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 8, 2021

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)**

203 Redwood Shores Pkwy, Suite 500
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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbols	Name of each exchange on which registered
Common Stock, $0.001 par value	**SLNO**	**NASDAQ**

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 March 8, 2021, Soleno Therapeutics, Inc. (the "Company") issued a press release discussing recent guidance from the U.S. Food and Drug Administration that an additional controlled clinical trial will be necessary to support an NDA submission for the Company's once-daily DCCR (diazoxide choline) extended release tablets for the treatment of Prader-Willi Syndrome (PWS).

A copy of the 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 No.	Description
99.1	Press release issued by Soleno Therapeutics, Inc. dated March 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 8, 2021

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

Soleno Therapeutics Provides Regulatory Update on
DCCR for the Treatment of Prader-Willi Syndrome

REDWOOD CITY, Calif., March 8, 2021 – Soleno Therapeutics, Inc. (“Soleno”) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided an update following recent interactions with the U.S. Food and Drug Administration (FDA) regarding the development of once-daily DCCR (diazoxide choline) extended release tablets for the treatment of Prader-Willi Syndrome (PWS).

Subsequent to the previously disclosed Type C meeting with the FDA on November 12, 2020 regarding the potential adequacy of data from studies with DCCR to support a New Drug Application (NDA) for the treatment of PWS, Soleno submitted additional analyses to the FDA from the Company’s Phase 3 trial, DESTINY PWS (C601). These data were from study visits that were completed prior to the significant disruptions caused by the COVID-19 pandemic. The data analyses showed statistically significant changes for DCCR compared to placebo in the primary and key secondary endpoints. Following its review of the data submitted by Soleno, the FDA informed the Company on March 5, 2021 that an additional controlled clinical trial will be necessary to support an NDA submission for DCCR in PWS.

“We intend to continue the dialogue with the FDA to ensure that DCCR is approved for individuals with PWS as expeditiously as possible,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “Based on the totality of data generated to date, we remain confident in DCCR’s potential to address the unmet need for a safe and effective treatment option for PWS patients. We are currently evaluating the appropriate next steps for our DCCR program.”

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births in the U.S. 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., obesity, diabetes, cardiovascular disease) and mortality (e.g., stomach rupture, 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 EU, and Fast Track Designation in the U.S.

About DCCR (Diazoxide Choline) Extended-Release Tablets

DCCR is a novel, proprietary extended-release dosage form containing the crystalline salt of diazoxide and 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 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in PWS patients. In the PWS Phase 3 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 other metabolic parameters.

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 extended-release tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase 3 clinical development program. For more information, please visit www.soleno.life.

Forward-Looking Statements This press release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of PWS. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including the risks and uncertainties associated with market conditions, as well as risks and uncertainties inherent in Soleno's business, including those described in the company's prior press releases and in the periodic reports it files with the SEC. The events and circumstances reflected in the company's forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Corporate Contact:

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