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 29, 2018

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 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 8.01 Other Events

On August 29, 2018, Xenon Pharmaceuticals Inc. (the "Company") issued a press release announcing positive pharmacodynamic data from the Company's Phase 1b transcranial magnetic stimulation (TMS) study for its product candidate XEN1101.

A copy of the Company's press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Xenon Pharmaceuticals Inc. dated August 29, 2018.

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 29, 2018

By: /s/ *Ian Mortimer*

Ian Mortimer
President & Chief Financial Officer

XENON

NEWS RELEASE

Xenon Announces Positive XEN1101 Pharmacodynamic Data from Phase 1b TMS Study

XEN1101 Demonstrates Statistically Significant Reduction in Corticospinal and Cortical Excitability as Measured by TMS-EMG and TMS-EEG

XEN1101 Demonstrates Greater Effect on TMS-EMG Resting Motor Threshold at Significantly Lower Dose When Compared to Historical Ezogabine Data

XEN1101 Phase 2 Clinical Trial in Adult Focal Seizures Expected to be Initiated in Fourth Quarter of 2018

Conference Call Today at 8:30 am ET

BURNABY, British Columbia, August 29, 2018 -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage, neurology-focused biopharmaceutical company, today announced positive data from its XEN1101 Phase 1b transcranial magnetic stimulation (TMS) study. XEN1101 is a Kv7 potassium channel opener being developed by Xenon for the treatment of epilepsy. Dr. Isabella Premoli, postdoctoral research fellow at King's College London and lead investigator for the XEN1101 Phase 1b TMS study, will be presenting the results in a podium presentation at the 13th European Congress on Epileptology held in Vienna, Austria today.

The completed Phase 1b TMS study was a double-blind, placebo-controlled, randomized cross-over study in 20 healthy male subjects and was initiated based on positive results from a Phase 1a pilot TMS study in 8 healthy subjects, which suggested XEN1101 has an ability to inhibit cortical excitability, an important CNS effect observed with approved anti-epileptic drugs (AEDs).

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "Today marks an important step forward in our XEN1101 epilepsy program. We opted to deploy the TMS assay for XEN1101 in order to obtain an early pharmacodynamic, or PD, read-out measuring impact on corticospinal and cortical excitability and to help shape our future development plans. These positive results from our randomized, placebo-controlled TMS study demonstrate that XEN1101 can impact the key EMG output – the resting motor threshold, or RMT – in a concentration-dependent manner with statistical significance over placebo at each time point measured, and to a greater extent than historical data for ezogabine, an earlier generation potassium channel modulator. With respect to TMS-EEG, similar to the EMG-RMT, XEN1101 demonstrated an ability to dampen cortical excitability in a concentration-dependent manner with statistical significance over placebo. Overall, these data show robust activity of XEN1101 in the TMS assay and support the advancement of XEN1101 into a Phase 2 clinical trial."

Dr. Isabella Premoli, postdoctoral research fellow at King's College London and lead investigator for the XEN1101 Phase 1a TMS pilot study and Phase 1b double-blind, placebo-controlled, randomized cross-over study, stated, "The TMS-EMG and TMS-EEG assays have been used previously in healthy subjects to measure cortical excitability of approved AEDs, such as ezogabine, levetiracetam, and lamotrigine. The XEN1101 Phase 1b TMS study has generated very promising results when placed in the context of our experience using TMS to measure effects of approved AEDs. These data indicate we are seeing a robust effect of XEN1101 on corticospinal and cortical excitability. Further, the results appear to be concentration dependent as we are seeing an increased signal in TMS measures as drug concentration levels in the plasma increase over 2-, 4-, and 6-hour time points demonstrating a strong PK-PD effect of XEN1101. Given what we know about the pharmacokinetics of XEN1101, we believe that some of the TMS measurements gathered in this study may potentially underestimate its steady state effect on corticospinal and cortical excitability. These results support the further study of XEN1101 in epilepsy patients."

Summary of XEN1101 Phase 1b TMS Study Results

- The TMS Phase 1b double-blind, placebo-controlled, randomized cross-over study included 20 healthy male subjects. TMS measurements were taken at 2 and 4 hours for all subjects and, due to a prolonged absorption phase displayed by XEN1101 pharmacokinetics, an additional TMS assessment time-point was added at 6 hours for a subset of subjects. Subjects were randomized initially to either a 20 mg dose of XEN1101 or placebo and then, after a wash-out period, crossed over to the other treatment arm.

- Consistent with the Phase 1a TMS pilot study, XEN1101 reduced corticospinal excitability, as demonstrated by a concentration dependent elevation in RMT, the key TMS-EMG measure. Single 20 mg doses of XEN1101 resulted in plasma levels of 15.7 ng/mL, 30.2 ng/mL and 44.4 ng/mL at 2, 4 and 6 hours, respectively and elevated RMT (as a percentage of maximum stimulator output) by 1.5±0.4% ($p<0.05$), 3.0±0.7% ($p<0.01$) and 4.3±0.8% ($p<0.01$) compared to time matched placebo changes of 0.4±0.3%, 0.7±0.4% and 0.9±0.3%. This compares to a literature publication of ezogabine (Ossemann et. al) where in a double-blind, placebo-controlled, cross-over study in 15 healthy subjects at a single dose of 400 mg, ezogabine increased the RMT by 2.4±3.6%.

- In the TMS-EEG portion of the study, a 20 mg XEN1101 dose statistically significantly modulated TMS-evoked potentials (TEPs) in a manner consistent with reductions in cortical excitability, potentially showing a unique "fingerprint" of activity as anticipated based on studies with other AEDs. Relative to time-matched placebo, at peak plasma levels, XEN1101 decreased the amplitude of TEPs measured at 25 ms (N15-P25: 4.5 vs 6.0 µV, $p<0.05$), 45 ms (N45: -2.3 vs -3.0 µV, $p<0.01$) and 180 ms (P180: 2.2 vs 3.0 µV, $p<0.01$) after the TMS pulse. Additional measures of cortical excitability including Global Mean Field Power were similarly impacted by XEN1101.

- XEN1101 was well tolerated with all adverse events (AEs) reported as mild or moderate and reversible. The most common AEs were dizziness and drowsiness, similar to marketed antiepileptic drugs. There were no withdrawals, serious AEs, or deaths.

Update on XEN1101 Phase 1 Clinical Trial and XEN901 Phase 1 Clinical Trial

In addition to completing both the Phase 1a pilot and Phase 1b TMS studies, Xenon has now completed enrollment in the XEN1101 Phase 1 clinical trial using a powder-in-capsule formulation, which is evaluating the safety, tolerability and pharmacokinetics of both single ascending doses (SAD) and multiple ascending doses (MAD) of XEN1101. The XEN1101 Phase 1 clinical trial included 5 SAD cohorts, a food effect cohort and 3 MAD cohorts of 66 healthy subjects. Interim results presented in May 2018 showed pharmacokinetic data confirming a half-life consistent with once daily dosing, drug exposure levels at doses tested above the EC_{50} in preclinical models, and safety data supporting further development of XEN1101. Xenon plans to publish the complete XEN1101 Phase 1 clinical trial results at an upcoming scientific meeting and anticipates initiating a Phase 2 clinical trial evaluating XEN1101 as a treatment for adult focal seizures in the fourth quarter of 2018.

Xenon is also developing XEN901, a potent, highly selective Nav1.6 sodium channel inhibitor, for the treatment of epilepsy. A randomized, double-blind, placebo-controlled Phase 1 clinical trial to evaluate XEN901's safety, tolerability and pharmacokinetics in both SAD and MAD cohorts is ongoing, with 6 SAD cohorts, a food effect cohort and 3 MAD cohorts completed and 74 subjects enrolled in the study to date. Interim results presented in May 2018 included favorable pharmacokinetic data that showed dose proportionality and supported twice daily or better dosing, with a predicted elimination half-life of 8 to 11 hours. The multiple dose levels tested yielded drug exposure above the efficacy range for EC_{70} in the pre-clinical Maximal Electroshock Seizure model. Based on experience with TMS in the XEN1101 studies, Xenon, along with its collaborators at King College, are exploring the use of the TMS assay in a small subset of a subjects in the ongoing XEN901 Phase 1 clinical trial. Upon completion of the Phase 1 clinical trial, a read-out of the final results is anticipated in the fourth quarter of 2018, and Xenon expects to initiate a Phase 2 clinical trial evaluating XEN901's efficacy as a treatment for adult focal seizures or for rare, pediatric forms of epilepsy as soon as feasible thereafter depending on planned discussions with regulatory agencies in the near term.

Dr. Pimstone added, "It is exciting to see the strong momentum generated by our clinical-stage epilepsy programs. Dosing in the XEN1101 Phase 1 clinical trial for the powder-in-capsule formulation is now complete, and pharmacokinetic, safety and tolerability data are consistent with the interim results presented in May 2018. We, along with our scientific steering committee, are planning for the initiation of a Phase 2 clinical trial that would evaluate XEN1101 as a treatment for adult focal seizures, which is expected to be initiated in the fourth quarter of this year. We look forward to presenting the complete XEN1101 Phase 1 results at a scientific meeting by the end of this year. Our XEN901 Phase 1 clinical trial also continues to make progress with dosing in MAD cohorts underway, and, to date, the data are consistent with the promising interim results presented in May 2018."

Comparisons of XEN1101 and ezogabine are not based on data resulting from head-to-head trials and are not direct comparisons of safety or efficacy. Different protocol designs, trial designs, patient selection and populations, number of patients, trial endpoints, trial objectives and other parameters that are not the same between the relevant trials may cause any comparisons of results from different trials to be unreliable.

Conference Call and Webcast Information
Xenon will host a conference call and webcast today at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time) to provide a corporate update and discuss the XEN1101 Phase 1b TMS study results. To participate in the call, please dial (855) 779-9075 or (631) 485-4866 for international callers and provide conference ID number 1675798. 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, neurology-focused biopharmaceutical company focused on developing innovative therapeutics to improve the lives of patients with neurological disorders. Building upon our extensive knowledge of human genetics and diseases caused by mutations in ion channels, known as channelopathies, we are advancing – both independently and with our collaborators – a novel product pipeline of central nervous system, or CNS, therapies to address areas of high unmet medical need, such as epilepsy, migraine and pain. 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 are not based on historical fact, and include statements regarding our expectations regarding the timing of and results from clinical trials and pre-clinical development activities, including those related to XEN901, XEN1101 and our other product candidates, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN901, XEN1101 and our other product candidates, the anticipated timing of IND, or IND equivalent, submissions and the initiation of future clinical trials for XEN901, XEN1101 and our other product candidates, the efficacy of our clinical trial designs, our ability to successfully develop and achieve milestones in the XEN901, XEN1101 and other development programs, the anticipated benefits of the unique mechanisms of action of XEN901 and XEN1101, the design of our clinical trials and anticipated enrollment, the potential for XEN1101 to support once daily dosing, the potential for XEN901 to support twice daily or better dosing, the progress and potential of our other ongoing development programs, and the timing of our public presentation and potential publication 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: promising results in preclinical and early clinical trials may not be replicated in subsequent clinical trials; clinical trials may not demonstrate safety and efficacy of any of our or our collaborators' 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; the impact of competition; 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.

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