Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2019 Financial Results

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REDWOOD CITY, Calif., March 04, 2020 (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, 2019.

"The recent completion of enrollment in our ongoing Phase III clinical trial, DESTINY PWS, evaluating once-daily Diazoxide Choline Controlled-Release (DCCR) tablets for patients with Prader Willi Syndrome (PWS), represents a significant achievement for our company," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We remain on track to announce top-line data during the first half of this year, and would like to thank the patients, families and investigators involved in this study, as well as the Foundation for Prader-Willi Research (FPWR) and Prader-Willi Syndrome Association (PWSA) USA and UK for their support of DESTINY PWS."

Fourth Quarter 2019 and Recent Corporate Highlights

- Completed enrollment for Phase III DESTINY PWS study of DCCR
  - Top-line data are anticipated in the first half of 2020.
  - A total of 127 subjects were randomized at 29 sites in the US and the UK. This includes additional patients who were in screening at the time target enrollment was met.
  - This final sample size is powered to detect a difference in change from baseline in HQ-CT score between DCCR and placebo of 4 points. The HQ-CT is a validated questionnaire to measure hyperphagia, the primary outcome measure for the Phase III study. The range of scores is 0-36, with scores above 13 typically considered to be moderate to severe hyperphagia.
  - A blinded review of preliminary data found that the median baseline HQ-CT score for all randomized subjects is approximately 22. Treatment assignments (DCCR or Placebo) for all patients remain blinded.
  - The duration of the open-label extension study (C602) has been increased from 12 months to up to 36 months. All subjects who have completed 12 months of open-label treatment in C602 have elected to continue to receive DCCR.
  - No new safety signals associated with DCCR have been identified to date and no serious, unexpected adverse events related to DCCR have been reported.
- The Data Safety Monitoring Board (DSMB) for the Phase III DESTINY PWS recommended, for the second time, the continuation of the trial without modification
  - The outcome of this second planned meeting was based on the review of data from more than 50% of subjects enrolled and treated.
- Closed an underwritten public offering of 12,841,667 shares of common stock, including 1,675,000 shares sold upon full exercise of the underwriters' option to purchase additional shares
  - Net proceeds from the offering was approximately $14.5 million.

Financial Results

Soleno's current research and development efforts are primarily focused on advancing its lead product candidate, DCCR for the treatment of PWS, through late-stage clinical development.

Fourth Quarter Ended December 31, 2019 Financial Results From Continuing Operations

Research and development expenses were $5.3 million for the quarter ended December 31, 2019, compared to $2.2 million in the same period of 2018. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $1.6 million for the quarter ended December 31, 2019, compared to $1.4 million in the same period of 2018. The increase was due to an increase in personnel related costs.

Total other income (expense) of ($7.9 million) and $3.9 million in 2019 and 2018, respectively, consisted primarily of the change in the fair value of the liability for warrants of approximately ($7.9 million) and $2.1 million in 2019 and 2018, respectively.

Net loss for the quarter ended December 31, 2019, was approximately $14.6 million, or $0.36 per basic and diluted share, compared to net income of approximately $0.3 million, or $0.01 per basic and diluted share, for the quarter ended December 31, 2018, which included a Loss from Discontinued Operations of $0.1 million.

Year Ended December 31, 2019 Financial Results From Continuing Operations

Research and development expenses were $16.3 million for the year ended December 31, 2019, compared to $7.2 million for the year ended December 31, 2018. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $6.9 million for the year ended December 31, 2019, compared to $6.6 million for the year ended December 31, 2018. The increase was due to an increase in personnel related costs.

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 DCCR 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, and is remeasured at the end of each of our reporting periods, including quarterly and at the end of each year. The fair value was estimated to be approximately $5.6 million at December 31, 2018 and $5.9 million at December 31, 2019, resulting in an increase in expense of approximately $0.3 million from the estimate as of December 31, 2018.

Total other income (expense) of ($7.3 million) and $2.5 million in 2019 and 2018, respectively, consisted primarily of the change in the fair value of the liability for warrants of approximately ($7.0 million) and $0.5 million in 2019 and 2018, respectively.

Net loss for the year ended December 31, 2019, was approximately $30.8 million, or $0.90 per basic and diluted share, compared to a net loss of approximately $13.3 million, or $0.64 per basic and diluted share, for the year ended December 31, 2018, which included a Loss from Discontinued Operations of $1.5 million.

As of December 31, 2019, Soleno had cash and cash equivalents of approximately $20.7 million, as compared to $23.1 million at December 31, 2018.

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., and Fast Track Designation in the U.S.

About the DESTINY PWS Trial
DESTINY PWS is a randomized, double-blind, placebo-controlled study of once-daily oral administration of DCCR versus placebo in 127 randomized subjects. Patients who complete DESTINY PWS have the option to enroll into an open-label extension study (C602) and continue treatment with DCCR.

For further information about DESTINY PWS (NCT03440814), please visit: www.clinicaltrials.gov.

About Diazoxide Choline Controlled-Release (DCCR) 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 data from five completed Phase I clinical studies 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, Diazoxide Choline Controlled Release (DCCR) tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (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 within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding the Company's expectations concerning, among other things, our ability to receive top-line data in the first half of 2020 from Phase III DESTINY PWS. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. These forward-looking statements speak only as of the date of this press release and are subject to a number of risks, uncertainties and assumptions, including the risks and uncertainties associated with market conditions, as well as risks and uncertainties inherent in Soleno's business, including those described in the company's prior press releases and in the periodic reports it files with the SEC. The events and circumstances reflected in the company's forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, the company does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 20,733	$ 23,099
Prepaid expenses and other current assets	411	529
Due from related party	—	64

Minority interest investment in former subsidiary	—	978
Total current assets	21,144	24,670
Long-term assets		
Property and equipment, net	22	12
Operating lease right-of-use assets	398	—
Finance lease right-of-use assets	24	—
Intangible assets, net	16,525	18,469
Other long-term assets	59	—
Total assets	$ 38,172	$ 43,151
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,995	$ 934
Accrued compensation	283	274
Accrued clinical trial site costs	1,999	320
Operating lease liabilities	305	—
Other current liabilities	382	349
Total current liabilities	4,964	1,877
Long-term liabilities		
Series A warrant liability	—	49
2017 PIPE Warrant liability	10,822	4,563
2018 PIPE Warrant liability	1,354	600
Contingent liability for Essentialis purchase price	5,938	5,649
Other long-term liabilities	147	—
Total liabilities	23,225	12,738
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at December 31, 2019 and December 31, 2018; zero shares issued and outstanding at December 31, 2019 and at December 31, 2018. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 44,658,054 and 31,755,169 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively.	45	32
Additional paid-in-capital	172,708	157,413
Accumulated deficit	(157,806)	(127,032)
Total stockholders' equity	14,947	30,413
Total liabilities and stockholders' equity	$ 38,172	$ 43,151

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

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses				
Research and development	$ 5,272	$ 2,192	$ 16,267	$ 7,178
General and administrative	1,608	1,365	6,930	6,556
Change in fair value of contingent consideration	(128)	(22)	289	567
Total operating expenses	6,752	3,535	23,486	14,301
Operating loss	(6,752)	(3,535)	(23,486)	(14,301)
Other (expense) income				
Change in fair value of warrants liabilities	(7,894)	2,071	(6,964)	522
Gain on deconsolidation of former subsidiary	—	1,994	—	1,994
Loss from minority interest investment	—	—	(478)	(160)

Interest and other income	21	(137)	154	104
Total other (expense) income	(7,873)	3,928	(7,288)	2,460
Loss from continuing operations	(14,625)	393	(30,774)	(11,841)
Loss from discontinued operations	—	(130)	—	(1,494)
Net loss	$ (14,625)	$ 263	$ (30,774)	$ (13,335)
Loss per common share from continuing operations, basic and diluted	$ (0.36)	$ 0.02	$ (0.90)	$ (0.56)
Loss per common share from discontinued operations, basic and diluted	—	(0.01)	—	(0.07)
Net loss per common share, basic and diluted	$ (0.36)	$ 0.01	$ (0.90)	$ (0.64)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	41,165,960	22,555,421	34,142,478	20,975,479



Source: Soleno Therapeutics