

**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, 2017**

SOLENO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-36593
(Commission File No.)

77-0523891
(IRS Employer Identification
Number)

1235 Radio Rd #110
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))

Item 7.01. Regulation FD Disclosure

Attached as Exhibit 99.1 to this Current Report on Form 8-K is an investor presentation that Soleno Therapeutics, Inc. (the "Company") may use in presentations to investors from time to time.

The investor presentation attached as Exhibit 99.1 to this Report includes "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation are "forward looking" rather than historical.

The information included 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 or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly

set forth by specific reference in such a filing. The Company undertakes no duty or obligation to update or revise information included in this Report or any of the Exhibits.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit is being filed as part of this Report.

Exhibit Number	Description
99.1	Presentation materials to be provided at investor meetings

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.

Date: July 10, 2017

SOLENO THERAPEUTICS, INC.

By: /s/ David O'Toole
David O'Toole
Chief Financial Officer

Corporate Presentation

July 2017 | Soleno Therapeutics





Certain Notices and Disclaimers

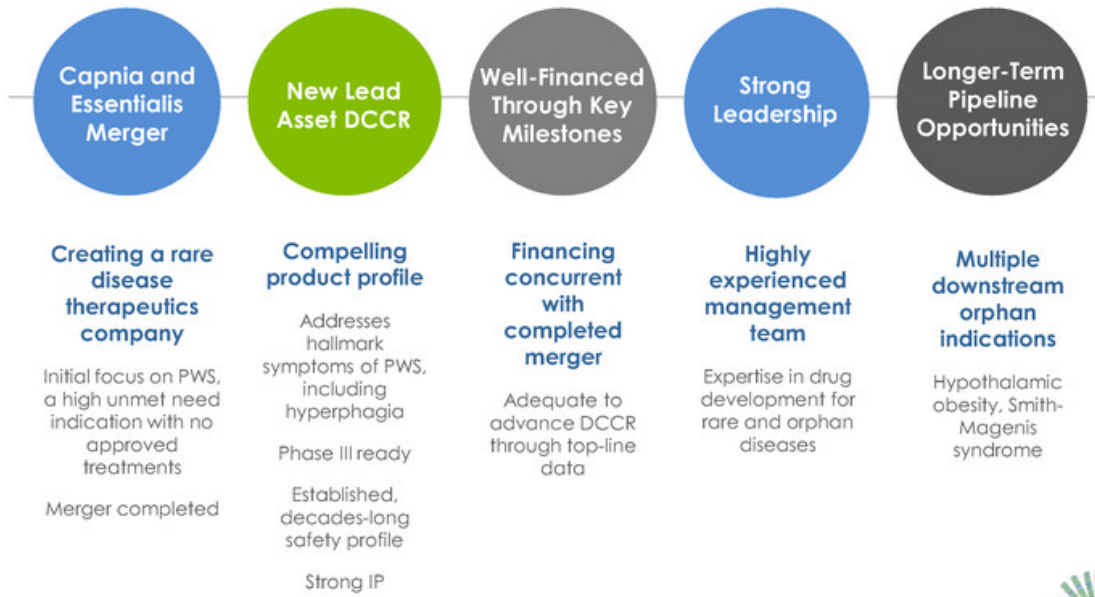
Forward-Looking Statements

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.

Investment Highlights



Leadership Team

- Anish Bhatnagar, M.D.
Chief Executive Officer
- David O'Toole
Senior VP, Chief Financial Officer
- Neil Cowen, Ph.D.
Senior VP, Drug Development
- Kristen Yen, M.S.
VP of Clinical Operations
- Patricia Hirano, M.P.H.
Head of Regulatory Affairs & Quality

Coulter
PHARMACEUTICAL

TITAN
PHARMACEUTICALS

CODEXIS

RESPONSE GENETICS

Dow

EPICYTE

Essentialis

CVT

PRAXHEALTHSCIENCES

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
- Afflicts about 1:15,000-1:25,000 individuals
- Elevated mortality rates
- Highest unmet needs
 - Hyperphagia
 - Aggressive behaviors
 - Body composition
- PWS families have low QOL
 - Normal siblings show high rates of PTSD

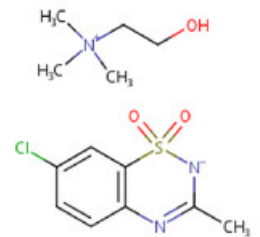


Diazoxide – Long History of Safe Use

DCCR – Extensive Pre-Clinical and Clinical Data

- Diazoxide I.V., Oral suspension and Capsule
 - K_{ATP} channel agonist approved in 1976
 - Previously used as IV treatment for malignant hypertension
 - BID/TID oral suspension for the treatment of hypoglycemia due to hyperinsulinism in infants, children and adults - remains global standard of care
- Diazoxide Choline Controlled-Release (DCCR) Tablet
 - QD tablet formulation of choline salt of diazoxide
 - Characterized in 5 Phase I and 3 Phase II studies in obese, dyslipidemic and PWS subjects
 - More than 210 treated subjects
 - Protected by multiple issued patents, including composition of matter

Diazoxide Choline





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
 - Express K_{ATP} channels
- NPY expression is markedly elevated in PWS
 - Loss of SNORD116 in the PWS critical region on chromosome 15
 - Results in hyperphagia
- Treatment with DCCR
 - Agonizes K_{ATP} channels in NPY/AgRP neurons
 - Reduces secretion of NPY
 - Reduces hyperphagia

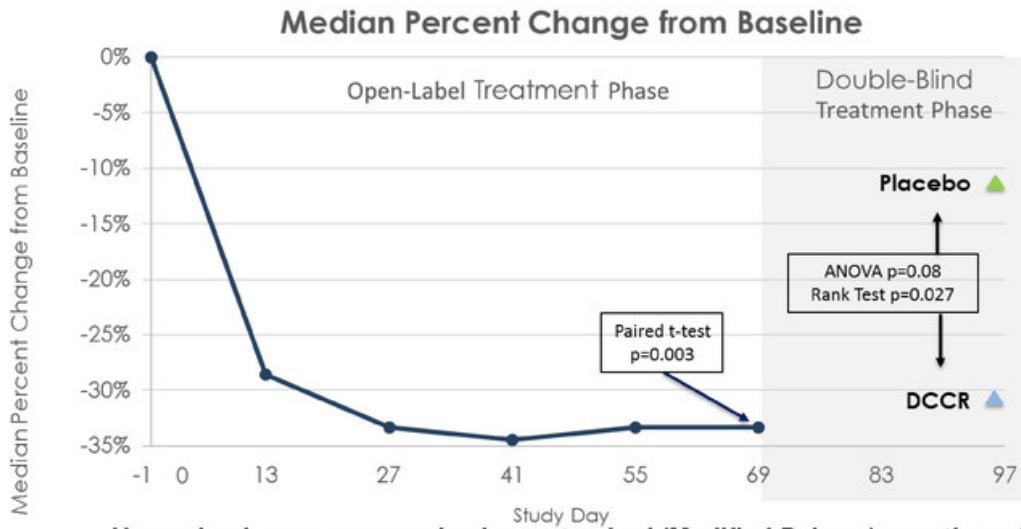
PC025 Pilot Study in PWS

- Randomized, Withdrawal, Single-Center Study of DCCR in overweight or obese, genetically-confirmed PWS patients between 10 and 22 years



The safety and efficacy results from the study were reviewed with a panel of PWS experts

DCCR: Significant Hyperphagia Response



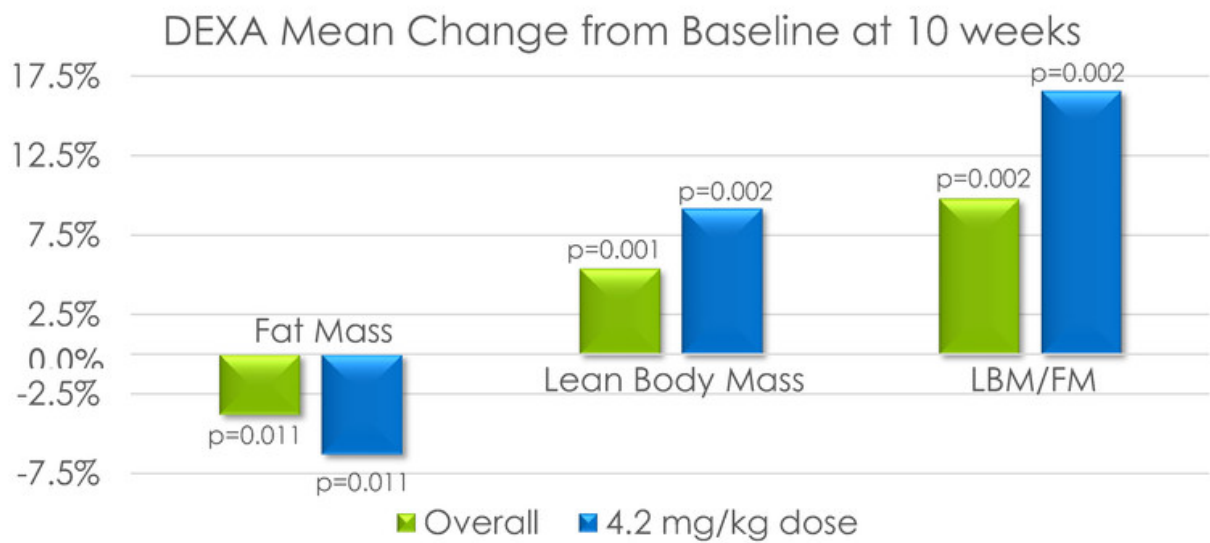
Hyperphagia was measured using a standard (Modified Dykens) questionnaire which assessed a range of PWS specific food-related behaviors

Presented by Essentials at the Annual Meeting of the Foundation for Prader-Willi Research on October 29, 2016

9 | © 2017 Soleno Therapeutics



DCCR Impacts Fat/Lean Body Mass



Presented by Essentials at the Annual Meeting of the Foundation for Prader-Willi Research on October 29, 2016

DCCR Reduces Aggressive Behaviors

- Based on the Behavioral Assessment Questionnaire from the Prader-Willi Syndrome Natural History Study
- Aggressive and destructive behaviors
 - 70% of subjects at Baseline
 - 30% of subjects at 10 weeks (p=0.006)

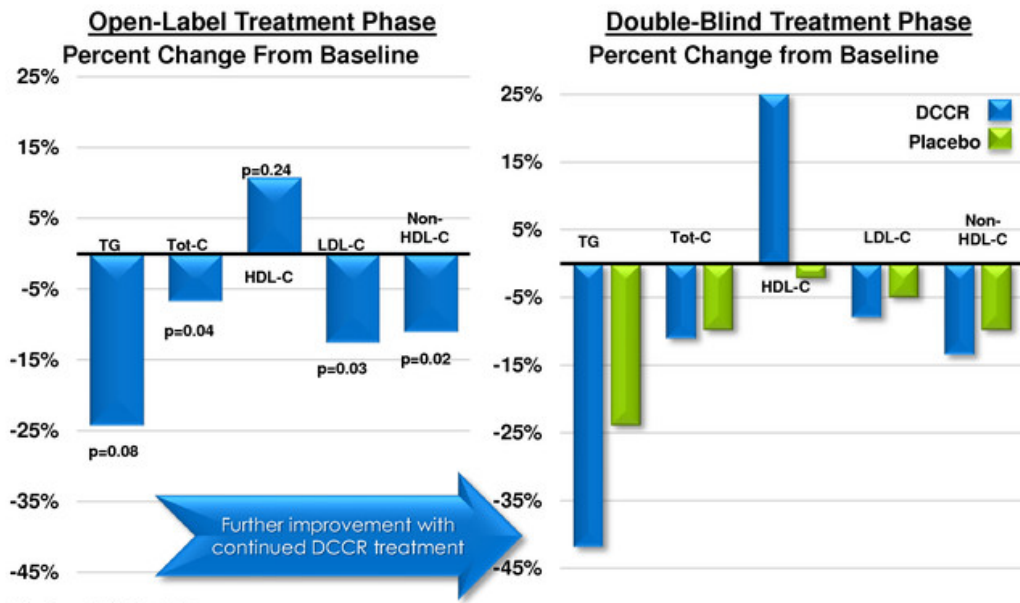
“From a family standpoint, the behavioral changes are huge. Aggression takes kids out of the home.”

- Dr. Theresa Strong, FPWR

“These behavioral changes can be life-changing for the family”

*- Dr. Jennifer Miller,
University of Florida*

DCCR Impacts CV Risk Factors



Presented by Essentials at the Annual Meeting of the Foundation for Prader-Willi Research on October 29, 2016



Diazoxide – Long History of Safe Use

DCCR – Extensive Pre-Clinical and Clinical Data

- The safety profile of Proglycem in chronic use is well-known
- In the development of DCCR, there have been no new safety findings
- The doses of DCCR that will continue in development are at the low end or below the labeled range for Proglycem
- More than 120,000 patient years of chronic use

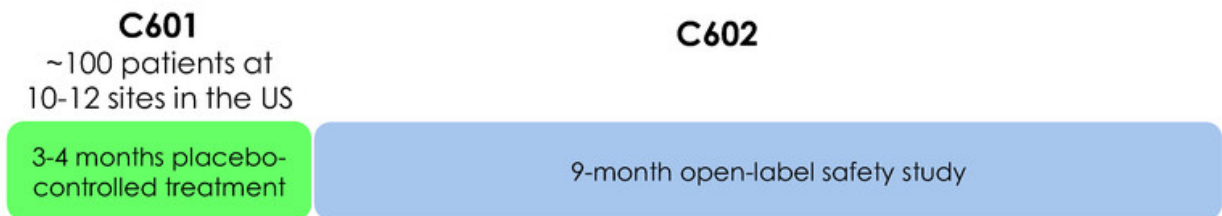


FDA Guidance Meeting (May 2017)

- The FDA supported change in hyperphagia score (without a change in weight) compared to placebo as the primary endpoint for the planned Phase III study.
- The dosing paradigm proposed for the Phase III study was acceptable.
- The FDA proposed and Soleno agreed that the duration of the randomized double-blind placebo controlled study should be shorter (3-4 months).
- Safety information about DCCR could be obtained in a long-term, safety extension study.
- There was agreement on several other aspects of the study and the overall development program, and additional regulatory input is being sought on others.

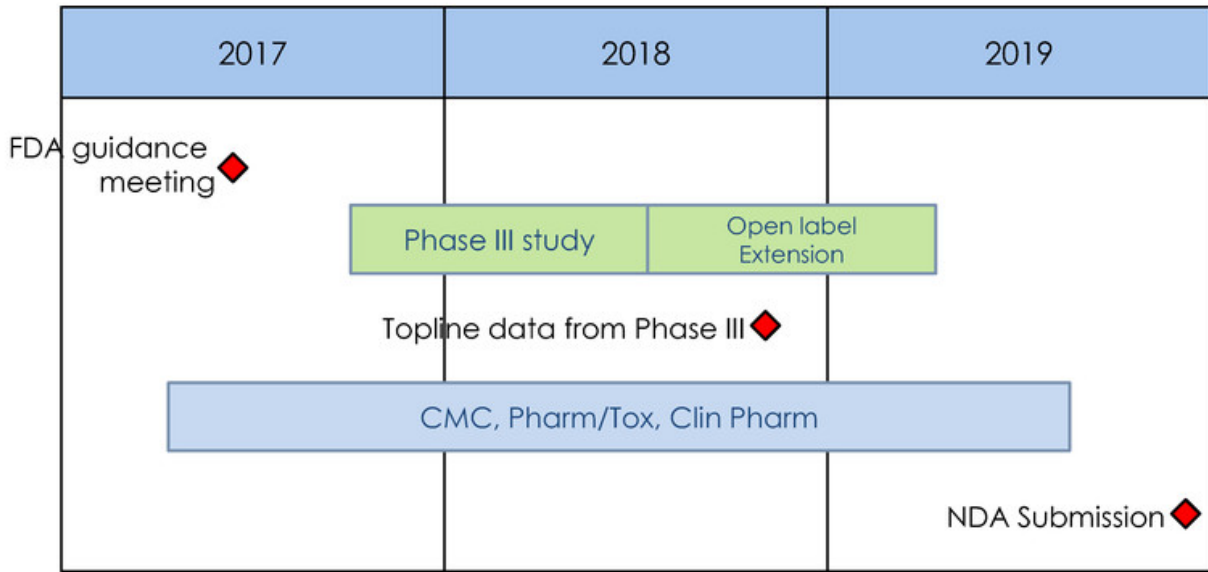
Phase III Proposed Study Design

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



- Patients will be randomized in a 2:1 ratio to DCCR or placebo
- Study start Q4 2017, 9 - 12 months duration
- Primary endpoint – change in hyperphagia compared to placebo
- All patients completing C601 are eligible to enroll in C602

DCCR Estimated Development Timeline





Extensive IP Protection

- Issued/Granted Patents
 - US: 3; EU: 3; JP: 1;
 - Also in China, India, Canada and Australia
 - Several pending applications
 - Expire in 2026 to 2029
 - Covers composition of matter, formulations, combinations, method of use and method of manufacture
- Protection in PWS
 - In addition to the protection of the product, our filings cover method of use of any K_{ATP} channel activator, diazoxide and DCCR in PWS
 - New filing based on data from PC025 could extend protection to 2035

Pipeline – Orphan Opportunities

Product	Indication	US Population Estimate	Estimated Timing to NDA
DCCR	Prader-Willi syndrome	12,500 – 21,000 ^a	2019
Upside Opportunities for DCCR			
DCCR	Hypothalamic Obesity	3,750 – 9,700 ^b	2021
DCCR	Smith-Magenis Syndrome	12,500 – 21,000 ^c	2021

Orphan drug designation was granted for PWS in the US in May 2014

^a Pediatrics 2011 127:195-204

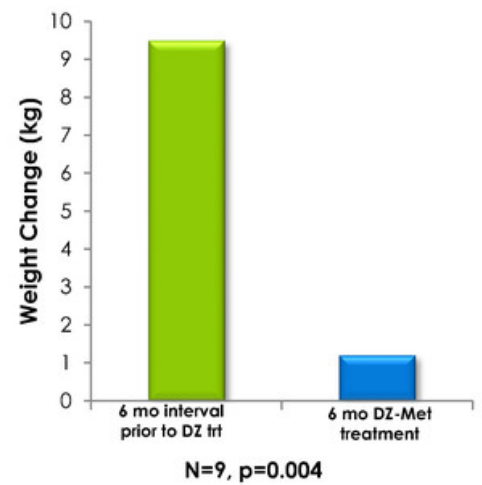
^b Front Endocrin 2011 2:1-8 & Orphanet J Rare Dis 2007 2:18

^c Am J Hum Genet 1991 49(6):1207-1218

Hypothalamic Obesity

- Intractable weight gain and endocrine complications following damage to the hypothalamus
- Most frequently follows excision of a cranial tumor, particularly craniopharyngioma
- Often evident within 1-2 months of surgery
- Dramatically reduced resting and voluntary energy expenditure
- No currently approved treatments
- Prevalence 1:50,000, with more than 50% being children and adolescents

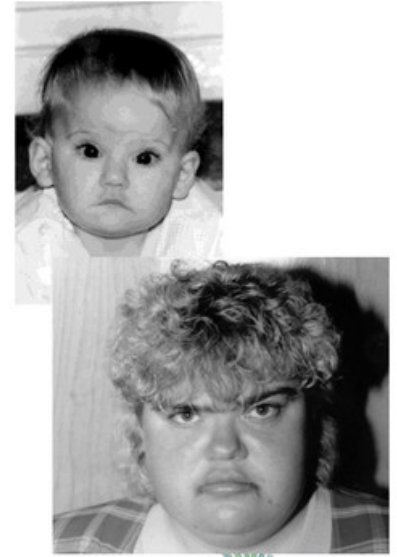
Weight change in adolescent hypothalamic obesity patients treated for 6 months with diazoxide and metformin



Inter J Pediatric Endocrin 2011;417949

Smith-Magenis Syndrome (SMS)

- Complex genetic neurobehavioral / metabolic disorder due to haploinsufficiency of the retinoic acid-induced 1 (RAI1) gene on chromosome 17p11.2
- Key aspects of the natural history parallels PWS
- Behavioral complications more prominent
- Highest unmet needs: aggressive behaviors, hyperphagia, body composition and sleep disturbances
- SMS families have low QOL
- There are no approved treatments
- Prevalence is 1:15,000 - 1:25,000



2017 Priorities / Milestones

- **1Q17** – Closed merger transaction with Essentialis; completed concurrent \$10M financing ✓
- **May 2017** – Name change to Soleno Therapeutics ✓
- **May 2017** – Complete FDA guidance meeting for DCCR ✓
- **2H17** – Initiate Phase III clinical study evaluating DCCR for the treatment of PWS
- **2017** – Explore strategic alternatives for legacy marketed products and product candidates
- **2017** – Secure orphan drug designation for DCCR in additional indications beyond PWS



Financial Highlights

Cash runway to value creating milestones
(millions)

	3/31/17
Cash	\$10.5
Debt	\$0
Shares outstanding:	
Common	47.5 ¹
Fully Diluted	65.4 ¹

¹ Does not include holdback shares of 900 thousand to be issued after 1 year and milestone shares of 4.6 million to be issued upon start of Phase II/III clinical trial

Investment Highlights

