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): January 10, 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))

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: January 10, 2020

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

Corporate Presentation

January 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.

Soleno Therapeutics (NASDAQ: SLNO)

Orphan asset in Phase III Study for Prader-Willi syndrome

Phase III enrollment complete. Topline data 1H 2020

Significant commercial potential in PWS, an orphan indication with high unmet need. No approved treatments for hyperphagia, the hallmark symptom of PWS

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 designation granted

Orphan designation in the US and EU. Fast Track granted

Significant upside potential in other indications

Compelling product profile

Addresses hallmark symptoms of PWS

Clinically relevant improvements in hyperphagia, aggressive behaviors, body composition, and CV risk parameters with established decades-long safety profile

Financed by leading healthcare investors

Financed through topline data in 1H2020

Leading HC-focused institutional investors, Abingworth, Vivo, Oracle Partners and Jack Schuler

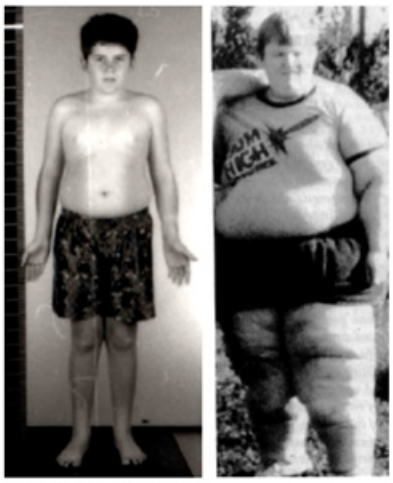
SOLENO THERAPEUTICS

Leadership Team

- Anish Bhatnagar, M.D.
  Chief Executive Officer
- Jim Mackaness
  Chief Financial Officer
- Neil M. Cowen, Ph.D.
  Senior VP, Drug Development
- Revati Shreeniwas, MD
  VP, Clinical Development
- Kristen Yen, M.S.
  VP, Clinical Operations
- Patricia C. Hirano, M.P.H.
  VP, Regulatory Affairs

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 live births
- Elevated mortality rates; average life expectancy ~30 years
- Highest unmet needs
  - Hyperphagia
  - Increases in lean body mass/reductions in fat mass
  - Aggressive behaviors
- PWS families have low QOL
  - Non-PWS siblings show high rates of post traumatic stress syndrome



SOLENO THERAPEUTICS

DCCR Once Daily Tablets

QD Dosing Critical to Facilitate Independence and Compliance

Tablet formulation of choline salt of diazoxide (diazoxide choline is an NCE)

DCCR allows for slow release of diazoxide over 24 hours, and ensures stable levels of free diazoxide

Protected by multiple issued patents, including composition of matter

Characterized in 5 Phase I and 3 Phase II studies in healthy volunteers, obese, dyslipidemic or PWS subjects

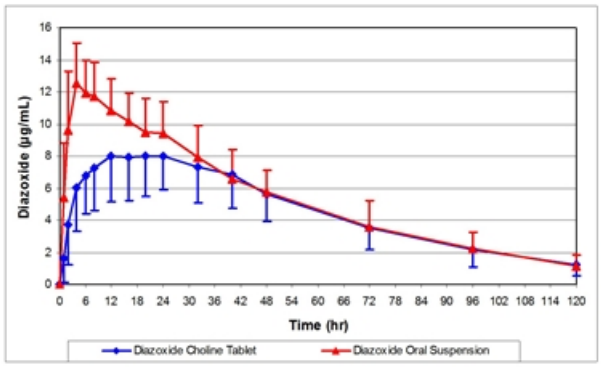
More than 210 subjects dosed before Phase III in PWS

SOLENO THERAPEUTICS

Diazoxide is Not Approved for Use in PWS

Use of diazoxide-based dosage forms in PWS blocked by issued Soleno patent claims

- Oral K_{ATP} channel agonist approved in 1976
- More than 40 years' chronic use in neonates/infants, children, and adults
- Only current use in ultra-rare condition of hyperinsulinism



- Only oral suspension currently marketed in US
- Long, bitter aftertaste
- Problems with dose uniformity
- Rapid protein binding of diazoxide

- BID/TID dosing required
- Rapid absorption → high C_{max}
- Several of the most common adverse events are C_{max}-associated

SOLENO THERAPEUTICS

DCCR Proposed Mechanism of Action

Appetite controlled by 2 sets of neurons in the hypothalamus

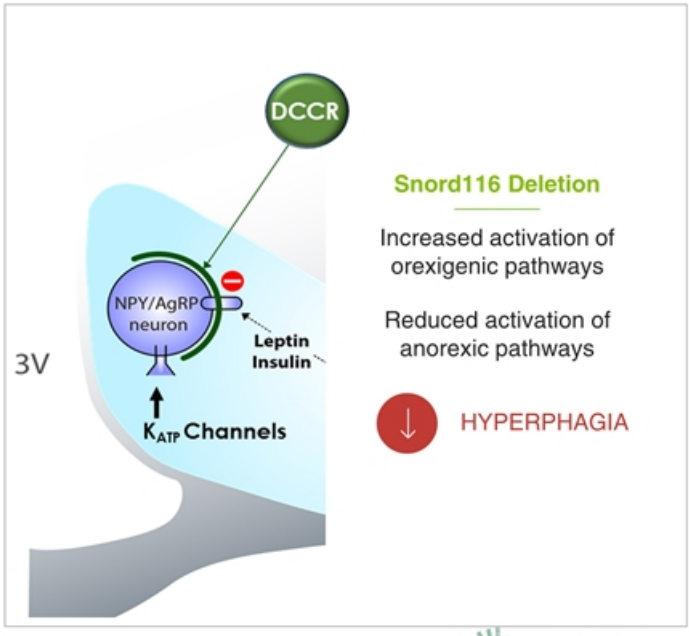
- NPY/AgRP: secrete NPY and AgRP, appetite stimulatory neuropeptides
- POMC: secretes POMC, an appetite suppressive neuropeptide

NPY expression is elevated in PWS

- Loss of SNORD116 in the PWS critical region on chromosome 15 leads to NPY overexpression
- Elevations in NPY drive hyperphagia

DCCR agonizes K_{ATP} channels in NPY/AgRP neurons

- Reduces secretion of NPY and AgRP, thereby reducing hyperphagia



SOLENO THERAPEUTICS

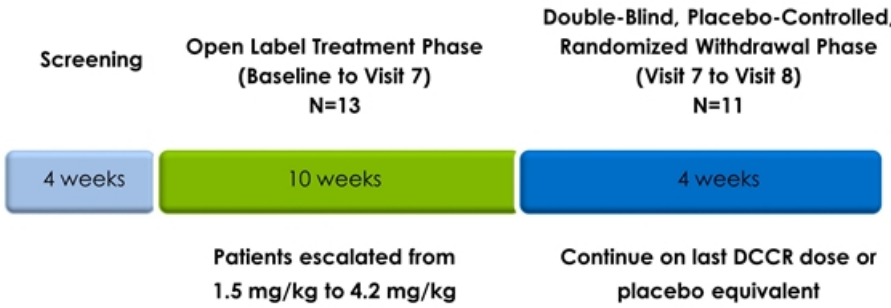
Evidence of efficacy in multiple animal models of NPY-associated obesity with hyperphagia

Animal model	Model of	Significant positive effects on	Reference
MAGEL2 mouse	Prader-Willi syndrome	Hyperphagia, body fat, glycemic control, energy expenditure	Mol Genet Metab 2018 123(4):511-517
Zucker fatty rat	LepR deficient obesity	Hyperphagia, rate of weight gain, glycemic control and insulin sensitivity	Endocrinology 1999 140(7):3197-3202.
Zucker diabetic fatty rat	LepR deficient obesity	Hyperphagia, rate of weight gain, glycemic control, leptin, adiponectin, circulating lipids and hepatic lipid content	Endocrinology 2004; 145:5476–5484 and Med Sci Monit 2005 11(12):BR439-448.
Db/Db mouse	LepR deficient obesity	Completely eliminated hyperphagia	Life Sci 1981 28(15-16):1829-40.
OLETF fatty rat	CCK1 receptor deficiency	Hyperphagia, rate of weight gain, body fat, glycemic control, hepatic lipid content	J Diabetes & Its Complications 2008; 22:46-55.
High fat diet induced obese mouse	Induced obesity with hyperphagia	Reduced caloric intake, weight loss, loss of body fat, circulating lipids, glycemic control	Mol Genet Metab 2018 123(4):511-517; Endocrin 2000 141(10):3630-3637
VMH lesioned rat	Hypothalamic obesity	Completely eliminated hyperphagia	Pharmacol Biochem & Behav 1978 9:717-720.
VMH lesioned chicken	Hypothalamic obesity	Hyperphagia	Physiol Behav 1983 30(3):325-329.

SOLENO THERAPEUTICS

DCCR Pilot Study in PWS

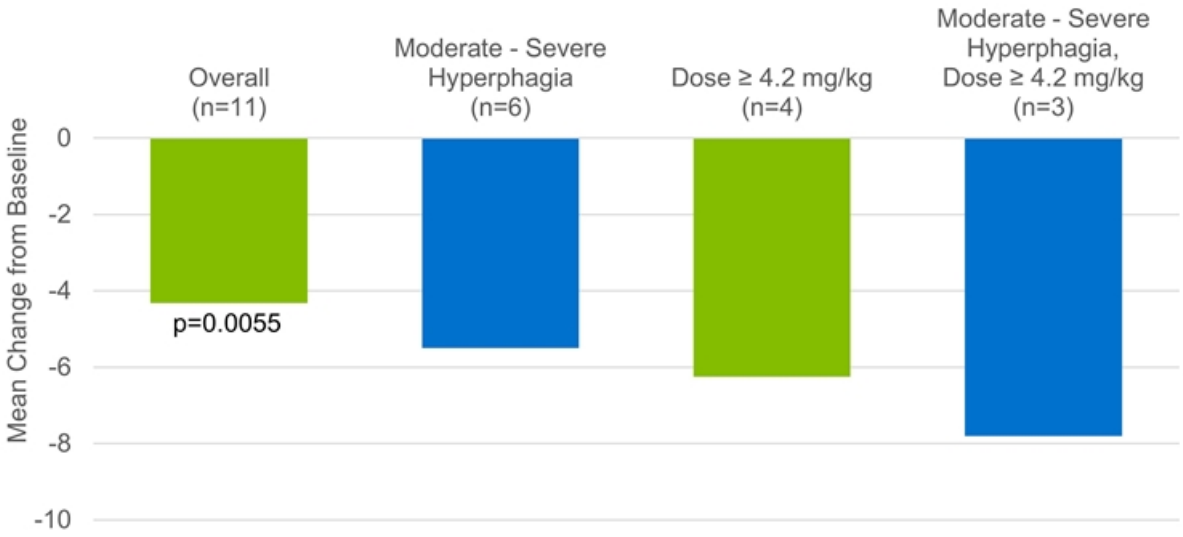
- Randomized, Placebo Withdrawal, Single-Center Study of DCCR in obese, genetically-confirmed PWS patients ages 10 to 22 years
  - Included subjects with mild as well as moderate-to-severe hyperphagia
  - 5 subjects enrolled in a subsequent 6-month open-label extension study



SOLENO THERAPEUTICS

Hyperphagia Response During Open-Label Treatment

Greater at Highest Dose and Moderate-Severe Hyperphagia

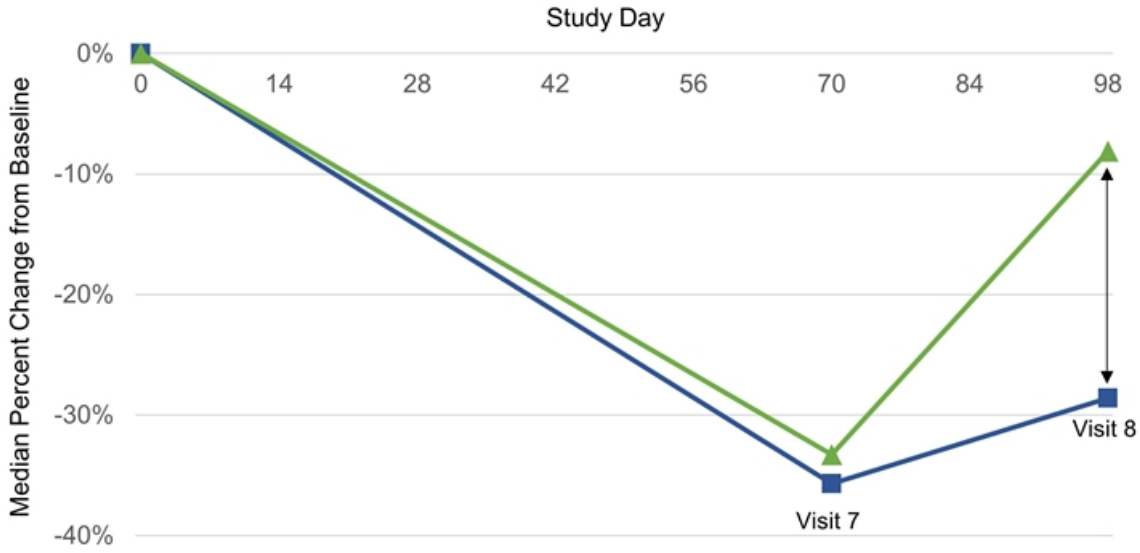


PLoS One. 2019 Sep 23;14(9):e0221615

SOLENO THERAPEUTICS

Placebo Reverses DCCR Treatment Effect

Patients with Moderate-Severe Hyperphagia

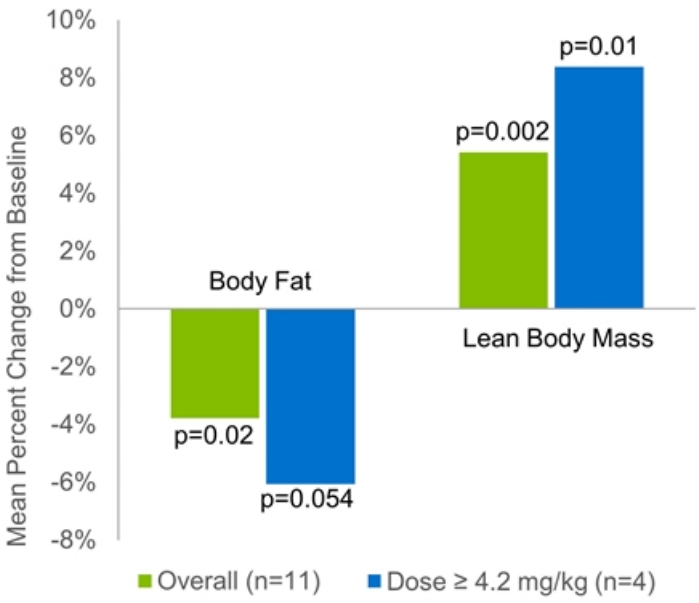


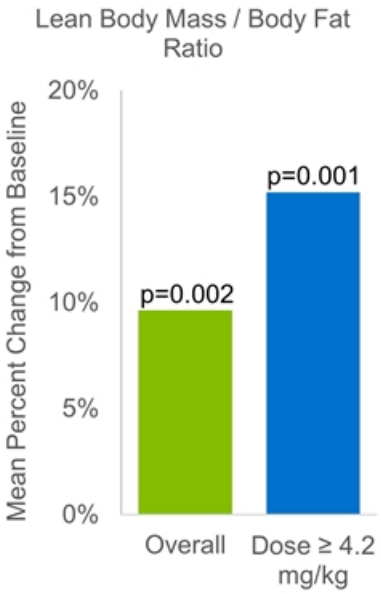
PLoS One. 2019 Sep 23;14(9):e0221615

DCCR (n = 3) Placebo (n = 3)

SOLENO THERAPEUTICS

DCCR Impacts Body Fat and Lean Body Mass





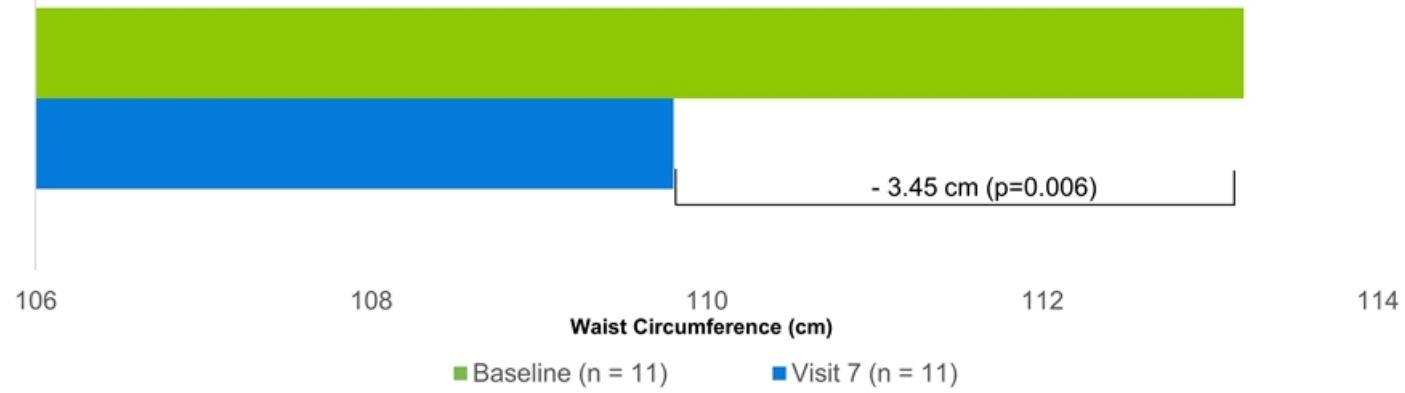
PLoS One. 2019 Sep 23;14(9):e0221615

SOLENO THERAPEUTICS

Waist Circumference

Significant Reduction from Baseline-V7

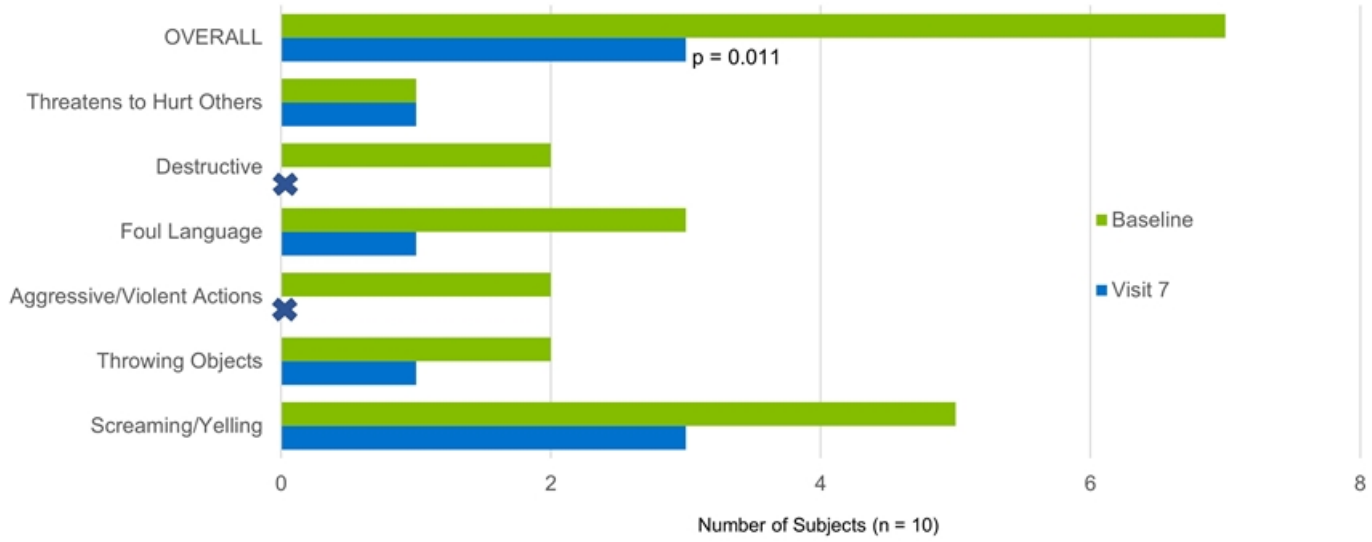
- Reduction consistent with a loss of visceral fat.



PLoS One. 2019 Sep 23;14(9):e0221615

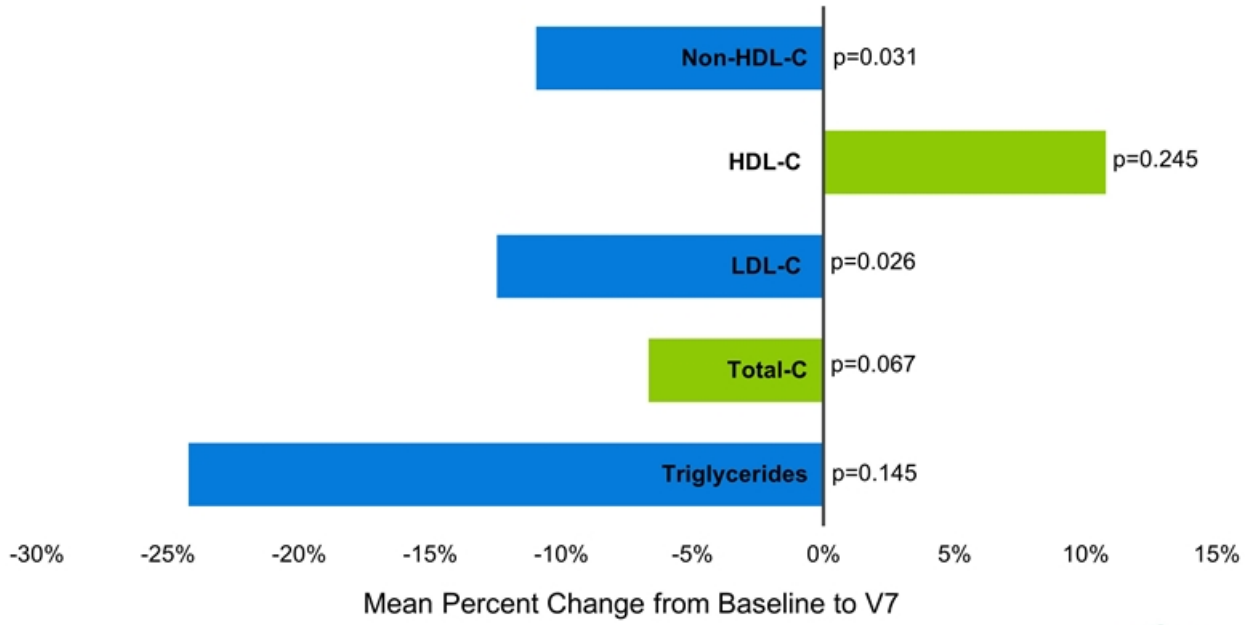
SOLENO THERAPEUTICS

DCCR Reduces Aggressive Behaviors



PLoS One. 2019 Sep 23;14(9):e0221615

DCCR Impacts CV Risk Factors



PLoS One. 2019 Sep 23;14(9):e0221615

SOLENO THERAPEUTICS

DCCR Safety

Consistent with Long History of Safe Use of Diazoxide

Safety profile of diazoxide in chronic use is well-known

Safety of DCCR consistent with that diazoxide

The most common adverse events with DCCR include hyperglycemia and peripheral edema

No serious, unexpected adverse events related to DCCR

Doses of DCCR used in the PWS studies are at the low end or below the equivalent labeled range for diazoxide

Estimated more than 120,000 patient-years of chronic use of diazoxide

SOLENO THERAPEUTICS

Regulatory Status

- FDA interactions in May 2017 (Type C) and Jan 2018 (EOP2) confirmed key aspects of Phase III development program in PWS
  - Hyperphagia as the primary endpoint
  - HQ-CT as the appropriate tool to assess hyperphagia
  - 3 months as appropriate randomized study duration (safety data in 9 month open-label study)
  - Patients as young as 4 years eligible
  - No BMI requirement for study entry
- US and EU Orphan Designation granted
- Fast Track designation granted for diazoxide choline development program in PWS

SOLENO THERAPEUTICS

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

- Patients randomized in a 2:1 ratio to DCCR or placebo
  - Genetically-confirmed PWS patients who are hyperphagic
- Study started May 2018, enrollment completed Jan 2020, topline data 1H 2020
- Primary endpoint – change in hyperphagia compared to placebo
- All patients completing C601 are eligible to enroll in C602

SOLENO THERAPEUTICS

Phase III Program Update*

29

ACTIVE SITES

100%

PATIENTS ENROLLED

C601	C602
>95%	**>95%**
PATIENTS EITHER CONTINUING ON STUDY OR HAVE COMPLETED	PATIENTS CONTINUING ON STUDY

DSMB has recommended continuation of C601 study without any change at two pre-defined times during the study

* As of January 2020

SOLENO THERAPEUTICS

Collaboration with Casimir

The FDA's 21st Century Cures Act defines the importance of individual patient experience to the FDA's regulatory decision-making process

Soleno is collaborating with Casimir, a rare disease research organization, to collect individual patient outcome data from patients participating in C601/602

Outcome assessments will be based on interviews and/or videos before and during treatment with DCCR on C601/602

Casimir's past work has assisted with the approval of EXONDYS 51® for DMD

SOLENO THERAPEUTICS

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 for treating subjects with PWS or SMS PWS relevant claims: reductions in aggressive behavior + others

- Extensive protection of DCCR drug active, drug product, method of manufacture in the treatment of PWS and more generally in syndromic obesity expiring 2025-2035
- Composition of matter (potential for extension to 2034 in US and to 2031 in EU)
- Up to 6 patents are orange book listable (up to 3 expiring in 2035)

SOLENO THERAPEUTICS

Pipeline – Other Opportunities for DCCR

	Indication	US Population Estimate
Syndromic Obesity	Prader-Willi syndrome	21,000 – 28,000
	Potential Upside Opportunities for DCCR	
	Fragile X-PWS Phenotype	6,700 - 8,500
	Prader-Willi Like Syndrome	300 - 500
	Smith Magenis Syndrome	21,000 - 28,000
	MC4R deficiency	32,700 - 163,000
Other	Chronic Hyperinsulinism	820 - 1,100
	Glycogen Storage Disease Type 1	2,800 - 6,800

SOLENO THERAPEUTICS

Financial Highlights

Financed Through Topline Data

- Cash
  - Cash balance at end of Q3 2019 $11.2M
  - Additional cash raised through CMPO Oct 2019 $14.5M
  - Potential additional cash post Topline Data* $12.0M
- No Debt
- Common shares outstanding after CMPO 44.6M
- Fully Diluted 53.6M

*** Potential for additional ~$12 M in cash with exercise of ~6M warrants from Dec 2017 PIPE which terminate at the earlier of Dec 15, 2020 or 30 days following positive Phase III results for DCCR in PWS**

SOLENO THERAPEUTICS

Soleno Therapeutics (NASDAQ: SLNO)

Orphan asset in Phase III Study for Prader-Willi syndrome

Phase III enrollment complete. Topline data 1H 2020

Significant commercial potential in PWS, an orphan indication with high unmet need. No approved treatments for hyperphagia, the hallmark symptom of PWS

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 designation granted

Orphan designation in the US and EU. Fast Track granted

Significant upside potential in other indications

Compelling product profile

Addresses hallmark symptoms of PWS

Clinically relevant improvements in hyperphagia, aggressive behaviors, body composition, and CV risk parameters with established decades-long safety profile

Financed by leading healthcare investors

Financed through topline data in 1H2020

Leading HC-focused institutional investors, Abingworth, Vivo, Oracle Partners and Jack Schuler

SOLENO THERAPEUTICS

Corporate Presentation

January 2020 | Soleno Therapeutics