



## Soleno Therapeutics Provides Corporate Update and Reports First Quarter 2018 Financial Results

May 16, 2018

REDWOOD CITY, Calif., May 16, 2018 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. ("Soleno") (NASDAQ:SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided a corporate update and announced financial results for the first quarter ended March 31, 2018.

"We continue to advance our lead product candidate, Diazoxide Choline Controlled-Release (DCCR), in the clinic for Prader-Willi Syndrome (PWS)," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We achieved a significant milestone recently with the initiation of our Phase III clinical trial. Based on the data generated to date, we believe that DCCR has the potential to be an effective treatment option, and look forward to conducting this trial, which we expect will take approximately 9-12 months to complete."

### Recent Corporate Highlights

- Initiated Phase III clinical trial of DCCR in PWS
  - Phase III trial is a randomized, double-blind, placebo-controlled study that will treat approximately 100 patients
  - Study is anticipated to take approximately 9-12 months to complete
- Completed and received minutes from successful End-of-Phase 2 Meeting with the U.S. Food and Drug Administration (FDA)
  - Confirmed that the FDA and Soleno are aligned on key aspects of Soleno's Phase III clinical trial for DCCR

### First Quarter Ended March 31, 2018 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce and to partner the CoSense and Serenz businesses, all revenue and expenses of these businesses have been excluded from continuing operations for all periods herein and reported as discontinued operations. All assets and liabilities of these businesses have been classified as assets and liabilities held for sale on the balance sheet. All prior period information has been recast to conform to this presentation.

Research and development expenses in the first quarter of 2018 were \$1.2 million, compared to \$0.3 million for the same period in 2017. The increase was primarily due to spending in preparation for the recently initiated Phase III trial of DCCR in PWS.

General and Administrative expenses in the first quarter of 2018 were \$1.9 million, compared to \$1.0 million for the same period in 2017. The increase was primarily due to amortization of the intangible asset acquired in the Essentialis merger and professional fees.

The change in the fair value of contingent consideration results from Soleno's obligation to make cash payments to Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Essentialis merger agreement. The fair value of the liability for the contingent consideration payable by Soleno was initially established as approximately \$2.6 million at the time of the merger in March 2017 and was estimated as approximately \$5.1 million at December 31, 2017. The fair value was estimated as approximately \$5.5 million at March 31, 2018, resulting in an increase in expense of approximately \$0.4 million in the quarter ended March 31, 2018.

The loss from continuing operations for the first quarter of 2018 was \$3.2 million, or \$0.17 per share.

The loss from discontinued operations for the first quarter of 2018 was \$0.5 million, or \$0.02 per share.

The net loss for the first quarter of 2018 was \$3.8 million, or \$0.19 per share, compared to the net loss of \$2.9 million, or \$0.57 per share, for the first quarter in 2017.

At March 31, 2018, Soleno had cash and cash equivalents of \$14.9 million, compared to \$17.1 million at December 31, 2017.

### About PWS

The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the US 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 US and EU.

### About Diazoxide Choline Controlled-Release 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 positive data from five completed Phase I clinical studies

in various metabolic indications or 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 symptoms of PWS.

#### **About Soleno Therapeutics, Inc.**

Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The company is currently advancing its lead candidate, DCCR, a once-daily oral tablet for the treatment of PWS, into a Phase III clinical development program in early 2018.

For more information, please visit [www.soleno.life](http://www.soleno.life).

#### **Forward-Looking Statements**

This press release contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ability to initiate the Phase III clinical development program of DCCR in PWS in early 2018.

We may 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 herein, 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. As a result of these factors, we cannot assure you that the forward-looking statements in this press release will prove to be accurate. Additional factors that could materially affect actual results can be found in Soleno's Form 10-Q filed with the Securities and Exchange Commission on November 14, 2017, including under the caption titled "Risk Factors." Soleno expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

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#### **Soleno Therapeutics, Inc.**

##### **Condensed Consolidated Balance Sheets**

(In thousands except share and per share data)

	<b>March 31, 2018</b>	<b>December 31, 2017</b>
	<b>(Unaudited)</b>	
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 14,866	\$ 17,100
Restricted cash	35	35
Prepaid expenses and other current assets	423	343
Current assets held for sale	484	516
Total current assets	15,808	17,994
Long-term assets		
Property and equipment, net	17	23
Other assets	126	126
Intangible assets, net	19,927	20,413
Long-term assets held for sale	453	466
Total assets	\$ 36,331	\$ 39,022
<b>Liabilities and stockholders' equity</b>		
Current liabilities		
Accounts payable	1,133	633
Accrued compensation and other current liabilities	721	973
Current liabilities held for sale	88	127
Total current liabilities	1,942	1,733
Long-term liabilities		
Series A warrant liability	291	352
Series C warrant liability	4	6
2017 PIPE warrant liability	4,927	5,076
Contingent liability for Essentialis purchase price	5,510	5,082
Other liabilities	13	13
Long-term liabilities held for sale	625	225
Total liabilities	13,312	12,487
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred Stock, \$.001 par value, 10,000,000 shares authorized:		

Series B convertible preferred stock, 13,780 are designated at March 31, 2018 and December 31, 2017; 3,571 and 4,571 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively.

Liquidation value of zero.

Common stock, \$0.001 par value, 100,000,000 shares authorized, 19,768,375 and 19,238,972 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively.

Additional paid-in-capital

Accumulated deficit

Total stockholders' equity

Total liabilities and stockholders' equity

—	—
20	19
140,733	140,495
(117,734	) (113,979
23,019	26,535
\$ 36,331	\$ 39,022

## Soleno Therapeutics, Inc.

### Condensed Consolidated Statements of Operations (unaudited)

(In thousands except share and per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2018</b>	<b>2017</b>
Operating expenses		
Research and development	\$ 1,180	\$ 327
Sales and marketing	—	27
General and administrative	1,867	1,019
Change in fair value of contingent consideration	428	—
Total operating expenses	3,475	1,373
Operating loss	(3,475	) (1,373
Other income (expense)		
Cease-use income (expense)	3	(2
Change in fair value of warrants liabilities	212	(69
Interest and other income (expense)	19	(601
Total other income (expense)	234	(672
Loss from continuing operations	(3,241	) (2,045
Loss from discontinued operations	(514	) (842
Net loss	\$ (3,755	) \$ (2,887
Loss per common share from continuing operations, basic and diluted	\$ (0.17	) \$ (0.40
Loss per common share from discontinued operations, basic and diluted	(0.02	) (0.17
Net loss per common share, basic and diluted	\$ (0.19	) \$ (0.57
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	19,530,311	5,090,581

 [Primary Logo](#)

Source: Soleno Therapeutics