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): July 10, 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.

Soleno Therapeutics, Inc., a Delaware corporation (the "Company"), is furnishing presentation materials included as Exhibit 99.1 to this report pursuant to Item 7.01 of Form 8-K. The Company is not undertaking to update this presentation. The information in this report (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 9.01.

Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation Materials
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

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: July 10, 2023

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

Exhibit 99.1

Corporate Presentation

July 2023 | 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" sections and other parts of our Annual Reports on Form 10-K and Quarterly Reports 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.

Analyses in this presentation are preliminary and may be subject to change

SOLENO THERAPEUTICS

Soleno Therapeutics (NASDAQ: SLNO)

Strategic Highlights

Orphan asset in Phase 3 Program for Prader-Willi syndrome (PWS)

Topline data reported in June 2020, long-term data in Sep 2021

Clinically relevant improvements in hyperphagia, behaviors, and body composition with DCCR* supported by decades-long safety profile of active moiety

IP protection to mid-2030s

Protected by multiple layers of granted and pending patents

Provides composition of matter protection, as well as protection of formulations, and method of use

Substantial potential for patent term extension

Orphan Drug and Fast Track Designations

Orphan designation in US and EU for PWS. Fast Track granted in US

Significant upside potential in other indications

Orphan designation granted for GSD1a in US

>$1bn PWS global market opportunity

Addresses hallmark symptoms of PWS

Significant commercial potential in PWS, an orphan indication with high unmet need.

No approved treatments for hyperphagia, the hallmark symptom of PWS

Financed by leading healthcare investors

Financed by leading HC-focused institutional investors

Dec 2023 $60m financing commitment from Nantahala, Abingworth and Vivo

*Diazoxide Choline Extended Release tablets

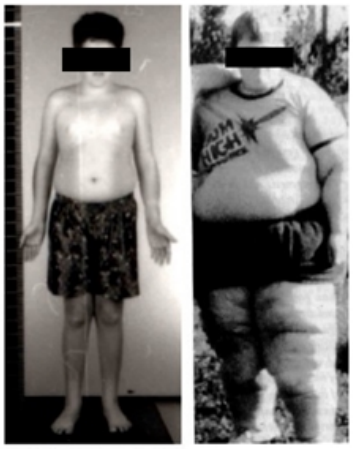
SOLENO THERAPEUTICS

Leadership Team

- Anish Bhatnagar, M.D.
  Chief Executive Officer
- Neil M. Cowen, Ph.D.
  Senior VP, Drug Development
- Patricia C. Hirano, M.P.H.
  VP, Regulatory Affairs
- Kristen Yen, M.S.
  VP, Clinical Operations
- Jim Mackaness
  Chief Financial Officer
- Scott Madsen
  VP, CMC
- Charles Horn
  VP, Quality

Prader-Willi Syndrome (PWS)

- Complex genetic neurobehavioral/metabolic disorder due to the loss or lack of expression of a set of genes on chromosome 15
- Birth incidence ~1:15,000 births
- Elevated mortality rates with mean age of death ~21 - 30 years
- Highest unmet needs
  - Hyperphagia
  - Low lean body mass/increased fat mass
  - PWS-related behaviors
- Families with a child with PWS have low quality of life
  - Caregiver burden higher for caregivers of people with PWS than those with Alzheimers



Butler MG, et al. Genet Med. 2017 Jun;19(6):635-642.
Bellis SA, et al.. The Eur J Med Genet. 2022 Jan;65(1):104379.
Kayadjanian N et al., PLoS One 2018 Mar 26; 12(3): e0194655

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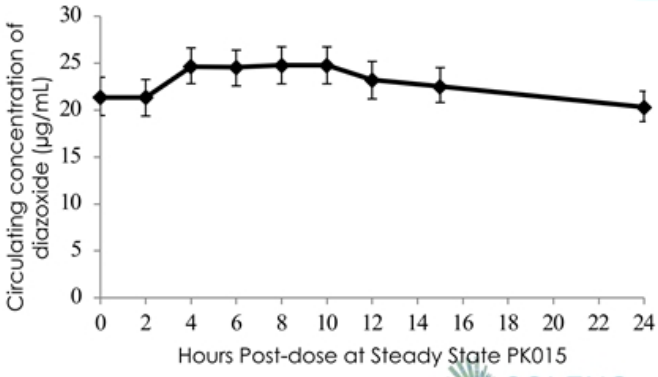
DCCR Was Developed to Facilitate Once Daily Dosing and Improve Response

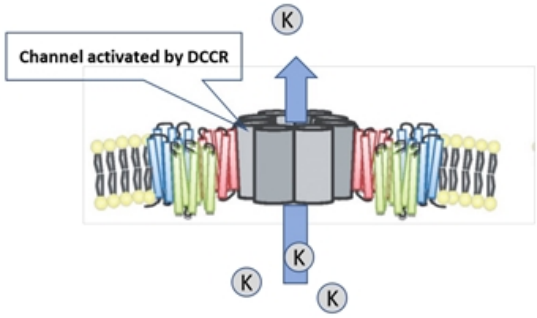
- Choline salt chosen to improve solubility
- Formulation developed to extend absorption throughout the GI tract

- Titration and dosing optimized to safely reach target dose and maintain therapeutic response

- DCCR dosed once daily to achieve stable intraday circulating drug levels
- Strong relationship between circulating drug levels with DCCR and therapeutic responses in PWS



Mechanism of Action in PWS



Membrane hyperpolarization

No Ca^{2+} influx

NPY/AgRP/GABA Neurons	Reduced NPY and AgRP secretion resulting in reduced hyperphagia
Subsets of DMV Neurons	Neuronal inhibition resulting in reduced hyperinsulinemia, improved insulin sensitivity, improved satiety and reduced appetite
Adipocytes	Reduced de-novo fatty acid biosynthesis and increased β-oxidation of fat resulting in reduced fat mass
Pancreatic β-cells	Reduced insulin secretion resulting in reduced hyperinsulinemia

Genes, 11(4), 450. https://doi.org/10.3390/genes11040450.

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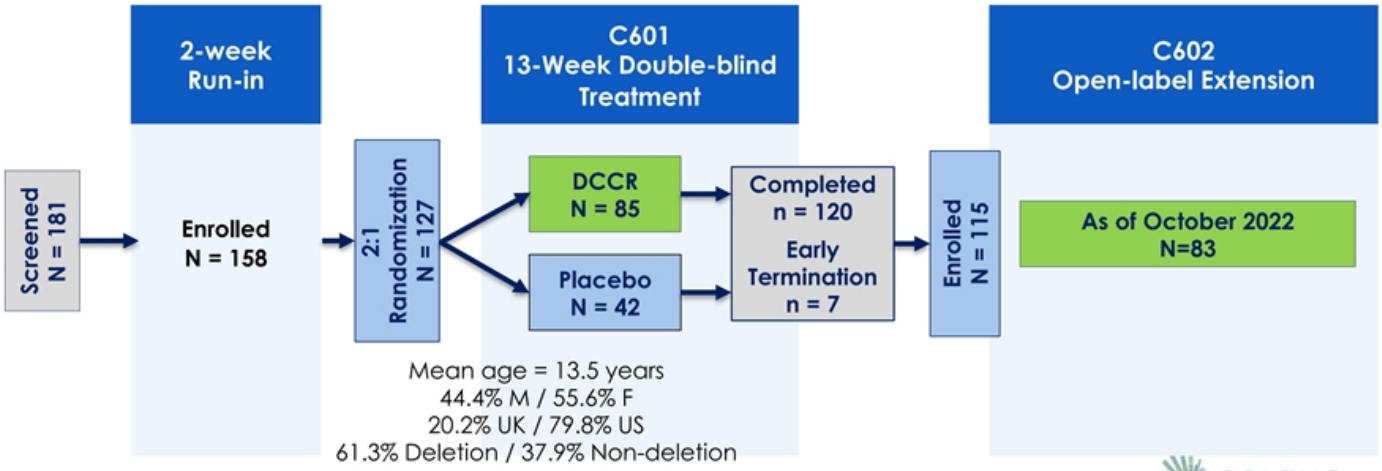
DCCR Phase 3 Clinical Program Design

- C601 (DESTINY PWS): Multi-center, randomized, double-blind, placebo-controlled, parallel arm study in patients with PWS (Phase 3)
- C602: Open-label safety extension study



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C601 Primary and Key Secondary Endpoints

Primary Endpoint	All Data		Data through March 1, 2020	
	DCCR (N = 82)	Placebo (N = 42)	DCCR (N = 82)	Placebo (N = 42)
Mean (SE) Change from Baseline in Hyperphagia at Visit 7	-5.94 (0.88)	-4.27 (1.15)	-6.64 (1.00)	-3.51 (1.28)
LS Mean Difference [DCCR-Placebo] (SE)	-1.67(1.29)		-3.13 (1.48)	
p-value	0.198		**0.037**	
Key Secondary Endpoints	**p-value**		**p-value**	
Clinical Global Impression of Improvement at Visit 7 (CGI-I)	**0.03**		**0.015**	
Mean Change From Baseline in Body Fat Mass (DXA) at Visit 7	**0.023**		**0.003**	
Caregiver Global Impression of Change at Visit 7 (Caregiver GI-C)	0.41		**0.031**	

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C601 Behavioral Endpoints

PWSP Domain	DCCR vs Placebo p-value
Aggressive Behaviors	**0.048**
Anxiety	**0.018**
Rigidity, Irritability	**0.003**
Compulsivity	**0.008**
Depression	0.185
Disordered Thinking	**0.011**
DBC-2	
Total Score	**0.009**
Communication Disturbance	**0.003**
Social Relating	**0.008**

Observed values through March 1, 2020

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C601 Key Hormonal and Metabolic Markers

Change from Baseline at Week 13	DCCR vs Placebo p-value
Decreased Acylated Ghrelin (active form)	0.0182
Decreased Leptin	<0.0001
Decreased Insulin	0.0110
Increased Adiponectin	<0.0001

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Long-term Data

DCCR 12 MONTHS INTERIM RESULTS AND COMPARISON TO PATH FOR PWS

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C601/C602 and PATH for PWS (PATH)

- C602 is an ongoing, open-label extension study of DCCR in subjects who completed DESTINY PWS successfully
- PATH is an ongoing study evaluating the natural history of subjects with PWS
  - Sponsored by FPWR
  - ~ 650 active participants
  - Completion of several questionnaires online every 6 months, including HQ-CT and PWSP by caregivers of people with PWS
  - PATH for PWS analysis set included subjects who met C601/602 inclusion criteria of age, baseline hyperphagia, weight and caregiver
- The statistical comparison of DCCR data to PATH was conducted by an independent CRO

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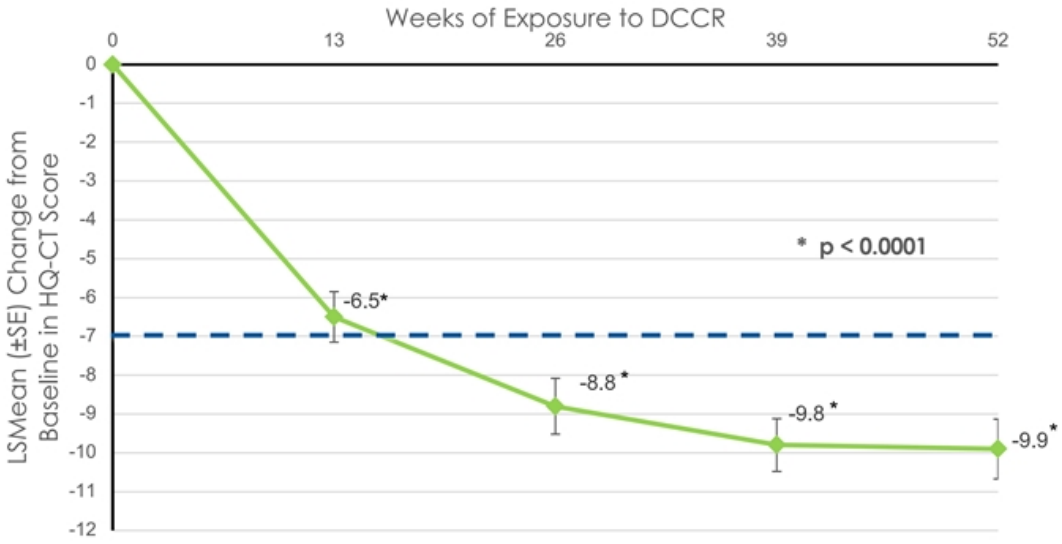
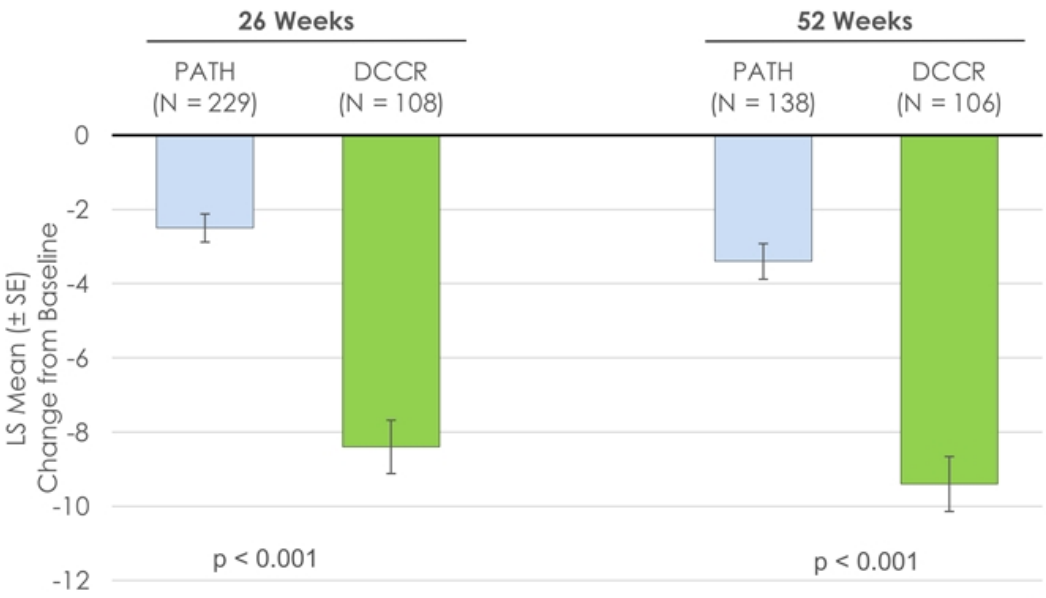
C601/C602 Hyperphagia Change from Baseline



Change in Hyperphagia with DCCR Compared to PATH



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C601/C602 PWS Profile Behavioral Change Results after One Year of DCCR

Domain	p-value
Aggressive Behaviors	<0.0001
Anxiety	<0.0001
Compulsivity	<0.0001
Depression	<0.0001
Disordered Thinking	<0.0001
Rigidity Irritability	<0.0001

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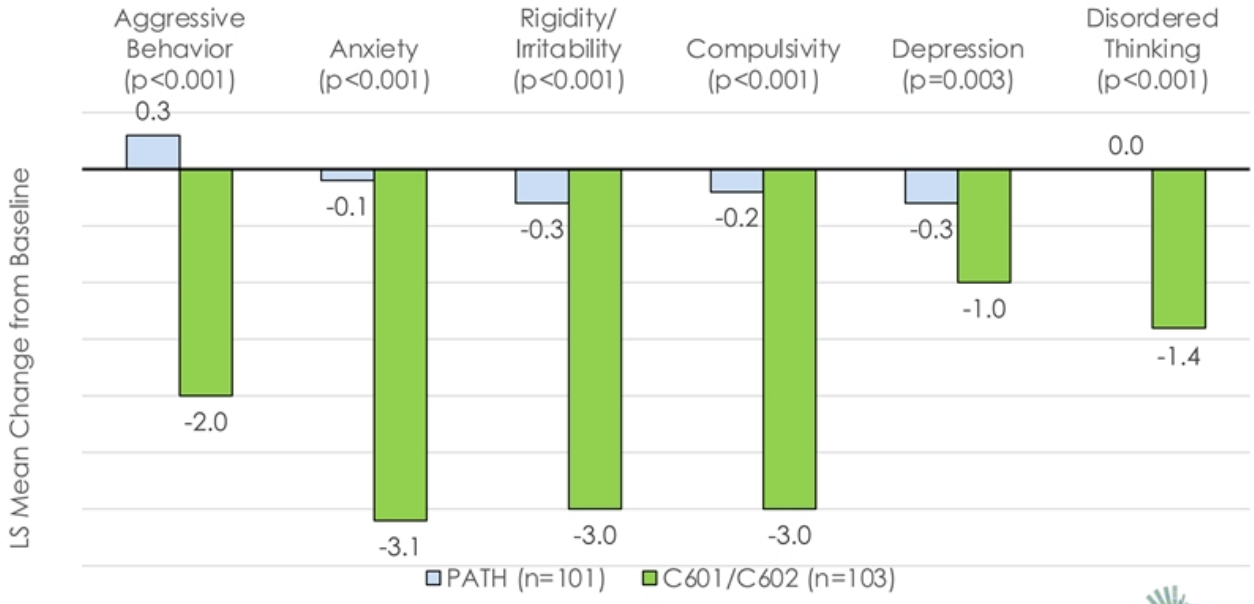
C601/C602 Comparison to PATH – LS Mean Change in Behaviors from Baseline at Week 52



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Endocrine and Hormonal Parameters After One-Year of DCCR

Mean change from Baseline at 1 Year	p-value
Decreased Leptin	**<0.0001**
Decreased Insulin	**0.0004**
Decreased HOMA-IR	**0.0033**
Increased Adiponectin	**<0.0001**

Impact of DCCR

- *Photos provided with consent of the DCCR study participant's caregiver through University of Florida, USA*
- *Changes not representative of all participants*
- *Changes occurred over 12 or more months of DCCR once daily*

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DCCR Safety Profile

- ~100 patients treated for more than one year
- Safety profile generally consistent with the known profile of diazoxide and prior experience with DCCR
- The most common adverse events reported were hypertrichosis, peripheral edema and hyperglycemia
- Most events were Grade 1 or 2 in severity, no Grade 4 or higher events
- Typically self limiting, some needing dose adjustment or treatment (e.g. with oral antidiabetics or short course diuretics)
- No DCCR-related serious unexpected adverse events (SUSARs)

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REGULATORY STATUS AND C602 RANDOMIZED WITHDRAWAL PERIOD

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DCCR Regulatory Status

- As a result of DESTINY PWS (C601) not meeting its primary endpoint in the overall analysis, FDA stated that additional controlled data are necessary to support an NDA submission
  - In June 2023, the FDA acknowledged that data from a proposed randomized withdrawal period of C602 would potentially suffice
    - Subjects currently enrolled in C602, no new subjects
    - Study initiated Q3 2023
    - Topline data anticipated Q3 2023

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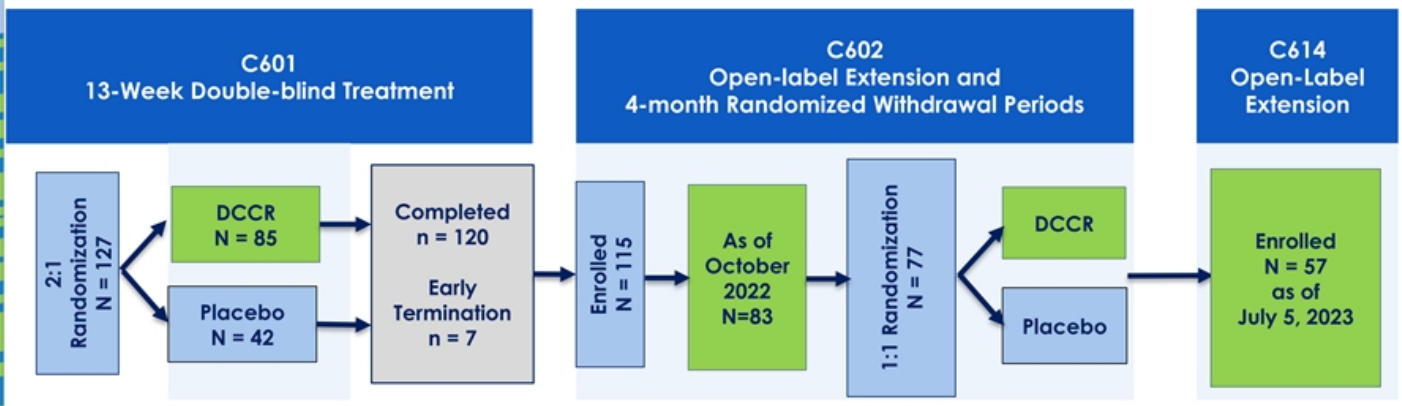
DCCR Phase 3 Updated Clinical Program

- C601 (DESTINY PWS): Multi-center, randomized, double-blind, placebo-controlled, parallel arm study in patients with PWS (Phase 3)
- C602: Study with open-label extension (OLE) and randomized withdrawal (RW) periods
- C614: Open-label safety extension study



Randomized Withdrawal Status

- Randomization completed May 2023
  - 77/83 (93% of participants) randomized
  - 6 of 83 total participants in the study (6%) declined to participate, in line with our expectation of non-participation
- Top-line data continue to be expected in third quarter 2023

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Scientific Outreach & Community Engagement

Increasing levels of engagement with PWS community, physicians and advocacy groups

Posters and presentations at medical and scientific conferences by key opinion leaders and study physicians

Growing body of clinical evidence supporting efficacy and safety

Independent FPWR and PWSA | USA-petition signed by 26,640 supporters requesting FDA regulatory flexibility for DCCR

Independent town hall meetings with study participants and caregivers sharing their testimony about DCCR

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Running for Research Funded, Investigator-Sponsored Study in Early Phase PWS

- Rationale for the research study
  - Biomarker changes in Soleno Phase 3 program suggest DCCR may delay or prevent progression of PWS from early phases to hyperphagic phase
- Study exclusively funded by Running for Research – PWS
  - Soleno to donate DCCR for study
  - To be conducted at four centers in the US, led by University of Florida
  - Enrollment goal: ~ 40 participants
  - Study initiation expected 2H 2023

Extensive IP Protection

Three families of patents being prosecuted in all major pharma markets – primary cases on all three issued

Pharmaceutical formulations of K_{ATP} channel activators and uses thereof

PWS relevant claims: treatment of hyperphagia

Salts of K_{ATP} channel activators and uses thereof

PWS relevant claims: treatment of PWS + Composition of Matter coverage of DCCR

Methods to treat PWS

Specific claims to behavioral and body composition changes in response to DCCR treatment

- Extensive protection of diazoxide choline, DCCR formulation and use, method of manufacture, treatment of PWS and more generally, in syndromic obesity expiring 2025 - 2035

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Commercial Supply Chain

Establishing supply chain to deliver DCCR to patients

- Preparing for validation of commercial scale for drug product
- Production at established, GMP-compliant CMOs
- Third-party Specialty Pharmacy and Hub Services being established

FINANCIAL INFORMATION

Up to $60m financing commitment

- Leading Healthcare Investors - Nantahala, Abingworth and Vivo Capital
  - $10m RECEIVED May 2023 upon completion of enrollment in RW study
  - $15m at positive top line data - Tranche A ~8.6m at $1.75
  - $35m after FDA approval - Tranche B 14m at $2.50
- Total $60m for 22.6 million shares, average price $2.65

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Financial Highlights

Pro Forma Cash and Equity

Cash	$ million		Shares Outstanding million*
June 30, 2023*	19.4		18.0
Positive top line data**	+15.0		26.6
FDA approval***	+35.0		40.6

* 11.2m common outstanding, March 2022 prefunded warrants + options and other warrants
** Includes exercise of 8.6m Tranche A warrants
*** Includes exercise of 14m Tranche B warrants

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Pipeline – Other Opportunities for DCCR

	Potential Upside Opportunities for DCCR	Estimated US Prevalence
Rare Genetic Obesities	SH2B1 deficiency obesity	2,255 – 3,376
	SIM1 deficiency obesity	1,747 – 2,572
	Early onset morbid obesity associated with PCSK1 deficiency	< 350
Other	Chronic Hyperinsulinism	820 – 1,100
	Glycogen Storage Disease Type 1*	2,800 – 6,800

* Orphan designation granted for diazoxide choline in 2021

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Corporate Presentation

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