Soleno Therapeutics Provides Corporate Update and Reports Third Quarter 2019 Financial Results

November 13, 2019

REDWOOD CITY, Calif., Nov. 13, 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 reported financial results for the third quarter and nine months ended September 30, 2019.

"We continue to be pleased with the progress of patient 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), and remain on track to announce top-line data in the first half of 2020," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We recently closed a successful public offering for net proceeds of approximately $14.5 million, which provides us with sufficient resources through the availability of top-line data from DESTINY PWS. Importantly, the Data Safety Monitoring Board (DSMB) recently, for the second time, recommended the continuation of the DESTINY PWS study without modification."

Recent Corporate Highlights

- Continued enrollment for Phase III DESTINY PWS study of DCCR
  - Top-line data are anticipated in the first half of 2020
- 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 of the offering were approximately $14.5 million
- DSMB recommended, for the second time, the continuation of the Company's Phase III DESTINY PWS trial without modification
  - The outcome of this second planned meeting was based on the review of data from more than 50% of patients enrolled and treated
- Results of the Phase II trial of DCCR for the treatment of PWS were published in a peer-reviewed journal for the first time
  - The data are available in the online edition of PLOS One, a peer-reviewed open access scientific journal published by the Public Library of Science: https://doi.org/10.1371/journal.pone.0221615.

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.

Third Quarter Ended September 30, 2019 Financial Results From Continuing Operations

Research and development expenses were $4.5 million for the quarter ended September 30, 2019, compared to $2.1 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 September 30, 2019, generally consistent with the same period of 2018.

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, at $5.5 million at March 31, 2018, $5.4 million at June 30, 2018, $5.7 million at September 30, 2018, $5.6 million at December 31, 2018, $5.9 million at March 31, 2019, and $6.0 million at June 30, 2019. The fair value was estimated to be approximately $6.0 million at September 30, 2019, resulting in an increase in expense of approximately $0.4 million from the balance at December 31, 2018.

Total Other income of $7.0 million and $1.6 million in 2019 and 2018, respectively, consisted primarily of the change in the fair value of the liability for warrants of approximately $7.1 million and $1.5 million in 2019 and 2018, respectively.

Net income for the quarter ended September 30, 2019, was approximately $0.9 million, or $0.03 per basic and diluted share, compared to a net loss of approximately $2.7 million, or $0.13 per basic and diluted share, for the quarter ended September 30, 2018, which included a Loss from Discontinued Operations of $0.4 million.

Nine Months Ended September 30, 2019 Financial Results From Continuing Operations

Research and development expenses were $11.0 million for the nine months ended September 30, 2019, compared to $5.0 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 $5.3 million for the nine months ended September 30, 2019, generally consistent with the expense during the nine months ended September 30, 2018.

Total Other income (expense) of $0.6 million and ($1.5 million) in 2019 and 2018, respectively, consisted primarily of the change in the fair value of the

liability for warrants of approximately $0.9 million and ($1.5 million) in 2019 and 2018, respectively.

Net loss for the nine months ended September 30, 2019, was approximately $16.1 million, or $0.51 per basic and diluted share, compared to a net loss of approximately $13.6 million, or $0.67 per basic and diluted share, for the nine months ended September 30, 2018, which included a Loss from Discontinued Operations of $1.4 million.

As of September 30, 2019, Soleno had cash and cash equivalents of approximately $11.2 million, as compared to $23.1 million at December 31, 2018. This cash balance does not include the proceeds from the public offering that was closed in October. The net proceeds of the offering were approximately $14.5 million, after deducting the underwriting discount and other offering expenses.

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 approximately 100 patients with a confirmed diagnosis of PWS. Patients who complete DESTINY PWS have the option to enroll into C602.

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.

Corporate Contact:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

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

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 11,225	$ 23,099
Prepaid expenses and other current assets	375	529
Due from related party	9	64
Minority interest investment in former subsidiary	—	978

Total current assets	11,609	24,670
Long-term assets		
Property and equipment, net	46	12
Intangible assets, net	17,011	18,469
Other long-term assets	59	—
Total assets	$ 28,725	$ 43,151
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,735	$ 934
Accrued compensation and other current liabilities	1,719	943
Total current liabilities	3,454	1,877
Long-term liabilities		
Series A warrant liability	25	49
2017 PIPE Warrant liability	3,667	4,563
2018 PIPE Warrant liability	590	600
Contingent liability for Essentialis purchase price	6,066	5,649
Other long-term liabilities	38	—
Total liabilities	13,840	12,738
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 shares designated at September 30, 2019 and December 31, 2018; zero shares issued and outstanding at September 30, 2019 and at December 31, 2018. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 31,793,292 and 31,755,169 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively.	32	32
Additional paid-in-capital	158,034	157,413
Accumulated deficit	(143,181)	(127,032)
Total stockholders' equity	14,885	30,413
Total liabilities and stockholders' equity	$ 28,725	$ 43,151

Soleno Therapeutics, 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,	
	2019	**2018**	**2019**	**2018**
Operating expenses				
Research and development	$ 4,490	$ 2,092	$ 10,995	$ 4,986
General and administrative	1,615	1,558	5,322	5,191
Change in fair value of contingent consideration	28	228	417	589
Total operating expenses	6,133	3,878	16,734	10,766
Operating loss	(6,133)	(3,878)	(16,734)	(10,766)
Other income (expense)				
Cease-use income	—	0	—	6
Change in fair value of warrants liabilities	7,116	1,543	930	(1,549)
Loss from minority interest investment	(123)	—	(478)	—
Interest income, net	29	26	133	75
Total other income (expense)	7,022	1,569	585	(1,468)
Income (loss) from continuing operations	889	(2,309)	(16,149)	(12,234)
Loss from discontinued operations	—	(427)	—	(1,364)
Net income (loss)	$ 889	$ (2,736)	$ (16,149)	$ (13,598)
Income (loss) per common share from continuing operations:				
Basic	$ 0.03	$ (0.11)	$ (0.51)	$ (0.60)
Diluted	$ 0.03	$ (0.11)	$ (0.51)	$ (0.60)
Loss per common share from discontinued operations:				
Basic	$ -	$ (0.02)	$ -	$ (0.07)
Diluted	$ -	$ (0.02)	$ -	$ (0.07)

Net income (loss) per common share:				
Basic	$ 0.03	$ (0.13)	$ (0.51)	$ (0.67)
Diluted	$ 0.03	$ (0.13)	$ (0.51)	$ (0.67)
Weighted-average common shares outstanding used in per-share calculation:				
Basic	31,793,292	21,432,482	31,775,590	20,443,044
Diluted	32,443,647	21,432,482	31,775,590	20,443,044

Source: Soleno Therapeutics