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

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- *Completed Successful FDA Meeting for DCCR in Prader-Willi Syndrome*
- *Preparing to begin Phase III program by the end of the year*
- *Monetized Non-Strategic Assets Through Sale of NeoForce, Inc. Subsidiary*

REDWOOD CITY, Calif., Aug. 11, 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 six months ended June 30, 2017.

"Following our recent successful meeting with the FDA, we expect to initiate a Phase III clinical trial of DCCR in Prader-Willi Syndrome by the end of the year," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We are in the process of finalizing the design of a Phase III, randomized, double-blind placebo-controlled study that will treat approximately 100 patients. We remain excited about the potential of DCCR to safely and effectively treat this catastrophic disease. We also recently strengthened our balance sheet through the sale of one of our non-strategic subsidiaries, NeoForce."

Recent Corporate Highlights

- Completion of FDA Meeting for Diazoxide Choline Controlled-Release (DCCR) in Prader-Willi Syndrome (PWS)
  - Received positive guidance on key elements of Phase III program
  - Company expects to initiate pivotal Phase III clinical trial by year-end 2017; will take approximately 9-12 months to complete
- Sold a non-strategic subsidiary, NeoForce, Inc., which manufactures and promotes a range of innovative pulmonary resuscitation solutions in the neonatal market, to Flexicare, Inc., a privately-held, leading UK-based manufacturer of airway management, anesthesia, and critical care medical devices

Second Quarter Ended June 30, 2017 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce and either divest or partner the CoSense business, all revenue and expenses for 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 second 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 second quarter of 2017 were $2.2 million, compared to $1.4 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, and an increase in stock compensation expense.

Net loss from continuing operations for the second quarter of 2017 was $3.2 million, or $0.06 per share, compared to a net loss of $2.4 million, or $0.15 per share, for the second quarter in 2016.

Net loss from discontinued operations for the second quarter of 2017 was $0.7 million, or $0.01 per share, compared to a net loss of $1.1 million, or $0.07 per share, for the second quarter in 2016.

Net loss for the second quarter of 2017 was $4.0 million, or $0.07 per share, compared to a net loss of $3.5 million, or $0.22 per share, for the second quarter in 2016.

Six-Months Ended June 30, 2017 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce, Inc. and either divest or partner the CoSense 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 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 six months ended June 30, 2017, were $1.5 million, compared to $1.6 million for the same period in 2016. The decrease was primarily due to a reduction in headcount.

General and Administrative expenses in the six months ended June 30, 2017, were $3.2 million, compared to $3.3 million for the same period in 2016. The decrease was primarily due to a decrease in legal fees and decreased headcount.

The change in fair value of warrants income for the six months ended June 30, 2017, was $0.1 million, which represents 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 six months ended June 30, 2016, was $1.1 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 six months ended June 30, 2017, was $5.5 million, or $0.14 per share, compared to a net loss of $4.3 million, or $0.29 per share, for the same period in 2016.

Net loss from discontinued operations for the six months ended June 30, 2017, was $1.4 million, or $0.03 per share, compared to a net loss of $2.4 million, or $0.16 per share, for the same period in 2016.

Net loss for the six months ended June 30, 2017, was $6.9 million, or $0.17 per share, compared to a net loss of $6.7 million, or $0.45 per share, for the same period in 2016.

Cash and cash equivalents at June 30, 2017, totaled $7.5 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. DCCR has received Orphan Drug Designation from the US FDA for the treatment of PWS.

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. Essentialis 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 two completed Phase II clinical studies and six 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.

About Soleno Therapeutics, Inc.

Soleno Therapeutics, Inc. 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 at the end of 2017. 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 this product 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 May 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.

Soleno Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share amounts)
(unaudited)

	As of June 30, 2017	As of December 31, 2016
Assets		
Current Assets		
Cash & Cash Equivalents	$ 7,547	$ 2,726
Accounts Receivable	3	3
Restricted Cash	35	35
Inventory	164	-
Prepaid expenses and other current assets	246	247
Current assets held for sale	2,323	790
Total Current Assets	10,318	3,801

Long-term Assets		
Property & Equipment, net	53	54
Other intangible assets, net	19,884	-
Other Assets	126	126
Long-term assets held for sale	-	1,584
Total Assets	$ 30,381	$ 5,565
Liabilities and stockholders' equity		
Current Liabilities		
Accounts Payable	$ 1,029	$ 411
Accrued compensation and other current liabilities	879	1,050
Current liabilities held for sale	214	246
Total Current Liabilities	2,122	1,707
Long-Term Liabilities		
Series A Warrant Liability	415	194
Series C Warrant Liability	24	86
Other liabilities	1,132	62
Long-term liabilities held for sale	-	81
Total Long-Term Liabilities	1,571	423
Total Liabilities	3,693	2,130
Stockholder's equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized		
Series B convertible preferred stock, 13,780 are designated at June 30, 2017 and December 31, 2016; 12,179 and 12,780 shares issued and outstanding at June 30, 2017 and at December 31, 2016, respectively. Liquidation value of zero	-	-
Common stock, $0.001 par value, 100,000,000 shares authorized, 47,587,647 and 16,786,952 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	48	17
Additional paid-in-capital	131,807	101,730
Accumulated deficit	(105,167)	(98,312)
Total stockholders' equity	26,688	3,435
Total liabilities and stockholders' equity	$ 30,381	$ 5,565

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Product revenue	1	2	4	2
Cost of product revenue	42	51	42	69
Gross profit (loss)	(41)	(49)	(38)	(67)
Expenses				
Research and Development	974	658	1,506	1,623
Sales and Marketing	-	165	27	360
General and Administrative	2,195	1,423	3,214	3,273
Total expenses	3,169	2,246	4,747	5,256
Operating income (loss)	(3,210)	(2,295)	(4,785)	(5,323)
Interest and other income (expense)				
Interest income	3	-	4	-
Change in fair value of warrant liabilities (expense)	(32)	(56)	(101)	1,095

Cease-use expense	-	-	(2)	(94)
Other expense	-	(16)	(602)	(18)
Interest and other income (expense), net	(29)	(72)	(701)	983
Net loss from continuing operations	(3,239)	(2,367)	(5,486)	(4,340)
Net loss from discontinued operations	(727)	(1,146)	(1,370)	(2,362)
Net loss	$ (3,966)	$ (3,513)	$ (6,856)	$ (6,702)
Net income (loss) per common share from continuing operations, basic and diluted	$ (0.06)	$ (0.15)	$ (0.14)	$ (0.29)
Net income (loss) per common share from discontinued operations, basic and diluted	(0.01)	(0.07)	(0.03)	(0.16)
Net loss per common share, basic and diluted	$ (0.07)	$ (0.22)	$ (0.17)	$ (0.45)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	53,060,868	15,528,922	40,029,547	15,162,520

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