Soleno Therapeutics Provides Corporate Update and Reports Third Quarter 2017 Financial Results

November 14, 2017

- *Completed Successful EMA Meeting for DCCR in Prader-Willi Syndrome*
- *Continued Preparations to Begin Phase III Program*
- *Presented Positive Updated Safety and Efficacy Data from Pilot Clinical Trial of DCCR for Treatment of Prader-Willi Syndrome*
- *Regained Compliance with NASDAQ Listing Requirements*

REDWOOD CITY, Calif., Nov. 14, 2017 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (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 three and nine months ended September 30, 2017.

"We continue to achieve significant progress in advancing our DCCR clinical development program for the treatment of PWS," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Our most recent key accomplishments include the receipt of constructive guidance from the EMA regarding the regulatory pathway in Europe for DCCR for the treatment of PWS, and the positive opinion received from the EMA recommending DCCR for designation as an orphan medicinal product. Importantly, we recently regained compliance with NASDAQ listing requirements, and our stock continues to be listed on The NASDAQ Capital Market. Looking ahead, we remain focused on finalizing the protocol for our Phase III, randomized, double-blind placebo-controlled study that will treat approximately 100 patients and is now expected to commence in the first quarter of 2018."

Recent Corporate Highlights

- Received scientific advice from the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) regarding Diazoxide Choline Controlled-Release (DCCR) tablet for the treatment of Prader-Willi syndrome (PWS), a rare and complex genetic neurobehavioral/metabolic disorder affecting appetite, growth, metabolism, cognitive function, and behavior.
  - o Received positive guidance on key elements of Phase III program
- Presented updated safety and efficacy data from the pilot clinical trial of DCCR for the treatment of PWS at the 10th International Meeting of Pediatric Endocrinology demonstrating a significant improvement from baseline in hyperphagia, as well as several other key parameters, such as body fat, lean body mass, aggressive behaviors, and lipid profile.
- Regained compliance with NASDAQ listing requirements
- Received a positive opinion recommending DCCR for designation as an orphan medicinal product for the treatment of PWS by EMA's Committee for Orphan Medicinal Products
- Issued multiple new U.S. patents for the use of DCCR
  - o Patent number 9,757,384 covers DCCR for the use of reducing aggressive behaviors in a subject with PWS or Smith-Magenis syndrome, a rare disorder with a distinct genetic basis, but a natural history similar to that of PWS
  - o Patent number 9,782,416 covers the use of diazoxide to treat hyperphagia in a subject with PWS

Third Quarter Ended September 30, 2017 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce, Inc. and either divest or 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 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 third quarter of 2017 were $1.0 million, compared to $0.7 million for the same period in 2016. The increase was primarily due to an increase in DCCR clinical activities.

General and Administrative expenses in the third quarter of 2017 were $1.7 million, compared to $1.3 million for the same period in 2016. The increase was primarily due to the amortization from the acquisition of intangibles from the completed Essentialis merger in March 2017.

Net loss from continuing operations for the third quarter of 2017 was $2.6 million, or $0.24 per share, compared to a net loss of $1.8 million, or $0.56 per share, for the third quarter in 2016.

Net loss from discontinued operations for the third quarter of 2017 was $1.2 million, or $0.11 per share, compared to a net loss of $1.0 million, or $0.31 per share, for the third quarter in 2016.

Net loss for the third quarter of 2017 was $3.8 million, or $0.35 per share, compared to a net loss of $2.8 million, or $0.87 per share, for the third quarter in 2016.

Nine-Months Ended September 30, 2017 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce, Inc. and either divest or 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 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 nine months ended September 30, 2017, were $2.0 million, essentially flat when compared to the same period in 2016.

General and Administrative expenses in the nine months ended September 30, 2017, were $4.9 million, compared to $4.5 million for the same period in 2016. The increase was primarily due to the amortization from the acquisition of intangibles from the completed Essentialis merger in March 2017.

The change in fair value of warrants income for the nine months ended September 30, 2017, was $29,000, which represented a decrease in the fair value of the Series A and Series C Warrants compared to the value of the warrants at December 31, 2016. The change in fair value of warrants income for the nine months ended September 30, 2016, was $1.3 million, which represented an increase in the fair value of the Series A, Series B and Series C Warrants compared to the value of the warrants at December 31, 2015.

Net loss from continuing operations for the nine months ended September 30, 2017, was $7.6 million, or $0.85 per share, compared to a net loss of $5.3 million, or $1.73 per share, for the same period in 2016.

Net loss from discontinued operations for the nine months ended September 30, 2017, was $3.0 million, or $0.34 per share, compared to a net loss of $4.1 million, or $1.35 per share, for the same period in 2016.

Net loss for the nine months ended September 30, 2017, was $10.6 million, or $1.19 per share, compared to a net loss of $9.5 million, or $3.08 per share, for the same period in 2016.

Cash and cash equivalents at September 30, 2017, totaled $5.6 million, compared to $2.7 million at December 31, 2016.

About PWS

PWS is a rare and complex genetic neurobehavioral/metabolic disorder affecting appetite, growth, metabolism, cognitive function and behavior. The committee on genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions: its estimated incidence is one in 15,000 to 25,000 live births. This disorder is typically characterized by hyperphagia, a chronic feeling of insatiable hunger, 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, in the absence of effective limitations to access to food, can lead to morbid obesity. In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia, which is the unrelenting hunger that severely diminishes the quality of life for patients and their families, 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.

About Diazoxide Choline Controlled-Release Tablet

Diazoxide choline controlled-release tablet is a novel, proprietary controlled-release, crystalline salt formulation of diazoxide, which is administered once-daily. The parent molecule, diazoxide, as an oral suspension, has been used for decades in thousands of patients in a few rare diseases in neonates, children and/or adults, but not in PWS. Soleno conceived of and is pursuing an extensive patent portfolio relating to various aspects of the therapeutic use of diazoxide and DCCR in patients with PWS. The DCCR development program is supported by positive data from two completed Phase II clinical studies and five completed Phase I clinical studies in various metabolic indications, as well as a pilot study in PWS patients. In the PWS pilot study, DCCR showed promise in addressing the hallmark symptoms of PWS, most notably hyperphagia. DCCR has received Orphan Drug Designation from the US FDA and a positive opinion for orphan designation from the EMA for the treatment of PWS.

About Soleno Therapeutics, Inc.

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. Soleno, through its wholly-owned subsidiary, Capnia, Inc., continues to market Capnia's innovative medical device, the CoSense® End-Tidal Carbon Monoxide (ETCO) monitor, which measures ETCO and is used by hospitals to detect hemolysis in newborns. It is expected that CoSense will be monetized and will not be a focus for the company in the long-term.

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 initiate the Phase III clinical development program of DCCR in PWS by the end of 2017.

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 presentation 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 August 11, 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.
(formerly known as Capnia, Inc.)
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)

	September 30, 2017	December 31, 2016
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 5,647	$ 2,726
Accounts receivable	—	3
Restricted cash	35	35
Prepaid expenses and other current assets	145	247
Current assets held for sale	563	790
Total current assets	6,390	3,801
Long-term assets		
Property and equipment, net	55	54
Other intangible assets, net	19,353	—
Other assets	126	126
Long-term assets held for sale	458	1,584
Total assets	$ 26,382	$ 5,565
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	642	411
Accrued compensation and other current liabilities	976	1,050
Current liabilities held for sale	113	246
Total current liabilities	1,731	1,707
Long-term liabilities		
Series A warrant liability	289	194
Series C warrant liability	20	86
Other long-term liabilities	1,132	62
Long-term liabilities held for sale	—	81
Total liabilities	3,172	2,130
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 are designated at September 30, 2017 and December 31, 2016; 10,049 and 12,780 shares issued and outstanding at September 30, 2017 and at December 31, 2016, respectively. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 9,970,538 and 3,357,390 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively. (Note 14)	10	4
Additional paid-in-capital	132,154	101,743
Accumulated deficit	(108,954)	(98,312)
Total stockholders' equity	23,210	3,435
Total liabilities and stockholders' equity	$ 26,382	$ 5,565

Soleno Therapeutics, Inc.
(formerly known as Capnia, 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,	
	2017	**2016**	**2017**	**2016**
Operating expenses				
Research and development	$ 982	$ 708	$ 2,046	$ 1,959
Sales and marketing	—	—	26	—
General and administrative	1,707	1,260	4,900	4,532
Total expenses	2,689	1,968	6,972	6,491
Operating loss	(2,689)	(1,968)	(6,972)	(6,491)
Interest and other income (expense)				
Interest Income	4	—	7	—
Change in fair value of warrants liabilities income (expense)	130	200	(29)	1,295
Cease-use expense	4	—	3	(94)
Other expense	—	(9)	(602)	(26)
Interest and other income (expense), net	138	191	(621)	1,175
Loss from continuing operations	(2,551)	(1,777)	(7,593)	(5,316)
Loss from discontinued operations:				
Operating loss	(1,027)	(973)	(2,841)	(4,136)
Loss on sale of assets	(208)	—	(208)	—
Total	(1,235)	(973)	(3,049)	(4,136)
Net loss	$ (3,786)	$ (2,750)	$ (10,642)	$ (9,452)
Loss per common share from continuing operations, basic and diluted (Note 14)	$ (0.24)	$ (0.56)	$ (0.85)	$ (1.73)
Loss per common share from discontinued operations, basic and diluted (Note 14):				
Operating	$ (0.09)	$ (0.31)	$ (0.32)	$ (1.35)
Loss on sale of assets	$ (0.02)	$ —	$ (0.02)	$ —
Total	$ (0.11)	$ (0.31)	$ (0.34)	$ (1.35)
Net loss per common share, basic and diluted (Note 14)	$ (0.35)	$ (0.87)	$ (1.19)	$ (3.08)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share (Note 14)	10,766,608	3,152,306	8,936,255	3,072,729

Source: Soleno Therapeutics