
**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): December 10, 2020

SOLENO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36593
(Commission
File No.)

77-0523891
(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))

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.

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

Item 8.01 Other Events.

On December 11, 2020, Soleno Therapeutics, Inc. (the “Company”) issued a press release announcing that it was in receipt of minutes from the U.S. Food and Drug Administration (“FDA”) in connection with a meeting the Company had with the FDA on November 12, 2020 to discuss the Company’s New Drug Application (“IND”) for the use of diazoxide choline controlled-release (DCCR) as a treatment for Prader-Willi syndrome (“PWS”). As stated in the minutes, the purpose of the meeting was to discuss the efficacy data obtained from the Company’s recently completed Phase III clinical trial of DCCR (C601), additional data to be obtained from the Company’s long-term extension study of patients treated on C601 (C602) and proposed next steps for developing DCCR as a treatment for PWS. The full text 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Soleno Therapeutics, Inc. dated December 11, 2020
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: December 11, 2020

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



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

Solenio intends to submit plans to FDA to conduct further analyses of clinical data from completed and ongoing studies of DCCR, together with external, natural history studies

REDWOOD CITY, Calif., December 11, 2020 – Solenio Therapeutics, Inc. (“Solenio”) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced the receipt of official meeting minutes from the November 12, 2020, Type C meeting with the U.S. Food and Drug Administration (FDA) regarding the development of once-daily Diazoxide Choline Controlled Release (DCCR) tablets for the treatment of Prader-Willi Syndrome (PWS). The meeting minutes confirmed the discussion with the FDA regarding the potential adequacy of data from completed and ongoing studies with DCCR, together with external, natural history studies to support a New Drug Application (NDA) for DCCR for the treatment of PWS. Solenio intends to submit formal plans for these analyses, which the FDA has stated it is committed to reviewing.

“We appreciate the guidance provided by the FDA and are finalizing our plans to conduct the analyses that were discussed at this meeting and look forward to submitting them to the FDA,” said Anish Bhatnagar, M.D., Chief Executive Officer of Solenio Therapeutics. “While we hope that these data, together with the additional analyses, will suffice as adequate for an NDA, we cannot, at this time, exclude the possibility that the FDA will require us to conduct an additional controlled clinical study. We look forward to working with the FDA to ensure that the necessary data and information are compiled for the NDA, which we are currently preparing to submit in the second half of 2021.”

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., 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 EU, and Fast Track Designation in the U.S.



About Diazoxide Choline Controlled-Release (DCCR) 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 III 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, Diazoxide Choline Controlled-Release (DCCR) tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase III 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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