Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2018 Financial Results

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REDWOOD CITY, Calif., March 18, 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 announced financial results for the fourth quarter and year ended December 31, 2018.

"We continue to enroll patients into our ongoing Phase III DESTINY PWS study, which is evaluating Diazoxide Choline Controlled-Release (DCCR) tablets for the treatment of Prader-Willi syndrome (PWS)," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We currently have 14 sites activated in the U.S. and continue the process of activating additional sites. In addition, I am pleased to report that, to date, approximately 90% of the patients who have completed the randomized, double-blind, placebo-controlled, Phase III DESTINY PWS study have elected to enroll in our 9-month open-label safety extension study, C602. Most recently, the Data Safety Monitoring Board (DSMB), the independent group of experts monitoring the safety of the DESTINY PWS study, recommended the continuation of the study without modification, further supporting DCCR's safety profile. We look forward to top-line data from DESTINY PWS late this year."

"The progress in our Phase III DESTINY PWS study, taken together with Fast Track designation granted by the FDA, presentations of DCCR data at national and international scientific meetings, a $16.5 million financing led by Abingworth, and the further strengthening of our DCCR patent portfolio resulted in an exciting 2018," continued Dr. Bhatnagar.

Recent Corporate Highlights

- Continued enrollment for Phase III DESTINY PWS study of DCCR
  - 14 activated U.S. trial sites, with additional sites being added. Most recent sites activated at the National Institutes of Health in Bethesda, MD, Children's Hospital Colorado in Aurora, CO, Nationwide Children's Hospital in Columbus, OH, and University of California, Irvine, in Irvine, CA
  - Approximately 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
  - Top-line data from the DESTINY PWS study expected in late 2019
- DSMB recommended the continuation of the DESTINY PWS study without modification
- DCCR development program for PWS granted Fast Track designation by the FDA
- Presented DCCR data at international and national conferences, including at the European Society of Pediatric Endocrinology, Foundation for Prader-Willi Research Annual Conference and The Obesity Society
  - Most recently, presented clinical data on the effects of DCCR on hyperphagia and fat loss in patients with PWS at the Obesity Society Meeting 2018
    - Patients who received 10 weeks of treatment with DCCR demonstrated statistically significant loss of total body fat mass, without additional caloric restrictions
- Multiple new patents issued
  - U.S. patent 10,058,557 - use of DCCR to increase lean body mass in PWS patients
  - U.S. patent 10,085,998 - use of DCCR to agonize the K_{ATP} channel in obese, overweight and obesity-prone individuals
  - EU patent 2404604 - use of DCCR in the treatment of diabetes
  - Australian patent 2015346196 - use of DCCR to reduce aggressive behaviors in PWS
- Raised approximately $16.5 million through the private placement of equity securities to support the DCCR development program
  - The recent financing was led by Abingworth LLP, a leading transatlantic bioscience investment firm
  - In connection with this financing, Andrew Sinclair, a Partner at Abingworth, joined Soleno's Board of Directors

Financial Results

Soleno focuses primarily on the development and commercialization of novel therapeutics for the treatment of rare diseases. The Company's current research and development efforts are primarily focused on advancing its lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development. 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.

Fourth Quarter Ended December 31, 2018 Financial Results for Continuing Operations

Research and development expenses were $2.2 million for the quarter ended December 31, 2018, compared to $1.0 million in the same period of 2017. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $1.4 million for the quarter ended December 31, 2018, compared to $1.7 million in the same period of 2017. The decrease was primarily due to lower professional and legal fees related to intellectual property aspects of discontinued operations and lower rent expense, as one of the Company's facilities leases concluded in June 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 at approximately $5.1 million at December 31, 2017, at $5.5 million at March 31, 2018, $5.4 million at June 30, 2018, and $5.7 million at September 30, 2018. The fair value was estimated to be approximately $5.6 million at December 31, 2018, resulting in a decrease in expense of approximately $0.1 million from the balance at September 30, 2018.

The operating loss from discontinued operations for the quarter ended December 31, 2018, was approximately $0.1 million, or $0.01 per share, resulting from consolidating the operating results of Capnia, the Company's previously wholly-owned subsidiary prior to Capnia's issuance of majority shares to OptAsia Healthcare Limited ("OAHL") in mid-October 2018.

Net Other Income of $3.9 million consisted primarily of the change in the fair value of the liability for warrants of approximately $2.1 million, and the $2.0 million gain recognized on the deconsolidation of Capnia upon the issuance of majority shares to OAHL, with whom Soleno entered into a joint venture agreement in December 2017.

Income from continuing operations for the quarter ended December 31, 2018, was approximately $0.4 million, or $0.02 per share, resulting primarily from the operating loss of approximately $3.5 million, which was offset by Net Other Income of $3.9 million.

Net income for the quarter ended December 31, 2018, was approximately $0.3 million, or $0.01 per share, compared to a net loss of approximately $4.7 million, or $0.41per share, for the quarter ended December 31, 2017.

Year Ended December 31, 2018 Financial Results for Continuing Operations

Research and development expenses were $7.2 million for the year ended December 31, 2018, compared to $3.1 million for the year ended December 31, 2017. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $6.6 million for the year ended December 31, 2018, which is consistent with the level of expenses incurred during the year ended December 31, 2017.

The loss from continuing operations for the year ended December 31, 2018, was $11.8 million, or $0.56 per share.

The loss from discontinued operations for the year ended December 31, 2018, was $1.5 million, or $0.07 per share.

The net loss for the year ended December 31, 2018, was $13.3 million, or $0.64 per share, compared to a net loss of $15.4 million, or $1.71 per share, for the year ended December 31, 2017.

As of December 31, 2018, Soleno had cash and cash equivalents of approximately $23.1 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 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 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.
Consolidated Balance Sheets
(in thousands except share and per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 23,099	$ 17,100
Restricted cash	—	35
Prepaid expenses and other current assets	593	343
Minority interest investment in former subsidiary	978	—
Current assets held for sale	—	516
Total current assets	24,670	17,994
Long-term assets		
Property and equipment, net	12	23
Other assets	—	126
Intangible assets, net	18,469	20,413
Long-term assets held for sale	—	466
Total assets	$ 43,151	$ 39,022
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 934	$ 633
Accrued compensation and other current liabilities	943	973
Current liabilities held for sale	—	127
Total current liabilities	1,877	1,733
Long-term liabilities		
Series A warrant liability	49	70
Series C warrant liability	—	6
2017 PIPE Warrant liability	4,563	5,076
2018 PIPE Warrant liability	600	—
Contingent liability for Essentialis purchase price	5,649	5,082
Other liabilities	—	13
Long-term liabilities held for sale	—	225
Total liabilities	12,738	12,205
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, 2018 and December 31, 2017; zero and 4,571 shares issued and outstanding at December 31, 2018 and at December 31, 2017, respectively. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 31,755,169 and 19,238,972 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively.	32	19
Additional paid-in-capital	157,413	140,495
Accumulated deficit	(127,032)	(113,697)
Total stockholders' equity	30,413	26,817
Total liabilities and stockholders' equity	$ 43,151	$ 39,022

Soleno Therapeutics, Inc.
Consolidated Statements of Operations

(in thousands except share and per share data)

	For the Quarters Ended December 31,	
	2018	**2017**
Operating expenses		
Research and development	$ 2,192	$ 1,023
General and administrative	1,365	1,684
Change in fair value of contingent consideration	(22)	2,492
Total operating expenses	3,535	5,199
Operating loss	(3,535)	(5,199)
Other income (expense)		
Cease-use income	-	1
Change in fair value of warrants liabilities	2,071	(656)
Gain on deconsolidation of subsidiary	1,994	-
Interest and other expense, net	(137)	5
Total other income (expense)	3,928	(650)
Gain (loss) from continuing operations before provision for income tax benefit	393	(5,849)
Provision for income tax benefit from continuing operations	-	1,650
Gain (loss) from continuing operations	393	(4,199)
Gain (loss) from discontinued operations:		
Operating loss	(130)	(558)
Gain on sale of assets, net of tax effect	-	14
Loss from discontinued operations	(130)	(544)
Net income (loss)	$ 263	$ (4,743)
Gain (loss) per common share from continuing operations, basic and diluted	$ 0.02	$ (0.36)
Loss per share from discontinued operations, basic and diluted	(0.01)	(0.05)
Net income (loss) per common share, basic and diluted	$ 0.01	$ (0.41)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	22,555,421	11,555,294

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

	For the Years Ended December 31,	
	2018	**2017**
Operating expenses		
Research and development	$ 7,178	$ 3,069
Sales and marketing	—	26
General and administrative	6,556	6,584
Change in fair value of contingent consideration	567	2,492
Total operating expenses	14,301	12,171
Operating loss	(14,301)	(12,171)
Other income (expense)		
Cease-use income	6	4
Change in fair value of warrants liabilities	522	(685)
Gain on deconsolidation of subsidiary	1,994	-
Interest and other income (expense)	(62)	(590)
Total other income (expense)	2,460	(1,271)

Loss from continuing operations before provision for income tax benefit	(11,841)	(13,442)
Provision for income tax benefit from continuing operations	—	1,650
Loss from continuing operations	(11,841)	(11,792)
Loss from discontinued operations:		
Operating loss	(1,494)	(3,399)
Other expense	—	(194)
Total	(1,494)	(3,593)
Net loss	$ (13,335)	$ (15,385)
Loss per common share from continuing operations, basic and diluted	$ (0.56)	$ (1.31)
Loss per common share from discontinued operations, basic and diluted	(0.07)	(0.40)
Net loss per common share, basic and diluted	$ (0.64)	$ (1.71)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	20,975,479	8,977,795



Source: Soleno Therapeutics