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 15, 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 May 15, 2018, Xenon Pharmaceuticals Inc. (the "Company") issued two press releases announcing a Phase 1 clinical update and supporting preclinical data for its product candidate XEN901 and interim Phase 1 data for its product candidate XEN1101.

Copies of the Company's press releases are attached hereto as Exhibit 99.1 and 99.2 and are 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 May 15, 2018.
99.2	Press Release issued by Xenon Pharmaceuticals Inc. dated May 15, 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: May 15, 2018

By: /s/ *Ian Mortimer*

Ian Mortimer
President & Chief Financial Officer

XENON

NEWS RELEASE

Xenon Presents XEN901 Phase 1 Clinical Update and Supporting Pre-clinical Data at 14th Eilat Conference

Company to Hold Conference Call at 8:00 am ET Today

Preliminary Phase 1 Clinical Data Support Drug Exposure Levels Higher than Required in Pre-clinical Efficacy Models with Excellent Tolerability and Safety

New Pre-clinical Data Support Selective Nav1.6 Mechanism of Action and XEN901 Efficacy Superior to Standard of Care Sodium Channel Blockers

BURNABY, British Columbia, May 15, 2018 -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today presented new pre-clinical data as well as preliminary clinical data from its ongoing XEN901 Phase 1 clinical trial in a podium presentation at the 14th Eilat Conference on New Antiepileptic Drugs and Devices (Eilat) held in Madrid, Spain.

XEN901 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed by Xenon for the treatment of epilepsy including treatment resistant adult and pediatric focal seizures, as well as rare, pediatric forms of epilepsy, such as EIEE13, an early infantile epileptic encephalopathy due to gain-of-function mutations in the SCN8A gene that encodes the Nav1.6 sodium channel.

Today, Xenon presented new pre-clinical data as well as interim data from its ongoing Phase 1 clinical trial, which is evaluating the safety, tolerability and pharmacokinetics (PK) of both single ascending doses (SAD) and multiple ascending doses (MAD) of XEN901 in approximately 64 healthy subjects.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "Today's presentation is a culmination of years of work to identify and develop a novel and highly differentiated anti-epileptic drug (AED) with the potential to be superior to other sodium channel blockers allowing more patients to achieve seizure freedom. Although sodium channel blockers are a mainstay in the treatment of epilepsy, utilizing these drugs to their maximal effect in patients is often limited by side effects. We have generated compelling data that highlight the Nav1.6 channel as the critical sodium channel in regulating cortical hyper-excitability and the mechanism by which non-selective sodium channels are having their effect. The pre-clinical profile and selectivity of XEN901 suggest it may provide a significant advancement in efficacy, safety and tolerability when compared with other broadly used sodium channel blockers, including phenytoin, carbamazepine and lacosamide."

Dr. Pimstone added, "The interim Phase 1 clinical data presented today demonstrate a favorable PK profile, with XEN901 reaching levels of drug exposure significantly above where we see efficacy in our pre-clinical models with an excellent safety and tolerability profile. We are looking forward to completing the Phase 1 clinical trial over the next few months, and we are looking forward to advancing XEN901 into a Phase 2 clinical trial in adult focal seizures. In parallel, we are working on a strategy to advance XEN901 into rare pediatric forms of epilepsy, such as the EIEE13 pediatric population."

Summary of XEN901 Interim Phase 1 Clinical Data

- The XEN901 interim Phase 1 results include data from six SAD cohorts ranging in dose from 5 to 45 mg (n=33, placebo=8).
- Favorable PK data show dose proportionality and support twice daily or better dosing, with predicted half-life of 8 to 11 hours. The multiple dose levels tested yield drug exposure above the efficacy range for EC_{70} in the pre-clinical Maximal Electroshock Seizure (MES) model.
- To date, all reported adverse events (AEs) are mild or moderate. Related AEs were mild and resolved spontaneously. The most common adverse event was headache. The interim preliminary safety results suggest XEN901 is overall safe and well tolerated.

Summary of XEN901 Supporting Pre-Clinical Data

- There is strong genetic validation for pursuing this particular target: children born with gain-of-function mutations in the SCN8A gene, the gene encoding the Nav1.6 channel, develop a very severe early onset form of epilepsy known as EIEE13.

- Xenon has generated compelling pre-clinical data that suggest Nav1.6 is the primary driver of efficacy for non-selective voltage-gated sodium channel targeted AEDs. By selectively targeting Nav1.6 and avoiding other sodium channel targets that do not appear relevant to seizure control, it is anticipated that XEN901 could maximize channel inhibition, yielding an enhanced effect – up to and including potential seizure freedom in a greater number of patients.

- A variety of models representative of both adult and pediatric epilepsy have shown XEN901's improved efficacy at significantly lower concentrations than approved AEDs such as carbamazepine, phenytoin, and lacosamide. Data presented today showed that XEN901 can completely suppress seizures in pre-clinical models.

    - Data presented today show that XEN901's level of selectivity leads to greater than 100-fold more potent in SCN8a gain-of-function transgenic animal models of EIEE13 when compared to phenytoin, carbamazepine and lacosamide.

    - XEN901 was also shown to be greater than 100-fold more potent than phenytoin, carbamazepine and lacosamide in a Maximal Electroshock Seizure (MES) model, which is used as a model for focal seizures.

- Driven by efficacy at very low plasma and brain concentrations, XEN901 demonstrates an improved therapeutic index over other sodium channel inhibitors in pre-clinical models; the preclinical safety margin for XEN901 is >100 versus <7 for phenytoin, carbamazepine and lacosamide.

The XEN901 Phase 1 clinical trial is anticipated to be completed in the second half of 2018, followed by a regulatory filing by year-end to support a Phase 2 trial evaluating XEN901 as a treatment for adult focal seizures. Xenon also intends to pursue a parallel plan to advance XEN901 into rare, pediatric forms of epilepsy, such as EIEE13, as soon as feasible thereafter. The incidence of EIEE13 has been estimated to be approximately 50 births per year in the United States.

Conference Call Information

Xenon will host a conference call and webcast today at 8:00 a.m. Eastern Time (5:00 a.m. Pacific Time) to provide a corporate update and discuss the XEN1101 and XEN901 Eilat presentations. To participate in the call, please dial (855) 779-9075, or (631) 485-4866 for international callers and provide conference ID number 5249928. 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 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 and our other product candidates, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN901 and our other product candidates, the anticipated timing of IND, or IND equivalent, submissions and the initiation of future clinical trials for XEN901 and our other product candidates, the efficacy of our clinical trial designs, our ability to successfully develop and achieve milestones in the XEN901 and other development programs, the anticipated benefits of the unique mechanisms of action of XEN901, the design of our clinical trials and anticipated enrollment, the potential for XEN901 to support twice daily or better dosing, the ability to replicate preclinical and Phase 1 data of XEN901 in head-to-head trials with competing products, and the progress and potential of our other 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: 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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XENON

NEWS RELEASE

Xenon Presents Positive XEN1101 TMS Pharmacodynamic Phase 1 Data at 14th Eilat Conference

Company to Hold Conference Call at 8:00 am ET Today

XEN1101 Pilot TMS-EEG Data Demonstrates Statistically Significant Effect of 20mg Dose versus Baseline (p<0.01) and Greater Effect on TMS-EMG Resting Motor Threshold at Significantly Lower Dose When Compared to Ezogabine

Phase 1 Pharmacokinetic Data Supports Potential for Once Daily Dosing

BURNABY, British Columbia, May 15, 2018 -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today presented positive interim data from its ongoing XEN1101 Phase 1 clinical trial in a podium presentation at the 14th Eilat Conference on New Antiepileptic Drugs and Devices (Eilat) held in Madrid, Spain.

XEN1101 is a Kv7 potassium channel opener being developed by Xenon for the treatment of epilepsy including: treatment-resistant adult and pediatric focal seizures as well as rare, pediatric forms of epilepsy, such as EIEE7, an early infantile epileptic encephalopathy associated with mutations in the KCNQ2 gene encoding the Kv7.2 potassium channel; and potentially other neurological disorders.

Today, Xenon presented interim data from its ongoing XEN1101 Phase 1 clinical trial, which is evaluating the safety, tolerability and pharmacokinetics of both single ascending doses (SAD) and multiple ascending doses (MAD) of XEN1101 in healthy subjects, along with results from the completed Phase 1a pilot transcranial magnetic stimulation (TMS) study in 8 healthy subjects. The pilot TMS study was designed to assess XEN1101's ability to inhibit cortical excitability, an important CNS effect observed with anti-epileptic drugs (AEDs). Based on this pilot Phase 1a TMS study, Xenon has initiated a double-blind, placebo-controlled, randomized cross-over Phase 1b TMS study, which is expected to include approximately 15 to 20 healthy subjects and be completed by mid-year, with data expected in the second half of 2018.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "The interim XEN1101 Phase 1 clinical data presented today are very exciting. We believe that the pre-clinical and interim clinical data presented, demonstrate a number of significant benefits of XEN1101 when compared to historical data for ezogabine, an earlier generation potassium channel modulator. These benefits include both pharmacokinetic (PK) and apparent safety benefits as well as achievement of a key pharmacodynamic (PD) readout at a 20 mg dose, which approximately 1/20th of that reported in historical data for ezogabine. The XEN1101 PK profile from the current Phase 1 clinical trial, supports the potential for once daily dosing with XEN1101 versus ezogabine's three-times daily dosing. From a safety perspective, the majority of adverse events were mild and resolved spontaneously, with an overall profile showing XEN1101 as safe and well tolerated. Importantly, this safety has been observed at drug exposures where we have now shown XEN1101 having an inhibitory effect on cortical excitation in humans."

Dr. Pimstone added, "In order to obtain an early PD read-out, we used the TMS assay as a measure of cortical excitability and indicator of drug activity in the target CNS tissue. We are pleased to see a robust PD effect in the TMS assay in healthy human volunteers. When compared with the historical data generated with ezogabine, XEN1101 had approximately twice the effect at significantly lower doses."

Dr. Isabella Premoli, postdoctoral research worker at King's College London and investigator for the XEN1101 Phase 1a TMS pilot study and Phase 1b placebo-controlled cross-over study, stated, "The TMS-EMG and TMS-EEG assays have been used for a number of years to measure cortical excitability and study the effect of approved AEDs, such as ezogabine, levetiracetam, and lamotrigine, when tested in healthy subjects. Based on our experience with TMS, we are extremely encouraged by the data generated in the XEN1101 Phase 1a TMS pilot study, which demonstrate an effect of XEN1101 on cortical hyperexcitability in healthy volunteers. In the TMS-EMG component, XEN1101 is clearly impacting the resting motor threshold: at the 20 mg dose, we see an effect that appears significantly greater than that observed with ezogabine, at a significantly lower dose, when compared to the historical data. In the TMS-EEG component, all three subjects at the 20 mg dose had a statistically significant effect when compared to their individual baseline measurements with changes observed in what appears to be a distinct pattern for all three subjects, suggesting TMS-EEG can detect an effect related to the Kv7 channel mechanism. Overall, we believe XEN1101 is having a robust and meaningful effect on cortical hyperexcitability at the single-subject level."

Dr. Premoli continued, "Our work with Xenon underscores our belief that the TMS assay has the potential to be used more broadly during the early stages of AED development to potentially provide early read-outs of a pharmacodynamic effect. I am looking forward to further validating these positive results from the XEN1101 Phase 1a TMS pilot study with the data generated from the XEN1101 Phase 1b TMS placebo-controlled cross-over study, which we expect to complete later this quarter."

Summary of XEN1101 Interim Phase 1 Clinical Data / Phase 1a Pilot TMS Study

- The XEN1101 interim Phase 1 results include data from five SAD cohorts (n=28, placebo=6) ranging in dose from 5 to 30 mg, and one MAD cohort at a 15 mg dose (n=6, placebo=2).

- Pharmacokinetic data confirms a half-life consistent with once daily dosing. Based on data generated from the MAD cohort, it is anticipated that steady state could be achieved at approximately seven days, and food enhances the exposure of XEN1101. Drug exposure levels in the Phase 1 clinical trial were observed above the EC_{50} in preclinical models.

- The preliminary XEN1101 interim Phase 1 data suggest that overall XEN1101 is safe and well tolerated, with no serious adverse events, and no clinically significant laboratory findings. The majority of adverse events were mild and resolved spontaneously. The most common adverse events were headache, dizziness and drowsiness. One severe adverse event, a vasovagal reaction, was observed following a blood draw and standing. Importantly, no urinary retention or hesitation adverse events were noted, which was one of the adverse events observed in historical clinical trials with ezogabine.

- The TMS Phase 1a pilot study included 8 male subjects where three doses were tested (10 mg, n=2; 15 mg, n=3; 20 mg, n=3). When measuring the resting motor threshold (RMT) in the TMS-EMG assay, the mean change (standard deviation) in RMT was 1.5% (±2.1), 1.33% (±0.58) and 4.33% (±0.58) for the 10 mg, 15 mg and 20 mg doses, respectively. 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, all three subjects at the 20 mg dose showed statistically significant ($p<0.01$) modulating activity at 4 hours post dose when compared to baseline. The effects of ezogabine within a TMS-EEG have not been tested.

- Based on pre-clinical *in vitro* metabolism studies, it is anticipated that there is a low risk of drug-drug interactions with XEN1101.

The release of the complete Phase 1 results, including the Phase 1b TMS data from approximately 15 to 20 subjects, is anticipated in the second half of 2018. Xenon anticipates initiating a Phase 2 clinical trial evaluating XEN1101 as a treatment for adult focal seizures by year end. Xenon also intends to explore a parallel plan to advance XEN1101 into rare, pediatric forms of epilepsy as soon as feasible thereafter.

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.

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