Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2017 Financial Results

April 2, 2018

REDWOOD CITY, Calif., April 02, 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 fourth quarter and year ended December 31, 2017.

"The past 12 months have been transformative for our company," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno. "In March of 2017, we completed the merger with Essentialis and refocused our business on the development of novel therapeutics for the treatment of rare diseases. In the short period of time since then, we have advanced our lead product candidate, Diazoxide Choline Controlled-Release ("DCCR") for the treatment of Prader-Willi Syndrome ("PWS"), towards a Phase III clinical trial, which we expect to initiate shortly. As a result of meetings with the U.S. Food and Drug Administration ("FDA") for DCCR in PWS, we now have alignment with the agency on key aspects of the planned Phase III clinical trial."

"In addition, we have strengthened our intellectual property around DCCR, and our lead product candidate received designation as an orphan medicinal product for the treatment of PWS in the European Union," continued Dr. Bhatnagar. "We also regained compliance with NASDAQ listing requirements and have monetized multiple non-core assets. Finally, we closed 2017 by securing a $15 million private placement led by leading healthcare-focused investors, and our DCCR clinical development program is now supported by a strong balance sheet."

Full-Year 2017 Corporate Highlights

- Completed successful interactions with key regulatory agencies concerning DCCR for PWS
  - Confirmed that the FDA and Soleno are aligned on key aspects of Soleno's planned Phase III clinical trial for DCCR
  - Received scientific advice from the Committee for Medicinal Products for Human Use of the European Medicines Agency ("EMA")
    - EMA indicated that a single pivotal trial would support a Marketing Authorisation Application, and indicated their general acceptance of several key aspects of the proposed development plan
- Significantly enhanced balance sheet
  - Completed $10 million financing in conjunction with closing of Essentialis merger
  - Raised additional aggregate gross proceeds of approximately $15 million through a private placement of Soleno's common stock
    - Led by Oracle Investment Management, Jack W. Schuler and Birchview Capital, and supported by certain of Soleno's existing investors
- EMA's Committee for Orphan Medicinal Products issued a positive opinion recommending DCCR for designation as an orphan medicinal product for the treatment of PWS
- Presented updated positive safety and efficacy data from the pilot clinical trial of DCCR in PWS at the 10th International Meeting of Pediatric Endocrinology
- Two new U.S. patents issued for DCCR in PWS
  - Patent number 9,757,384 is related to the use of pharmaceutical formulations of diazoxide and its salts, such as diazoxide choline, to reduce one or more aggressive behaviors in a subject with PWS or Smith-Magenis syndrome
  - Patent number 9,782,416 is related to the use of pharmaceutical formulations of diazoxide to treat hyperphagia in a subject with PWS
- Regained compliance with NASDAQ listing requirements
- Monetized multiple non-core assets
  - Entered into a joint venture agreement with OptAsia Healthcare Limited ("OAHL") for the development and commercialization of Sensalyze technology. OAHL may invest up to $2.2 million in tranches to purchase shares of Soleno's, subsidiary, Capnia, Inc. ("Capnia"). OAHL is responsible for funding operations of Capnia and has the option to buy up to all of the shares of Capnia at a prespecified future time, and at a value based on revenue.
  - Sold NeoForce, Inc. ("NeoForce"), 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

Fourth Quarter Ended December 31, 2017 Financial Results for Continuing Operations

As a result of the decision to sell NeoForce and to 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 and liabilities 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 fourth quarter of 2017 were $1.0 million, compared to $0.3 million for the same period in 2016. The increase was primarily due to spending in preparation for the upcoming Phase III trial of DCCR in PWS.

General and Administrative expenses in the fourth quarter of 2017 were $1.7 million, compared to $1.5 million for the same period in 2016. The increase was primarily due to amortization of the intangible asset acquired in the Essentialis merger and professional fees.

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. The fair value was estimated to be approximately $5.1 million at December 31, 2017, resulting in an increase in expense of approximately $2.5 million.

The loss from continuing operations for the fourth quarter of 2017 was $4.5 million, or $0.39 per share.

The loss from discontinued operations for the fourth quarter of 2017 was $0.5 million, or $0.05 per share.

The net loss for the fourth quarter of 2017 was $5.0 million, or $0.43 per share, compared to the net loss of $2.6 million, or $0.82 per share, for the fourth quarter in 2016.

At December 31, 2017, Soleno had cash and cash equivalents of $17.1 million, compared to $2.7 million at December 31, 2016.

Year Ended December 31, 2017 Financial Results for Continuing Operations
As a result of the decision to sell NeoForce and to 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 and liabilities 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 year ended December 31, 2017, were $3.1 million, compared to $2.2 million in the year ended December 31, 2016. The increase resulted primarily from spending in preparation for the upcoming Phase III trial of DCCR in PWS.

General and Administrative expenses in the year ended December 31, 2017, were $6.6 million, compared to $6.1 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 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. The fair value was estimated to be approximately $5.1 million at December 31, 2017, resulting in an increase in expense of approximately $2.5 million.

The change in fair value of warrants expense for the 12-months ended December 31, 2017, was $1.0 million, which represented an increase in the fair value of the Series A and Series C Warrants compared to the value of these warrants at December 31, 2016, and an increase in the fair value of the warrants issued in the 2017 private placement from the time of issuance in mid-December through December 31, 2017. The change in fair value of warrants income for the 12-months ended December 31, 2016, was $1.7 million, which represented a decrease in the fair value of the Series A, Series B and Series C Warrants compared to the value of these warrants at December 31, 2015.

The loss from continuing operations for the year ended December 31, 2017, was $12.1 million, or $1.35 per share, compared to the loss from continuing operations of $6.7 million, or $2.17 per share, for the year ended December 31, 2016.

The loss from discontinued operations for the year ended December 31, 2017, was $3.6 million, or $0.40 per share, compared to a net loss from discontinued operations of $5.3 million, or $1.72 per share, for the same period in 2016.

The net loss for the year ended December 31, 2017, was $15.7 million, or $1.75 per share, compared to the net loss applicable to common shareholders of $15.7 million, or $5.07 per share, which included the $3.7 million loss on extinguishment of convertible preferred stock, for the same period in 2016.

Cash and cash equivalents at December 31, 2017, totaled $17.1 million, compared to $2.7 million at December 31, 2016.

About PWS
The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people have PWS. 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 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, 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. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the US and EU.

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, as an oral suspension, has been used for decades in thousands of patients in a few rare diseases in neonates, infants, children and/or adults, but not 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 symptoms of PWS.

About 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.

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 in early 2018.

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-Q filed with the Securities and Exchange Commission on November 14, 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.)
Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	$17,099,507	$ 2,725,996
Restricted cash	35,000	35,000
Prepaid expenses and other current assets	342,927	246,570
Current assets held for sale	516,373	793,728
Total current assets	17,993,807	3,801,294
Long-term assets		
Property and equipment, net	22,885	42,021
Other assets	125,530	125,530
Intangible assets, net	20,413,056	—
Long-term assets held for sale	466,387	1,596,007
Total assets	$39,021,665	$ 5,564,852
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 633,104	$ 410,512
Accrued compensation and other current liabilities	973,054	1,050,466
Current liabilities held for sale	126,611	246,400
Total current liabilities	1,732,769	1,707,378
Long-term liabilities		
Series A warrant liability	351,713	194,048
Series C warrant liability	5,880	85,490
2017 PIPE Warrant liability	5,076,000	—
Contingent liability for Essentialis purchase price	5,081,840	—
Other liabilities	13,163	61,739
Long-term liabilities held for sale	225,392	81,000
Total liabilities	12,486,757	2,129,655
Commitments and contingencies (Note 7)		
Stockholders' equity		

Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at December 31, 2017, and December 31, 2016; 4,571 and 12,780 shares issued and outstanding at December 31, 2017, and at December 31, 2016, respectively. Liquidation value of zero.	5	13
Common stock, $0.001 par value, 100,000,000 shares authorized, 19,238,972 and 3,357,387 shares issued and outstanding at December 31, 2017, and December 31, 2016, respectively.	19,239	3,357
Additional paid-in-capital	140,494,976	101,743,714
Accumulated deficit	(113,979,312)	(98,311,887)
Total stockholders' equity	26,534,908	3,435,197
Total liabilities and stockholders' equity	$ 39,021,665	$ 5,564,852

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
Consolidated Statement of Operations

	For the Quarters Ended December 31,	
	2017	**2016**
Operating Expenses		
Research and development	$ 1,022,781	$ 288,370
General and administrative	1,684,358	1,544,664
Change in fair value of contingent consideration	2,492,192	-
Total operating expenses	5,199,331	1,833,034
Operating loss	(5,199,331)	(1,833,034)
Interest and other income (expense)		
Cease-use income (expense)	1,606	-
Change in fair value of warrants liabilities income (expense)	(938,211)	371,809
Other income (expense)	4,456	39,918
Total other income (expense)	(932,149)	411,727
Loss from continuing operations before provision for income tax benefit	(6,131,480)	(1,421,307)
Provision for income tax benefit from continuing operations	1,650,467	-
Loss from continuing operations	(4,481,013)	(1,421,307)
Loss from discontinued operations:		
Operating loss	(566,454)	(1,191,790)
Loss on sale of assets, net of tax effect	21,700	-
Loss from discontinued operations	(544,754)	(1,191,790)
Net loss	(5,025,767)	(2,613,097)
Loss per common share from continuing operations, basic and diluted	$ (0.39)	$ (0.45)
Loss per common share from discontinued operations, basic and diluted	(0.05)	(0.37)
Net loss per common share, basic and diluted	$ (0.43)	$ (0.82)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	11,555,294	3,187,173

Soleno Therapeutics, Inc.
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Consolidated Statements of Operations

	For the Years Ended December 31,	
	2017	**2016**
Operating Expenses		
Research and development	$ 3,068,742	$ 2,247,141
Sales and marketing	25,731	—

General and administrative	6,584,650	6,076,976
Change in fair value of contingent consideration	2,492,192	—
Total operating expenses	12,171,315	8,324,117
Operating loss	(12,171,315)	(8,324,117)
Interest and other income (expense)		
Cease-use income (expense)	4,167	(93,749)
Change in fair value of warrants liabilities	(967,055)	1,667,117
Other income (expense)	(590,114)	13,129
Total other income (expense)	(1,553,002)	1,586,497
Loss from continuing operations before provision for income tax benefit	(13,724,317)	(6,737,620)
Provision for income tax benefit from continuing operations	1,650,467	—
Loss from continuing operations	(12,073,850)	(6,737,620)
Loss from discontinued operations:		
Operating loss	(3,407,596)	(5,327,594)
Loss on sale of assets, net of tax effect	(185,979)	—
Loss from discontinued operations	(3,593,575)	(5,327,594)
Net loss	(15,667,425)	(12,065,214)
Loss on extinguishment of convertible preferred stock	—	3,651,172
Net loss applicable to common stockholders	(15,667,425)	$ (15,716,386)
Loss per common share from continuing operations, basic and diluted	$ (1.35)	$ (2.17)
Loss per common share from discontinued operations, basic and dilute	(0.40)	(1.72)
Loss per common share from extinguishment of convertible preferred stock	—	(1.18)
Net loss per common share, basic and diluted	$ (1.75)	$ (5.07)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	8,977,795	3,101,496

Primary Logo

Source: Soleno Therapeutics