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): April 14, 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 April 14, 2021, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing that Anish Bhatnagar, M.D., the Company's Chief Executive Officer, participated in a Prader-Willi Syndrome ("PWS") Town Hall meeting hosted by the PWS Community. The Town Hall was held on Wednesday, April 14, 2021 and discussed the use of Diazoxide Choline Extended-Release Tablets ("DCCR") in PWS. The event featured speakers from the PWS community who provided insights into the challenges of living with PWS as well as patient and caregiver perspectives on DCCR treatment. As part of the meeting Dr. Bhatnagar's spoke and his remarks highlighted the unmet medical needs facing PWS patients, the company's ongoing commitment to obtaining regulatory approval for DCCR and an outline of the necessary steps to obtain regulatory approval of DCCR. The remarks have been published as an open letter to the PWS community.

A copy of the open letter to the PWS community is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Open letter to the PWS community dated April 14, 2021.
99.2	Press release issued by Soleno Therapeutics, Inc. dated April 14, 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: April 15, 2021

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

Exhibit 99.1

Dear members of the PWS community,

We at Soleno Therapeutics would like to provide an update on the status of DCCR.

As we have worked with the PWS community over the last several years, whether it is with advocacy leaders from PWSA USA and FPWR, or with leading clinical investigators, we have also had the opportunity to meet many individuals with PWS and their families. We have been struck by the scale of the unmet medical needs of the community, the resilience of the patients and the dedication of their families to find new treatments.

As you may know, to make a drug commercially available to patients in the US, a company must submit a New Drug Application, or NDA, to the FDA for review. This review period generally takes 6 to 10 months, during which the FDA evaluates all data to ensure that any drug they approve is safe and effective, and that the benefits outweigh the risks. To collect these data for an NDA, we ran a clinical trial – DESTINY PWS – and some of you may have children who participated in it.

We announced the results of DESTINY PWS in June of last year. The primary goal of the study was to evaluate whether DCCR treated patients showed a statistically significant improvement in hyperphagia compared to those treated with placebo. Unfortunately, the study did not meet this goal. However, the data did provide other evidence of efficacy while showing that most common side effects with DCCR (such as effects on glucose, edema and hypertrichosis) were as expected and, typically, manageable.

As you all know, PWS affects many body systems. Although there are similarities, the disease can be very different from individual to individual. We believe that it is important, in this rare disease setting, to consider both the evidence obtained from the study as well as from individual patient experiences. We also feel it is important to include analyses that account for the impact of the COVID-19 pandemic. It is this totality of evidence that we believe provides information on the potential risks and benefits of DCCR in PWS.

Prior to submitting an NDA, the typical process involves first discussing with the FDA the data from clinical studies to support submission. We have provided the overall topline DESTINY PWS analysis as well as our analyses accounting for the impact of the COVID-19 pandemic to the FDA. We do not have any agreement with the FDA on the submission of an NDA, and most recently the FDA informed us that a new clinical trial will be required. We are continuing our dialog with the FDA around the existing study data.

Recently, through PWSA USA and FPWR, many of you shared the experiences you had during the DESTINY PWS study and continue to have in Study C602, the extension study. This information was compiled and sent to FDA by the organizations last week. We believe that individual patient experiences and the voice of the community are important and ask that you continue to work through these organizations to ensure that the FDA hears a single, united voice.

I know that one of your immediate concerns is for those who are on DCCR in C602. At this time, we have no immediate plans to stop the study and we will continue to provide DCCR to all active subjects in the study. Our goal remains to obtain regulatory approval for DCCR to make DCCR available commercially, which is the most effective way to provide broad access to this community. To achieve this goal, we need to ensure that there is a reasonable and clear path forward with the FDA, which we continue to be committed to. We will continue to provide public updates, but please know that these interactions with FDA take time and generally occur on a 3- to 4-month timeframe.

Thank you again for your continuing efforts to find new treatments and for your interest in DCCR and particularly to all those whose loved ones participated in the DESTINY PWS. You motivate and inspire us every day.

Anish Bhatnagar, MD
CEO
On behalf of all of us at Soleno

Soleno Therapeutics Participates in Prader-Willi Syndrome (PWS) DCCR Town Hall

REDWOOD CITY, Calif., April 14, 2021 – Soleno Therapeutics, Inc. ("Soleno") (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that Anish Bhatnagar, M.D., Chief Executive Officer, participated in a Prader-Willi Syndrome (PWS) DCCR Town Hall on Wednesday, April 14, 2021.

The event featured speakers from the PWS community who discussed the challenges of living with PWS as well as patient and caregiver perspectives on DCCR treatment.

Dr. Bhatnagar's remarks highlighted the unmet medical needs facing PWS patients, the Company's ongoing commitment to obtaining regulatory approval for DCCR and an outline of the necessary steps to obtain regulatory approval. The remarks have been published as an open letter to the PWS community which can be accessed here: https://investors.soleno.life/eventsand-presentations/event-calendar

In addition, Dr. Bhatnagar referenced the work completed by the Foundation for Prader-Willi Research and Prader-Willi Syndrome Association | USA in collecting the experiences of patients and caregivers during the completed DESTINY PWS Phase III clinical trial and in the going C602 open-level study. This information was compiled by these organizations and sent together with a letter to the U.S. Food and Drug Administration on DCCR. Further information can be found by visiting their respective websites: www.fpwr.org and www.pwsusa.org.

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.

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