends to initiate a Phase 2 clinical trial in late 2016 or early 2017. The research term for Xenon's second collaboration with Genentech, which is centered on pain genetics, was recently extended for another year until March 2017.
- Xenon is eligible to receive a royalty on commercial sales of Glybera, which is licensed to uniQure Biopharma B.V. for the treatment of the orphan disorder lipoprotein lipase deficiency. The first patient treated with Glybera as a commercially-available gene therapy was announced by uniQure in November 2015 and enabled by its commercialization partner in the EU, Chiesi Farmaceutici S.p.A.

Second Quarter 2016 Financial Results

Cash and cash equivalents and marketable securities as of June 30, 2016 were \$50.7 million, compared to \$58.7 million as of December 31, 2015. There were 14,415,347 common shares outstanding as of June 30, 2016.

For the quarter ended June 30, 2016, Xenon reported total revenue of \$0.4 million, compared to \$4.0 million for the same period in 2015. Revenue in both periods was primarily derived from Xenon's collaboration agreements with Teva and Genentech. The decrease of \$3.6 million was primarily attributable to revenue recognized relating to the upfront payment from the collaborative development and license agreement with Teva which was fully recognized by December 2015 as well as revenue related to the upfront payment from the March 2014 collaborative agreement with Genentech which was fully recognized by March 2016. The remaining decrease was due to less full time equivalent funding from Genentech as we shifted resources from supporting our collaborations to our proprietary programs.

Research and development expenses for the quarter ended June 30, 2016 were \$5.1 million, compared to \$3.7 million for the same period in 2015. The increase of \$1.4 million was primarily attributable to an increase in spending on our Nav1.6 sodium channel inhibitor program as well as XEN801 which entered Phase 2 clinical development in February 2016, partially offset by a decrease in Genentech collaboration expenses.

General and administrative expenses for the quarter ended June 30, 2016 were \$1.7 million, compared to \$0.2 million in 2015. In the quarter ended June 30, 2015, a \$2.2 million recovery was recognized due to a decrease in the fair value of liability classified stock options granted to directors and certain consultants; these options were subsequently reclassified back to equity in September 2015. The remaining change is due to one-time severance costs resulting from an internal reorganization and acceleration of stock based compensation expense for certain consultants that occurred in the second quarter of 2015.

Other income for the quarter ended June 30, 2016 was \$0.4 million, compared to \$1.0 million for the same period in 2015. The decrease of \$0.6 million was primarily attributable to a decrease in unrealized foreign exchange gains arising from the translation of Canadian denominated balances to U.S. dollars as compared to the same period in 2015.

Net loss for the quarter ended June 30, 2016 was \$6.0 million, compared to net income of \$1.2 million for the same period in 2015. The change was primarily attributable to lower revenues, higher general and administrative expenses largely due to stock based compensation recovery, higher research and development expenses and lower unrealized foreign exchange gains.

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 2016 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 99339060. 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.

Xenon is a clinical-stage biopharmaceutical company discovering and developing a pipeline of differentiated therapeutics for orphan indications that it intends to commercialize on its own and for larger market indications that the company intends to partner with global pharmaceutical companies. Xenon has built a core enabling discovery platform, referred to as Extreme Genetics, for the discovery of validated drug targets by studying rare human diseases with extreme traits, including diseases caused by mutations in ion channels, known as channelopathies. Xenon's Extreme Genetics platform has yielded the first approved gene therapy product in the European Union and a broad development pipeline and multiple pharmaceutical partnerships, including with Teva and Genentech. For more information, please visit <u>www.xenon-pharma.com</u>.

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 are not based on historical fact, and include statements regarding our ability to achieve milestones in both our proprietary and partnered development programs, the anticipated enrollment in the Phase 2 clinical trial of XEN801, the anticipated timing of IND submissions with regulatory agencies, the initiation of future clinical trials, the timing of and results from our and our collaborators' ongoing clinical trials and pre-clinical development activities, the plans of our collaboration partners and their interactions with regulatory agencies, the potential efficacy, future development plans and commercial potential of our and our collaborators' product candidates and the progress and potential of ongoing development programs. 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 Extreme Genetics discovery platform or ongoing collaborations 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 pursuant to our collaboration agreements; 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 forwardlooking statements.

"Xenon," the Xenon logo, and "Extreme Genetics" are registered trademarks or trademarks of Xenon Pharmaceuticals Inc. in various jurisdictions. All other trademarks belong to their respective owner.

XENON PHARMACEUTICALS INC.

Condensed Balance Sheets (Unaudited) (Expressed in thousands of U.S. dollars)

	June 30, 2016	December 31, 2015		
Assets				
Current assets:				
Cash and cash equivalents and marketable securities	\$ 50,738	\$	58,651	
Other current assets	2,654		2,215	
Other assets	2,295		3,083	
Total assets	\$ 55,687	\$	63,949	
Liabilities				
Current liabilities:				
Accounts payable and accrued expenses	2,929		2,625	
Deferred revenue			157	
Non-current liabilities	101		133	
Total liabilities	\$ 3,030	\$	2,915	
Shareholders' equity	\$ 52,657	\$	61,034	
Total liabilities and shareholders' equity	\$ 55,687	\$	63,949	

XENON PHARMACEUTICALS INC.

Condensed Statements of Operations

(Unaudited)

(Expressed in thousands of U.S. dollars except share and per share amounts)

	 Three Months Ended June 30,				Six Months Ended June 30,				
	2016	2015		2016		2015			
Revenue:									
Collaboration revenue	\$ 412	\$	4,044	\$	981	\$	8,054		
Royalties	1		2		33		2		
	413		4,046		1,014		8,056		
Operating expenses:									
Research and development	5,103		3,669		9,467		7,096		
General and administrative	1,676		178		3,571		6,898		
	6,779		3,847		13,038		13,994		
Loss from operations	(6,366)		199		(12,024)		(5,938)		
Other income (expense)	350		969		2,745		(2,050)		
Net income (loss)	\$ (6,016)	\$	1,168	\$	(9,279)	\$	(7,988)		
Net income (loss) per common share:									
Basic	\$ (0.42)	\$	0.08	\$	(0.64)	\$	(0.56)		
Diluted	\$ (0.42)	\$	(0.07)	\$	(0.65)	\$	(0.56)		
Weighted-average shares outstanding:									
Basic	14,408,108		14,241,827		14,401,054		14,227,203		
Diluted	14,434,602		15,129,978		14,428,160		14,227,203		

Investor/Media Contact:

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