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): June 8, 2020

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))

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 7.01 Regulation FD.

On June 8, 2020, Soleno Therapeutics, Inc. (the "Company") will host a conference call to discuss the top-line results from its Phase III Trial of DCCR for the treatment of Prader-Willi Syndrome. A copy of the Company's slide presentation accompanying the conference call is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

ITEM 8.01 Other Events

On June 8, 2020, the Company issued a press release announcing the top-line results from its Phase III Trial of DCCR for the treatment of Prader-Willi Syndrome.

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	Corporate slide presentation, dated June 8, 2020
99.2	Press release issued by Soleno Therapeutics, Inc. dated June 8, 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: June 8, 2020

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

DESTINY PWS
Top-Line Data Call

June 8, 2020 | Soleno Therapeutics

Certain Notices and Disclaimers

Forward-Looking Statements

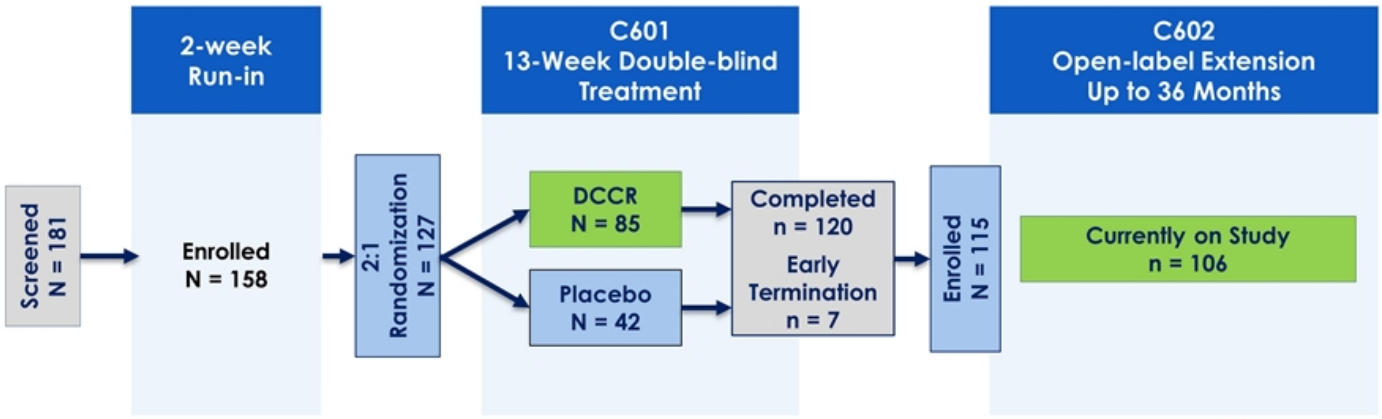
This presentation contains forward-looking statements that are subject to many risks and uncertainties. Forward looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned product development and clinical trials; the timing of, and our ability to make, regulatory filings and obtain and maintain regulatory approvals for our product candidates; our intellectual property position; the degree of clinical utility of our products, particularly in specific patient populations; our ability to develop commercial functions; expectations regarding product launch and revenue; our results of operations, cash needs, and spending of the proceeds from this offering; financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation.

You should also read carefully the factors described in the "Risk Factors" section and other parts of our Quarterly Report on Form 10-Q, available at www.sec.gov, in order to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this presentation will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation or to reflect the occurrence of unanticipated events.

Phase III Program Design

- C601 (DESTINY PWS): Multi-center, randomized, double-blind, placebo-controlled, parallel arm study in patients with PWS (Phase III)
- C602: Open-label safety extension study



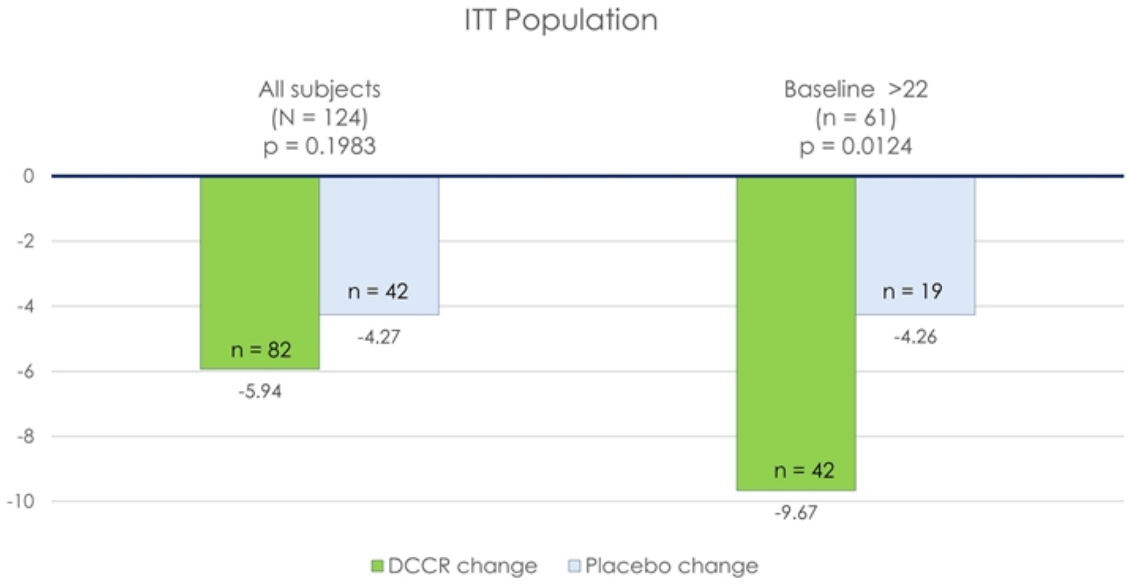
C601 Demographics and Baseline Characteristics (ITT Population)

Parameter	DCCR (N = 82)	Placebo (N = 42)	Overall (N = 124)
Mean Age (years) (SD)	13.4 (6.82)	13.6 (7.37)	13.5 (6.98)
Gender, n (%)			
Male	36 (43.9)	19 (45.2)	55 (44.4)
Female	46 (56.1)	23 (54.8)	69 (55.6)
Country, n (%)			
United Kingdom	19 (23.2)	6 (14.3)	25 (20.2)
United States	63 (76.8)	36 (85.7)	99 (79.8)
PWS Type, n (%)			
Deletion	48 (58.5)	28 (66.7)	76 (61.3)
Non-deletion	33 (40.2)	14 (33.3)	47 (37.9)
Not Available	1 (1.2)	0 (0.0)	1 (0.8)

C601 Primary Analysis – Change From Baseline in Hyperphagia to Visit 7

	DCCR (N = 82)	Placebo (N = 42)
LS Mean (SE)	-5.94 (0.879)	-4.27 (1.145)
95% CI	(-7.68, -4.20)	(-6.53, -2.00)
LS Mean Difference [DCCR-Placebo] (SE)	-1.67 (1.294)	
95% CI	(-4.24, 0.89)	
p-value	0.1983	

Changes from Baseline in HQ-CT at Visit 7



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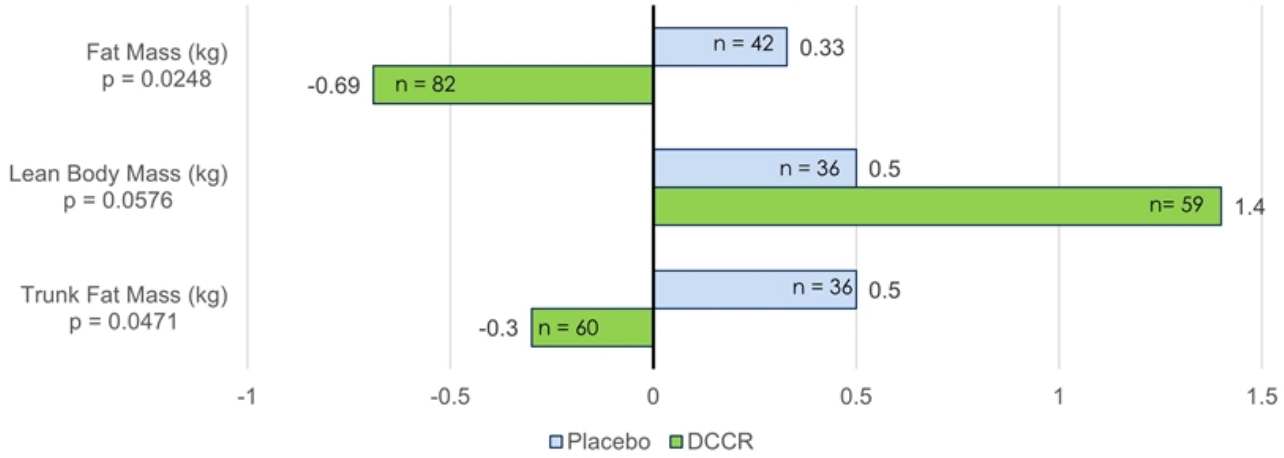
Key Secondary Endpoints

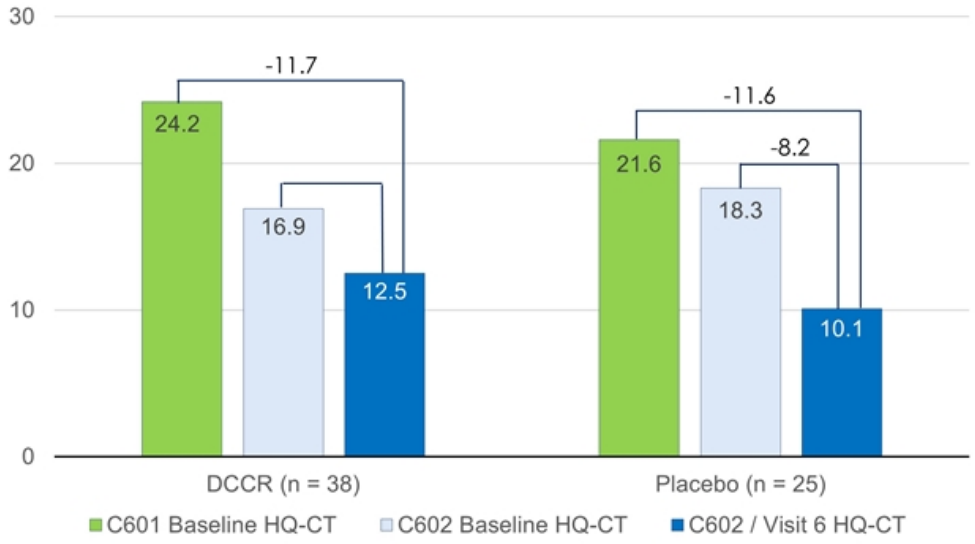
Endpoint	p-value
Clinical Global Impression of Improvement at Visit 7 (CGI-I)	0.029
Mean Change From Baseline in Body Fat Mass (DXA)	0.025
Caregiver Global Impression of Change at Visit 7 (CGI-C)	0.409

C601 Changes in Body Composition



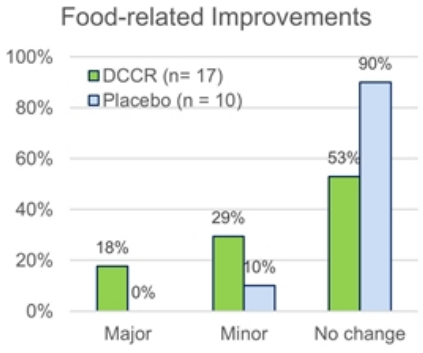
Endpoint	p-value
Lean Body Mass to Fat Mass Ratio	0.001

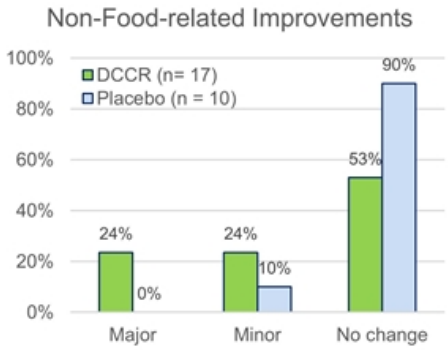
Changes in HQ-CT after 13 or 26 Weeks of DCCR Treatment in C601 and C602

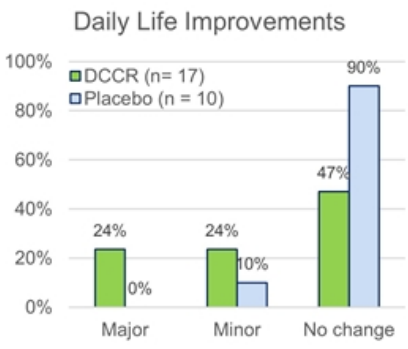


PWS Outcomes Assessment – Interim Analysis

- *Caregiver interviews at the end of C601*
- *Positive improvements in all 3 domains reported for a significant proportion of DCCR patients (~48%); major improvements reported for 18 - 24% of the patients*
- *Minor improvements reported for one placebo patient (10%); no major improvements were reported for the placebo patients*







"Minor" includes improvements classified as between major and minor, as well as mixed.

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C601 Safety

Summary of Adverse Events		
Number (%) of subjects with at least one:	**DCCR (N=84) n (%)**	**Placebo (N=42) n (%)**
TEAE	70 (83.3)	31 (73.8)
TEAE resulting in premature discontinuation of study drug	4 (4.8)	1 (2.4)
SAE	6 (7.1)	0 (0)
SAE related to study drug	1 (1.2)	0 (0)
SAE leading to premature discontinuation of study drug	2 (2.4)	0 (0)

TEAEs in >5% of DCCR Subjects		
Preferred Term	**DCCR (N=84) n (%)**	**Placebo (N=42) n (%)**
Hypertrichosis	30 (35.7)	6 (14.3)
Hirsutism	6 (7.1)	3 (7.1)
Upper Respiratory Tract Infection	9 (10.7)	5 (11.9)
Edema, peripheral	17 (20.2)	4 (9.5)
Pyrexia	5.0 (6)	0 (0)
Headache	5 (6)	6 (14.3)
Blood glucose increased	5.0 (6)	2 (4.8)
Hyperglycemia	10 (11.9)	0 (0)

DCCR Safety Profile

- The safety profile of DCCR in C601 was generally consistent with the known profile of diazoxide and prior experience with DCCR.
- Most events were Grade 1 in severity, including all events of hypertrichosis (except one Grade 2 in the placebo group).
- No Grade 4 or higher events were reported in this study.
- There were no serious unexpected adverse events (SUSARs) related to DCCR.

DESTINY PWS
Top-Line Data Call

June 8, 2020 | Soleno Therapeutics

Soleno Therapeutics Announces Top-line Results from Phase III Trial of DCCR for Treatment of Prader-Willi Syndrome

Study Did Not Meet Statistical Significance for Primary Endpoint, but Showed Significant Improvements in Prespecified Subgroup with Severe Hyperphagia

Significant Positive Changes Also Seen in Two of Three Key Secondary Endpoints

Interim Analysis of Ongoing Extension Study (C602) Showed
Further Reductions in Hyperphagia of 48% after Six Months of DCCR Treatment

Soleno to Host Conference Call and Live Webcast Today at 5:00 PM ET/2:00 PM PT

REDWOOD CITY, Calif., June 8, 2020 — Soleno Therapeutics, Inc. ("Soleno") (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced top-line results from the Company's Phase III trial, DESTINY PWS (C601), evaluating once-daily Diazoxide Choline Controlled Release (DCCR) tablets for patients with Prader-Willi Syndrome (PWS).

DESTINY PWS/C601

The study did not meet its primary endpoint of change from baseline in hyperphagia. The change was measured by the total score of a Hyperphagia Questionnaire for Clinical Trials (HQ-CT, 0-36). An improvement in HQ-CT is represented by a decrease in the score. The mean (SE) change from baseline for DCCR was -5.94 (0.879) and for placebo was -4.27 (1.145). The least squares mean difference in HQ-CT score of DCCR compared with placebo was -1.67 (1.294); 95% confidence interval (-4.24, 0.89); p=0.1983.

Significant changes were observed in two of three key secondary endpoints from baseline to week 13 in subjects receiving DCCR as compared to placebo:

- Improvement in Clinical Global Impression of Improvement (CGI-I) score as assessed by the investigator (p=0.029)
- Reduction of body fat mass measured by DXA scan (p=0.025)

In a prespecified subgroup of subjects (n=61) with more severe hyperphagia, as identified by a dichotomized median baseline HQ-CT score of >22, the mean (SE) change from baseline for DCCR (n=42) was -9.67 (1.429) and for placebo (n=19) was -4.26 (1.896). The least squares mean difference in HQ-CT score of DCCR compared with placebo was -5.41 (2.093); 95% confidence interval (-9.60, -1.22); p=0.0124.

In addition to the reduction in total body fat mass, other body composition changes in DCCR compared to placebo included significant decreases in trunk fat mass (p = 0.047), and improvement in lean body mass to fat mass ratio (p=0.001). Fat mass changes were most pronounced in subjects in the highest weight band (n=18, 100-135 kg); p=0.024.

“Hyperphagia, the predominant symptom of PWS, is an unrelenting hunger that can cause life-threatening co-morbidities, including obesity, and is a condition for which no treatments are available,” said Jennifer L. Miller, M.D., Professor in the Division of Pediatric Endocrinology at the University of Florida and a Principal Investigator in the Soleno study. “PWS also leads to significant quality-of-life challenges for patients and families. These data show that DCCR therapy results in meaningful improvements in hyperphagia in severe patients, as well as various other positive impacts in behaviors and body composition, and if approved, could offer a safe and effective treatment to PWS patients struggling to manage their symptoms. My experience with DCCR in the largest cohort of patients in this study is consistent with the overall effects seen in DESTINY PWS.”

DESTINY PWS is a multi-center, randomized, double-blind, placebo-controlled study of once-daily oral administration DCCR in 127 PWS patients at 29 sites in the U.S. and UK. The objective of the study was to assess the safety and efficacy of DCCR in subjects ages four years and older, with genetically-confirmed PWS. Patients who completed the double-blind study were eligible to enroll in study C602. For further information about DESTINY PWS (NCT03440814) and Study C602 (NCT03714373), please visit: www.clinicaltrials.gov.

Study C602 – Long-term Safety Extension Study – Interim Data

A total of 115 subjects were enrolled into C602, an ongoing open-label, safety extension study of DCCR in PWS patients completing C601, and >90% of them are continuing to be treated at this time. An interim analysis of subjects (n=63) who have completed three months of treatment on C602 shows continuing improvements in hyperphagia. DCCR subjects from C601 (n= 38) at six months of treatment demonstrated a reduction in hyperphagia score of -11.7 (-48%) and placebo subjects from C601 who switched to DCCR showed a similar change following three months of treatment in C602.

Behaviors related to PWS are measured using a PWS Profile Questionnaire (PWS-P), which consists of caregiver responses to questions in six domains: aggressive behaviors, anxiety, rigidity-irritability, compulsivity, depression and disordered thinking. Improvements in most domains were seen in C601with DCCR treatment. In subjects from C601 treated with DCCR, each domain showed further improvement in C602. Placebo subjects from C601 who switched to DCCR showed a similar change following three months of treatment in C602.

PWS Outcomes Study – Interim Data

An interim analysis of a subset of subjects in the PWS outcomes study was conducted consisting of data from interviews at the end of C601 for caregivers of 27 patients (17 DCCR and 10 placebo). The interviews evaluated individual patient experiences with DCCR and placebo using three domains: food-related improvements, non-food-related improvements and daily life improvements. In each of these domains, approximately 48% participants on DCCR reported at least some positive improvement, with 18-24% reporting a major improvement in the PWS patient. In the placebo group, a single participant (10%) reported a minor improvement in their PWS patient, and none reported a major difference.

“While we are disappointed to have not achieved statistical significance on the study’s primary endpoint, we are excited by the results observed in those subjects with severe hyperphagia, as well as the changes in body composition and behavioral endpoints,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “Based on these data, we will continue treatment of patients on C602. We are continuing to evaluate the data from C601 and C602 and plan to meet with regulatory authorities to determine next steps. On behalf of the Soleno team, I would like to thank the patients, families and investigators involved in this study, as well as the Foundation for Prader-Willi Research and Prader-Willi Syndrome Association USA and UK, for their support of the DCCR Phase III development program.”

DCCR Safety

The safety profile of DCCR in C601 was generally consistent with the known profile of diazoxide and prior experience with DCCR. Treatment emergent adverse events (TEAEs) were reported in 70 (83.3%) DCCR subjects and 31 (73.8%) placebo subjects. TEAEs that were reported more frequently in the DCCR group vs. placebo and occurred in at least 5% of DCCR subjects were hypertrichosis (35.7% vs. 14.3%), peripheral edema (20.2% vs 9.5%), blood glucose increase (6% vs. 4.8%), hyperglycemia (11.9% vs. 0%) and pyrexia (6% vs. 0%). Most events were Grade 1 in severity, including all events of hypertrichosis (other than one Grade 2 in the placebo group). No Grade 4 or higher events were reported in this study. Five subjects discontinued from the study early due to adverse events, four in the DCCR group and one in the placebo group. Six subjects had serious TEAEs in the DCCR group and none in the placebo group. There were no serious unexpected adverse events (SUSARs) related to DCCR.

Study visits in C601 and C602 conducted after approximately mid-March were impacted by COVID-19. Certain evaluations could have been conducted in a different manner and evaluations, such as DXA, were not conducted in most cases during this period. Additional analyses will evaluate the impact of these changes.

DCCR has orphan designation for the treatment of PWS in the U.S. and EU and Fast Track designation from the U.S. Food and Drug Administration.

Conference Call

Soleno will host a conference call and webcast to discuss these results today, June 8, 2020, at 5:00 PM Eastern Time. Dr. Miller will be joining Dr. Bhatnagar to discuss the results of the study. Details to participate in the call are below.

Conference Call Details

5:00 PM Eastern Time / 2:00 PM Pacific Time

Toll Free:	1-877-407-4018
International:	1-201-689-8471
Conference ID:	13705103
Webcast (with slides):	http://public.viavid.com/index.php?id=140230

About PWS

The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the U.S. 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 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 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, 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 the Company’s expectations concerning, among other things, our ability to commercialize DCCR for 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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LifeSci Advisors, LLC
212-915-2578