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): September 26, 2023

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 7.01 Regulation FD Disclosure

On September 26, 2023, Soleno Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing the top-line results of the Randomized Withdrawal Study of 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.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. This report will not be deemed an admission as to the materiality of any information herein (including Exhibit 99.1).

ITEM 8.01 Other Events

The Press Release contained the following disclosures regarding the Company's C602 Randomized Withdrawal Period Design and Key Top-Line Results:

Trial Design:

The multi-center, randomized, double-blind, placebo-controlled randomized withdrawal period enrolled 77 patients previously enrolled in Study C602 who had been on open-label treatment with DCCR for between two and four years. Participants were randomized 1:1 to receive either DCCR (n=38) or placebo (n=39) for a period of four months. The primary endpoint was the change from baseline in hyperphagia-related behaviors as assessed by the hyperphagia questionnaire for clinical trials (HQ-CT), a caregiver-completed nine item validated questionnaire for assessing hyperphagia in PWS. Secondary endpoints included investigator assessments of participants' overall severity of illness and change in condition, as measured by Clinical Global Impression of Severity (CGI-S) and Clinical Global Impression of Improvement (CGI-I) ratings, respectively.

Key Top-line Results:

- Hyperphagia-related behaviors markedly worsened in the placebo group compared to DCCR, represented by a highly statistically significant, clinically meaningful difference in mean change from baseline in the HQ-CT total score of 5.0 at week 16 (p=0.0022).
- Secondary endpoints of CGI-S and CGI-I both showed strong trends towards worsening in the placebo group compared to DCCR over the course of the randomized withdrawal period (p=0.08 and 0.09), respectively.
- DCCR continued to be generally well-tolerated in the randomized withdrawal period with no new or unexpected safety signals, including no serious adverse events or discontinuations due to adverse events occurring in any participants in the DCCR group.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Soleno Therapeutics, Inc. dated September 26, 2023
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: September 26, 2023

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

Exhibit 99.1

Soleno Therapeutics Announces Positive Statistically Significant Top-line Results from

Randomized Withdrawal Period of Study C602 of DCCR for Prader-Willi Syndrome

Study Met Primary Endpoint; Highly Statistically Significant Difference in Change from Baseline in HQ-CT Total Score for DCCR Compared to Placebo (p=0.0022)

Soleno Intends to Submit a New Drug Application for DCCR in PWS Mid-Year 2024

Company to Host Conference Call and Webcast Today at 9:00 AM ET

REDWOOD CITY, Calif., September 26, 2023 – Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced positive top-line results from the randomized withdrawal period of Study C602, a long-term treatment study of DCCR (Diazoxide Choline) Extended-Release tablets for the treatment of Prader-Willi syndrome (PWS).

“We are delighted with the highly statistically significant results from the randomized withdrawal phase of Study C602,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. “These results will support our planned submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) mid-year of next year. We would like to thank the patients, families, investigators, study site personnel and the advocacy community involved in this study, as well as the entire Soleno team for their support of the DCCR development program. We remain committed to the goal of delivering DCCR, if approved, as an effective and safe therapy to individuals with PWS as expeditiously as possible.”

The FDA previously acknowledged that data from this study have the potential to support an NDA submission for DCCR, which has Orphan Drug designation for the treatment of PWS in the U.S. and E.U. and Fast Track designation from the FDA.

C602 Randomized Withdrawal Period Design:

The multi-center, randomized, double-blind, placebo-controlled randomized withdrawal period enrolled 77 patients previously enrolled in Study C602 who had been on open-label treatment with DCCR for between two and four years. Participants were randomized 1:1 to receive either DCCR (n=38) or placebo (n=39) for a period of four months. The primary endpoint was the change from baseline in hyperphagia-related behaviors as assessed by the hyperphagia questionnaire for clinical trials (HQ-CT), a caregiver-completed nine item validated questionnaire for assessing hyperphagia in PWS. Secondary endpoints included investigator assessments of participants’ overall severity of illness and change in condition, as measured by Clinical Global Impression of Severity (CGI-S) and Clinical Global Impression of Improvement (CGI-I) ratings, respectively.

Key Top-line Results:

- Hyperphagia-related behaviors markedly worsened in the placebo group compared to DCCR, represented by a highly statistically significant, clinically meaningful difference in mean change from baseline in the HQ-CT total score of 5.0 at week 16 (p=0.0022).
- Secondary endpoints of CGI-S and CGI-I both showed strong trends towards worsening in the placebo group compared to DCCR over the course of the randomized withdrawal period (p=0.08 and 0.09), respectively.
- DCCR continued to be generally well-tolerated in the randomized withdrawal period with no new or unexpected safety signals, including no serious adverse events or discontinuations due to adverse events occurring in any participants in the DCCR group.

Soleno entered into a Securities Purchase Agreement with Nantahala Capital Management, LLC, Abingworth LLP and Vivo Capital, LLC in December 2022, which may result in gross proceeds to Soleno of up to $60 million (the Securities Purchase Agreement). To date, pursuant to the Securities Purchase Agreement, Soleno has received $10 million in exchange for Tranche A and Tranche B warrants to purchase common stock. Under the terms of the Securities Purchase Agreement, the investors are required to exercise Tranche A warrants to purchase 8,598,870 shares of common stock at $1.75 for a total of approximately $15 million within 30 days of the announcement of positive top-line data from the randomized withdrawal period of Study C602.

Conference Call and Webcast Details

Soleno will host a conference call and webcast to discuss these results today, September 26, 2023 at 9:00 AM ET. Details can be found below:

Title:	Randomized Withdrawal Period of Study C602 Top-line Results
Date:	Tuesday, September 26, 2023
Time:	9:00 AM ET
Conference Call Details:	Toll-free: 1-877-423-9813 International: 1-201-689-8573 Conference ID: 13741535
Call me™ Feature (avoid waiting for operator):	Click Here
Webcast:	Webcast Link – Click here

A replay of the call will be available following the call on the Investors section of the Soleno website.

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The hallmark symptom of this disorder is hyperphagia, a chronic and life-threatening feeling of intense, persistent hunger, food pre-occupation, extreme drive to food seek and consume food that severely diminish the quality of life for patients with PWS 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 and 92.9% rated body composition as either 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.

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, diazoxide choline 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 patients with PWS. In the PWS Phase 3 clinical development program, 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. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the U.S. and E.U., and Fast Track Designation in the U.S.

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 PWS, recently completed its Phase 3 development program to support a planned NDA submission. 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 the potential receipt of gross proceeds from the warrant financing under the Securities Purchase Agreement, management's assessment of the top-line data results from the randomized withdrawal period, and the timing and pathway of the regulatory process and clinical development path for seeking approval of 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," "goal," "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 U.S. Securities and Exchange Commission. 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:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578