Soleno Therapeutics Provides Corporate Update and Reports Third Quarter 2018 Financial Results

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REDWOOD CITY, Calif., Nov. 15, 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 third quarter and nine months ended September 30, 2018.

"Our ongoing Phase III trial, DESTINY PWS, evaluating Diazoxide Choline Controlled-Release (DCCR) tablets for the treatment of Prader-Willi syndrome (PWS), continues to enroll patients at multiple sites," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We now have 10 sites activated in the U.S. screening patients and intend to activate additional sites in the coming months. Most recently, we amended the trial protocol to allow children as young as four years of age into the study, permitting inclusion of those children with an earlier age of hyperphagia onset. We also presented clinical data supporting the safety and efficacy of DCCR in PWS at both the European Society of Paediatric Endocrinology and Foundation for Prader-Willi Research Annual Conference."

Recent Corporate Highlights

- Continued enrollment for Phase III DESTINY PWS clinical trial of DCCR
  - 10 activated U.S. trial sites. Additional sites are being activated and resources being deployed to support timely completion of the trial
  - Safety consistent with known profile of DCCR and no serious unexpected adverse reactions to date
  - C602, the 9-month open-label safety extension study, has commenced for patients completing three months of treatment in the DESTINY PWS study
- Protocol amendment to DESTINY PWS trial submitted to and accepted by the U.S. Food and Drug Administration (FDA)
  - Amended protocol reduces the age of inclusion to four years of age, from eight years of age previously
  - Allows inclusion of PWS patients who develop symptoms of hyperphagia, the central characteristic of PWS by age 4, with nearly all patients exhibiting hyperphagia by age 8
- Granted Fast Track designation by the FDA for DCCR for the treatment of PWS
- Presented clinical data on DCCR at Late Breaking Session of European Society of Paediatric Endocrinology
  - Pharmacokinetic data presented clearly demonstrated that DCCR is suitable for once-daily dosing, which is important for patient compliance, particularly in children
  - Placebo-controlled data indicated that DCCR's intraday circulating drug levels have the potential to reduce the likelihood of adverse events that can be associated with drug level fluctuations
- Presented clinical data on DCCR at 2018 Foundation for Prader-Willi Research Annual Conference (FPWR)
  - Data presented indicate that DCCR targets the underlying neural mechanisms of hyperphagia in PWS
  - Safety data presented showed that DCCR's once-daily dosing demonstrates potential for improved safety and provides justification for current dosing regimen
- Issued U.S. patent (No. 10/058,557) related to the use of pharmaceutical formulations of diazoxide and diazoxide choline to increase lean body mass and the lean body mass/fat mass ratio in patients with PWS

Third Quarter Ended September 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 $2.1 million for the three months ended September 30, 2018, compared to $1.0 million in the same period of 2017. The increase was primarily due to spending related to the Phase III trial of DCCR in PWS.

General and administrative expense was $1.6 million for the three months ended September 30, 2018, compared to $1.7 million in the same period of 2017. The decrease was primarily a result of a decrease in personnel-related expenses of $92,000 as well as a $30,000 decrease in rent expense as the lease on one of the Company's facilities expired on June 30, 2018.

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, at $5.5 million at March 31, 2018, and $5.4 million at June 30, 2018. In the third quarter ended September 30, 2018, the fair value was estimated as approximately $5.7 million, resulting in an increase in expense of approximately $0.2 million in the period.

The loss from continuing operations for the third quarter of 2018 was $2.3 million, or ($0.11) per share.

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

The net loss for the third quarter of 2018 was $2.7 million, or ($0.13) per share, compared to a net loss of $3.8 million, or ($0.39) per share, for the third quarter of 2017.

Nine months Ended September 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 $5.0 million for the nine months ended September 30, 2018, compared to $2.0 million in the same period of 2017. The increase was primarily due to spending related to the Phase III trial of DCCR in PWS.

General and administrative expense was $5.2 million for the nine months ended September 30, 2018, compared to $4.9 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 nine months ended September 30, 2018, was $12.2 million, or ($0.60) per share.

The loss from discontinued operations for the nine months ended September 30, 2018, was $1.4 million, or ($0.07) per share.

The net loss for the nine months ended September 30, 2018, was $13.6 million, or ($0.67) per share, compared to a net loss of $10.6 million, or ($1.31) per share, for the same nine month period of 2017.

As of September 30, 2018, Soleno had cash and cash equivalents of approximately $10.2 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 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.

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

	September 30, 2018	December 31, 2017
	(Unaudited)	
Assets		
Current assets		

Cash and cash equivalents	$ 10,239	$ 17,100
Restricted cash	—	35
Prepaid expenses and other current assets	327	343
Current assets held for sale	847	516
Total current assets	11,413	17,994
Long-term assets		
Property and equipment, net	14	23
Other assets	—	126
Intangible assets, net	18,955	20,413
Long-term assets held for sale	453	466
Total assets	$ 30,835	$ 39,022
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,245	$ 633
Accrued compensation and other current liabilities	1,153	973
Current liabilities held for sale	110	127
Total current liabilities	2,508	1,733
Long-term liabilities		
Series A warrant liability	58	70
Series C warrant liability	2	6
2017 PIPE warrant liability	6,641	5,076
Contingent liability for Essentialis purchase price	5,671	5,082
Other liabilities	—	13
Long-term liabilities held for sale	1,750	225
Total liabilities	16,630	12,205
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 September 30, 2018 and December 31, 2017; nil and 4,571 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively. Liquidation value of zero	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 21,435,241 and 19,238,972 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	21	19
Additional paid-in-capital	141,479	140,495
Accumulated deficit	(127,295)	(113,697)
Total stockholders' equity	14,205	26,817
Total liabilities and stockholders' equity	$ 30,835	$ 39,022

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

	Three Months Ended September 30,	Nine Months Ended September 30,

	2018	2017	2018	2017
Operating expenses				
Research and development	$ 2,092	$ 946	$ 4,986	$ 2,046
Sales and marketing	—	—	—	26
General and administrative	1,558	1,685	5,191	4,900
Change in fair value of contingent consideration	228	—	589	—
Total operating expenses	3,878	2,631	10,766	6,972
Operating loss	(3,878)	(2,631)	(10,766)	(6,972)
Other income (expense)				
Cease-use income	—	5	6	3
Change in fair value of warrants liabilities	1,543	131	(1,549)	(29)
Interest and other income (expense)	26	3	75	(595)
Total other income (expense)	1,569	139	(1,468)	(621)
Loss from continuing operations	(2,309)	(2,492)	(12,234)	(7,593)
Loss from discontinued operations				
Operating loss	(427)	(1,086)	(1,364)	(2,841)
Loss on sale of assets	—	(208)	—	(208)
Total	(427)	(1,294)	(1,364)	(3,049)
Net loss	$ (2,736)	$ (3,786)	$ (13,598)	$ (10,642)
Loss per common share from continuing operations, basic and diluted	$ (0.11)	$ (0.26)	$ (0.60)	$ (0.94)
Loss per common share from discontinued operations, basic and diluted	(0.02)	(0.13)	(0.07)	(0.37)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.39)	$ (0.67)	$ (1.31)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	21,432,482	9,670,543	20,443,044	8,109,187

Source: Soleno Therapeutics