



Solenio Therapeutics Provides Corporate Update and Reports Second Quarter 2018 Financial Results

August 14, 2018 8:05 PM EDT

REDWOOD CITY, Calif., Aug. 14, 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 second quarter and six months ended June 30, 2018.

"Our Phase III clinical program for Diazoxide Choline Controlled-Release (DCCR) in Prader-Willi Syndrome (PWS) continues to advance according to plan," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We enrolled the first patient in our ongoing Phase III clinical trial in the second quarter, and have activated several clinical sites across the country to advance enrollment over the next few months. Most recently, we were granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for DCCR in PWS. This significant regulatory milestone provides us with multiple benefits, including increased collaboration with the FDA."

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
- Granted Fast Track designation for DCCR for the treatment of PWS
 - Fast Track designation allows additional meetings with the FDA to discuss Soleno's development plan to ensure the appropriate data are collected and encourages frequent written communication with the FDA regarding design of clinical trials and use of biomarkers
 - If certain criteria are met, the drug will be eligible for Accelerated Approval and Priority Review and also Rolling Review, which allows Soleno to submit to the FDA sections of its New Drug Application as they are finished instead of waiting for all sections to be completed before submitting the marketing application
- Presented a corporate overview at the BIO International Convention

Second Quarter Ended June 30, 2018 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce, partner the CoSense business and divest the Serenz business, 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 expense was \$1.7 million for the three months ended June 30, 2018, compared to \$0.8 million in the same period of 2017. The increase was primarily due to spending in preparation for the recently initiated Phase III trial of DCCR in PWS.

General and administrative expense was \$1.8 million for the three months ended June 30, 2018, compared to \$2.2 million in the same period of 2017. The decrease was due primarily to incurring lower professional fees in 2018 compared to those incurred in 2017 associated with the acquisition of Essentialis, and to a decrease in personnel-related expenses reflecting a reduction in full-time headcount in 2018 compared to 2017.

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, and at \$5.5 million at March 31, 2018. The fair value was estimated as approximately \$5.4 million at June 30, 2018, resulting in a decrease in expense of approximately \$0.1 million in the quarter ended June 30, 2018.

The loss from continuing operations for the second quarter of 2018 was \$7.2 million, or (\$0.36) per share.

The loss from discontinued operations for the second quarter of 2018 was \$0.4 million, or (\$0.02) per share.

The net loss for the second quarter of 2018 was \$7.6 million, or (\$0.38) per share, compared to a net loss of \$4.0 million, or (\$0.42) per share, for the second quarter of 2017.

Six Months Ended June 30, 2018 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce, partner the CoSense business and divest the Serenz business, 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 expense was \$2.9 million for the six months ended June 30, 2018, compared to \$1.1 million in the same period of 2017.

The increase was primarily due to spending in preparation for the recently initiated Phase III trial of DCCR in PWS.

General and administrative expense was \$3.6 million for the six months ended June 30, 2018, compared to \$3.2 million in the same period of 2017. The increase was primarily due to amortization of the intangible asset acquired in the Essentialis merger.

The loss from continuing operations for the six months ended June 30, 2018, was \$10.5 million, or (\$0.52) per share.

The loss from discontinued operations for the six months ended June 30, 2018, was \$0.9 million, or (\$0.05) per share.

The net loss for the six months ended June 30, 2018, was \$11.4 million, or (\$0.57) per share, compared to a net loss of \$6.9 million, or (\$0.94) per share, for the same six month period of 2017.

At June 30, 2018, Soleno had cash and cash equivalents of \$12.6 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 U.S. and E.U.

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 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, DCCR, a once-daily oral tablet for the treatment of 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 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 complete the Phase III clinical development program of DCCR in PWS in 2019.

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-K filed with the Securities and Exchange Commission on April 2, 2018, 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.

CONTACT:

Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

Soleno Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)

	<u>June 30, 2018</u>	<u>December 31, 2017</u>
	<u>(Unaudited)</u>	
Assets		
Current assets		
Cash and cash equivalents	\$ 12,593	\$ 17,100
Restricted cash	—	35
Prepaid expenses and other current assets	248	343
Current assets held for sale	470	516
Total current assets	<u>13,311</u>	<u>17,994</u>

Long-term assets			
Property and equipment, net		13	23
Other assets		126	126
Intangible assets, net		19,441	20,413
Long-term assets held for sale		453	466
Total assets		<u>\$ 33,344</u>	<u>\$ 39,022</u>
Liabilities and stockholders' equity			
Current liabilities			
Accounts payable	\$	981	\$ 633
Accrued compensation and other current liabilities		862	973
Current liabilities held for sale		102	127
Total current liabilities		<u>1,945</u>	<u>1,733</u>
Long-term liabilities			
Series A warrant liability		1,015	352
Series C warrant liability		5	6
2017 PIPE warrant liability		8,036	5,076
Contingent liability for Essentialis purchase price		5,443	5,082
Other liabilities		13	13
Long-term liabilities held for sale		1,050	225
Total liabilities		<u>17,507</u>	<u>12,487</u>
Commitments and contingencies (Note 7)			
Stockholders' equity			
Preferred Stock, \$0.001 par value, 10,000,000 shares authorized:			
Series B convertible preferred stock, 13,780 are designated at June 30, 2018 and December 31, 2017; nil and 4,571 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively. Liquidation value of zero.		—	—
Common stock, \$0.001 par value, 100,000,000 shares authorized, 21,413,867 and 19,238,972 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively.		21	19
Additional paid-in-capital		141,187	140,495
Accumulated deficit		(125,371)	(113,979)
Total stockholders' equity		<u>15,837</u>	<u>26,535</u>
Total liabilities and stockholders' equity		<u>\$ 33,344</u>	<u>\$ 39,022</u>

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	\$ 1,714	\$ 773	\$ 2,894	\$ 1,100
Sales and marketing	—	—	—	27

General and administrative	1,766	2,195	3,633	3,214
Change in fair value of contingent consideration	(67)	—	361	—
Total operating expenses	<u>3,413</u>	<u>2,968</u>	<u>6,888</u>	<u>4,341</u>
Operating loss	<u>(3,413)</u>	<u>(2,968)</u>	<u>(6,888)</u>	<u>(4,341)</u>
Other income (expense)				
Cease-use income (expense)	3	—	6	(2)
Change in fair value of warrants liabilities	(3,834)	(91)	(3,622)	(160)
Interest and other income (expense)	<u>30</u>	<u>3</u>	<u>49</u>	<u>(598)</u>
Total other income (expense)	<u>(3,801)</u>	<u>(88)</u>	<u>(3,567)</u>	<u>(760)</u>
Loss from continuing operations	(7,214)	(3,056)	(10,455)	(5,101)
Loss from discontinued operations	<u>(423)</u>	<u>(913)</u>	<u>(937)</u>	<u>(1,755)</u>
Net loss	<u>\$ (7,637)</u>	<u>\$ (3,969)</u>	<u>\$ (11,392)</u>	<u>\$ (6,856)</u>
Loss per common share from continuing operations, basic and diluted	\$ (0.36)	\$ (0.32)	\$ (0.52)	\$ (0.70)
Loss per common share from discontinued operations, basic and diluted	<u>(0.02)</u>	<u>(0.10)</u>	<u>(0.05)</u>	<u>(0.24)</u>
Net loss per common share, basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.42)</u>	<u>\$ (0.57)</u>	<u>\$ (0.94)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	20,345,437	9,516,108	19,940,126	7,315,569



Source: Soleno Therapeutics