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 14, 2018

SOLENO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36593**	**77-0523891**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification Number)**

1235 Radio Road, Suite 110
Redwood City, CA 94065
(Address of principal executive offices)

(650) 213-8444
(Registrant's telephone number, including area code)

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:

☐ 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 14, 2018, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing the initiation of the Phase III trial for Diazoxide Choline Controlled Release Tablet as a treatment for Prader-Willi Syndrome, a complex metabolic/neurobehavioral disorder. A copy of the Company's press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Soleno Therapeutics, Inc. dated May 14, 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.

SOLENO THERAPEUTICS, INC.

Date: May 14, 2018

By: /s/ Anish Bhatnagar
Anish Bhatnagar
Chief Executive Officer

Soleno Therapeutics Announces Initiation of Phase III Clinical Trial of DCCR in Prader-Willi Syndrome

REDWOOD CITY, Calif., May 14, 2018 — Soleno Therapeutics, Inc. ("Soleno") (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that it has initiated its multi-center Phase III clinical trial of Diazoxide Choline Controlled-Release ("DCCR") for the treatment of Prader-Willi Syndrome ("PWS"). Seattle Children's Hospital is the first site to be activated and Parisa Salehi, M.D., is the Principal Investigator for the trial at this site.

"Prader-Willi Syndrome leads to hyperphagia that can cause life-threatening obesity if left uncontrolled" said Dr. Salehi. "This excessive hunger can cause significant harm to the lives of these individuals and their families. There is a lack of effective medical therapy targeting hunger in this population, and such a drug would be life-altering. Based on the data generated to date, DCCR has the potential to address this treatment void. We look forward to further evaluating DCCR in this important Phase III trial."

"The initiation of the Phase III clinical trial of DCCR for the treatment of PWS represents a significant milestone for Soleno," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. "Importantly, following meetings with the U.S. Food and Drug Administration, we have alignment with the agency on the key aspects of the Phase III clinical trial. We look forward to working with our clinical trial sites and the PWS community to successfully complete the trial."

The Phase III clinical trial is a multi-center, randomized, double-blind, placebo-controlled study for DCCR that will treat approximately 100 PWS patients at 10-15 sites in the U.S. This trial is anticipated to take approximately 9-12 months to complete. DCCR has orphan designation for the treatment of PWS in the US and in the EU.

About PWS

The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the US have PWS. The hallmark symptom of this disorder is hyperphagia, a chronic feeling of insatiable hunger that severely diminishes the quality of life for PWS patients and their families. Additional characteristics of PWS include behavioral problems, cognitive disabilities, low muscle tone, short stature (when not treated with growth hormone), the accumulation of excess body fat, developmental delays, and incomplete sexual development. Hyperphagia can lead to significant morbidities (e.g., stomach rupture, obesity, diabetes, cardiovascular disease) and mortality (e.g., choking, accidental death due to food seeking behavior). In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia as the most important or a very important symptom to be relieved by a new medicine. There are currently no approved therapies to treat the hyperphagia/appetite, metabolic, cognitive function, or behavioral aspects of the disorder. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the US and EU.

About Diazoxide Choline Controlled-Release Tablet

Diazoxide choline controlled-release tablet is a novel, proprietary extended-release, crystalline salt formulation of diazoxide, which is administered once-daily. The parent molecule, diazoxide, has been used for decades in thousands of patients in a few rare diseases in neonates, infants, children and adults, but has not been approved for use in PWS. Soleno conceived of and established extensive patent protection on the therapeutic use of diazoxide and DCCR in patients with PWS. The DCCR development program is supported by positive data from five completed Phase I clinical studies in various metabolic indications or in healthy volunteers and three completed Phase II clinical studies, one of which was in PWS patients. In the PWS Phase II study, DCCR showed promise in addressing hyperphagia, the hallmark symptoms of PWS.

About Soleno Therapeutics, Inc.

Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company is currently advancing its lead candidate, DCCR, a once-daily oral tablet for the treatment of PWS, into a Phase III clinical development program in early 2018.

For more information, please visit www.soleno.life.

Forward-Looking Statements

This press release contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ability to initiate the Phase III clinical development program of DCCR in PWS in early 2018.

We may use terms such as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “approximately” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained herein, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation. As a result of these factors, we cannot assure you that the forward-looking statements in this press release will prove to be accurate. Additional factors that could materially affect actual results can be found in Soleno’s Form 10-K filed with the Securities and Exchange Commission on April 2, 2018, including under the caption titled “Risk Factors.” Soleno expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

CONTACT:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578