Soleno Therapeutics Provides Corporate Update and Reports First Quarter 2019 Financial Results

May 13, 2019

REDWOOD CITY, Calif., May 13, 2019 (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 reported financial results for the three months ended March 31, 2019.

“Enrollment in our Phase III DESTINY PWS trial evaluating Diazoxide Choline Controlled-Release (DCCR) tablets for the treatment of Prader-Willi Syndrome (PWS) continues to progress,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We recently received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) of our clinical trial application (CTA) in the UK and are in the process of activating several sites there. Moreover, we are strongly encouraged that more than 90% of the patients who have completed the randomized, double-blind, placebo-controlled, Phase III DESTINY PWS study have enrolled in our 9-month, open-label, safety extension study, C602. We continue to look forward to top-line data from DESTINY PWS late this year.”

Recent Corporate Highlights

- Continued enrollment for Phase III DESTINY PWS study of DCCR
  - Trial enrollment continuing at U.S. sites
  - Received CTA approval from the MHRA
  - Intend to initiate several additional sites both in the UK and in the U.S. shortly
  - Over 90% of subjects who were randomized and completed the DESTINY PWS study elected to continue in C602, the 9-month open-label safety extension study
  - Data Safety Monitoring Board recommended the continuation of the DESTINY PWS study without modification
  - Top-line data from the DESTINY PWS study expected in late 2019
- Appointed Gwen A. Melincoff, a biotechnology and pharmaceutical industry veteran, to Board of Directors
- Presented at multiple investor conferences

Financial Results

Soleno’s current research and development efforts are primarily focused on advancing its lead product candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development.

First Quarter Ended March 31, 2019 Financial Results for Continuing Operations

Research and development expenses were $2.8 million for the quarter ended March 31, 2019, compared to $1.2 million in the same period of 2018. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $2.0 million for the quarter ended March 31, 2019, compared to $1.9 million in the same period of 2018. The increase was primarily a result of increased legal fees, primarily related to intellectual property.

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 at approximately $5.1 million at December 31, 2017, at $5.5 million at March 31, 2018, $5.4 million at June 30, 2018, $5.7 million at September 30, 2018, and $5.6 million at December 31, 2018. The fair value was estimated to be approximately $5.9 million at March 31, 2019, resulting in an increase in expense of approximately $0.2 million from the balance at December 31, 2018.

Total Other Expense of $2.1 million consisted primarily of the change in the fair value of the liability for warrants of approximately $1.9 million.

Net loss for the quarter ended March 31, 2019, was approximately $7.0 million, or ($0.22) per share, compared to a net loss of approximately $3.8 million, or ($0.19) per share, for the quarter ended March 31, 2018.

As of March 31, 2019, Soleno had cash and cash equivalents of approximately $19.4 million, as compared to $23.1 million at December 31, 2018.

Results of Discontinued Operations during Quarter Ended March 31, 2018

Discontinued operations during the quarter ended March 31, 2018, consisted of the Company’s activities previously dedicated to the development and commercialization of innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz® Allergy Relief, or Serenz; CoSense® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis; and, products that included temperature probes, scales, surgical tables and patient surfaces. These operations were discontinued as a result of the decision to sell NeoForce, partner the CoSense® business and divest the Serenz business.

About PWS
The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the U.S. 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 C601 study in PWS during 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 annual and quarterly reports filed with the Securities and Exchange Commission, 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.

Corporate Contact:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

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

	March 31, 2019	December 31, 2018
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 19,402	$ 23,099
Prepaid expenses and other current assets	603	529
Due from related party	72	64
Minority interest investment in former subsidiary	788	978
Total current assets	20,865	24,670
Long-term assets		
Property and equipment, net	19	12
Intangible assets, net	17,983	18,469
Total assets	$ 38,867	$ 43,151
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,258	$ 934
Accrued compensation and other current liabilities	992	943
Total current liabilities	2,250	1,877
Long-term liabilities		
Series A warrant liability	73	49
2017 PIPE Warrant liability	6,274	4,563

2018 PIPE Warrant liability	784	600
Contingent liability for Essentialis purchase price	5,855	5,649
Total liabilities	15,236	12,738
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at March 31, 2019 and December 31, 2018; zero and 4,571 shares issued and outstanding at March 31, 2019 and at December 31, 2018, respectively. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 31,776,584 and 31,755,169 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively.	32	32
Additional paid-in-capital	157,661	157,413
Accumulated deficit	(134,062)	(127,032)
Total stockholders' equity	23,631	30,413
Total liabilities and stockholders' equity	$ 38,867	$ 43,151

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

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses		
Research and development	$ 2,760	$ 1,180
General and administrative	2,012	1,867
Change in fair value of contingent consideration	206	428
Total operating expenses	4,978	3,475
Operating loss	(4,978)	(3,475)
Other income (expense)		
Cease-use income	—	3
Change in fair value of warrants liabilities	(1,919)	163
Loss from minority interest investment	(190)	—
Interest income	57	19
Total other income (expense)	(2,052)	185
Loss from continuing operations	(7,030)	(3,290)
Loss from discontinued operations	—	(514)
Net loss	$ (7,030)	$ (3,804)
Loss per common share from continuing operations, basic and diluted	$ (0.22)	$ (0.17)
Loss per common share from discontinued operations, basic and diluted	—	(0.02)
Net loss per common share, basic and diluted	$ (0.22)	$ (0.19)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	31,756,120	19,530,311

See accompanying notes to condensed consolidated financial statements

Source: Soleno Therapeutics