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): March 14, 2019

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 Section13(a) of the Exchange Act. ☐

Item 8.01.

Other Events.

On March 14, 2019, Soleno Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release regarding the Data Safety Monitoring Board's recommendation of the continuation of the Company's Phase III trial in Prader-Willi Syndrome (PWS) patients, DESTINY PWS, without any changes. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01.

Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on March 14, 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.

SOLENO THERAPEUTICS, INC.

Date: March 15, 2019

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

Exhibit 99.1

Soleno Therapeutics Announces Positive Outcome from Planned Data Safety Monitoring Board Review of Phase III DESTINY PWS Clinical Trial of DCCR in Prader-Willi Syndrome

Soleno Therapeutics, Inc. (SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that the Data Safety Monitoring Board (DSMB) has recommended the continuation of the Company's Phase III trial in Prader-Willi Syndrome (PWS) patients, DESTINY PWS, without any changes.

"We are delighted with the DSMB's positive recommendation to continue the Phase III trial as planned as it further supports DCCR's safety profile," said Dr. Anish Bhatnagar, Chief Executive Officer of Soleno. "We are continuing to enroll patients with 14 sites activated in DESTINY PWS. In addition, patients continue to roll over into C602, the 9-month open-label safety extension study for patients completing blinded treatment in the DESTINY PWS study."

The Phase III DESTINY PWS trial is a randomized, double-blind, placebo-controlled study of once daily oral administration of DCCR versus placebo in approximately 100 patients with a confirmed diagnosis of PWS. The primary endpoint is change from baseline hyperphagia score at Week 13. Patients who complete DESTINY PWS have the option to enroll into C602.

The DSMB is a group of independent experts monitoring the safety of the DESTINY PWS study. The DSMB reviews safety information and can make recommendations to either continue the study without modification, modify the study or terminate the study due to safety concerns.

In July 2018, the U.S. Food and Drug Administration designated the investigation of DCCR for the treatment of PWS to be a Fast Track development program. Prior to this, diazoxide choline received orphan designation for the treatment of PWS in the U.S. and in the E.U.

For further information about the trial (NCT03440814), please visit: www.clinicaltrials.gov.

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 U.S. and E.U.

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 data from five completed Phase I clinical studies 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 symptom of PWS, as well as several other symptoms such as aggressive/destructive behaviors, fat mass and abnormal lipid profiles.

About Soleno Therapeutics, Inc.

Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company's lead candidate, DCCR, a once-daily oral tablet for the treatment of PWS, is currently being evaluated in a Phase III clinical development program. For more information, please visit www.soleno.life.