



Solenio Therapeutics Provides Corporate Update and Reports Second Quarter 2019 Financial Results

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REDWOOD CITY, Calif., Aug. 07, 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 second quarter and six months ended June 30, 2019.

"We are pleased with the progress 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). We currently anticipate the availability of top-line data from DESTINY PWS in the first half of 2020," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Additionally, we are encouraged by the continued interest of families and investigators in keeping patients on DCCR, as 90% of those subjects completing the DESTINY PWS study have elected to continue in C602, our open-label safety extension study. Moreover, 90% of those patients enrolled in study C602 have continued to receive DCCR treatment."

Recent Corporate Highlights

- Continued enrollment for Phase III DESTINY PWS study of DCCR
 - Approximately 50% of the targeted number of patients have been enrolled into the DESTINY PWS clinical study, and approximately 90% of them have either successfully completed or continue to be treated in the study
 - Approximately 90% of those completing the DESTINY PWS study have elected to continue in C602, Soleno's open-label safety extension study, and approximately 90% of those enrolled have continued to receive DCCR treatment in study C602
 - The duration of C602 has been increased from 9 to 12 months, and Soleno is in the process of initiating another open-label study for patients who complete the C602 study
 - No serious, unexpected adverse events related to DCCR have been reported in these studies to date
 - Approximately 20 sites in the U.S. and Europe are active and able to enroll patients
 - Enrollment in DESTINY PWS is expected to conclude around the end of 2019
 - Top-line data are anticipated in the first half of 2020
- Entered into a collaboration with Casimir, a rare disease research organization that designs outcome measures capturing the real-world impact of treatment interventions on individual patients' quality-of-life
 - Casimir will collaborate with Soleno on the development of DCCR for patients with PWS
- Appointed Birgitte Volck, M.D., Ph.D., a veteran biopharmaceutical industry executive, to Board of Directors

Financial Results

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

Second Quarter Ended June 30, 2019 Financial Results for Continuing Operations

Research and development expenses were \$3.7 million for the quarter ended June 30, 2019, compared to \$1.7 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 \$1.7 million for the quarter ended June 30, 2019, generally consistent with the same period of 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, \$5.7 million at September 30, 2018, \$5.6 million at December 31, 2018, and \$5.9 million at March 31, 2019. The fair value was estimated to be approximately \$6.0 million at June 30, 2019, resulting in an increase in expense of approximately \$0.4 million from the balance at December 31, 2018.

Total Other expense of \$4.4 million and \$3.2 million in 2019 and 2018, respectively, consisted primarily of the change in the fair value of the liability for warrants of approximately \$4.3 million and \$3.3 million in 2019 and 2018, respectively.

Net loss for the quarter ended June 30, 2019, was approximately \$10.0 million, or (\$0.31) per share, compared to a net loss of approximately \$7.1 million, or (\$0.35) per share, for the quarter ended June 30, 2018, which includes a Loss from Discontinued Operations of \$0.4 million.

Six Months Ended June 30, 2019 Financial Results for Continuing Operations

Research and development expenses were \$6.5 million for the six months ended June 30, 2019, compared to \$2.9 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 \$3.7 million for the six months ended June 30, 2019, generally consistent with the same period of 2018.

Total Other expense of \$6.4 million and \$3.0 million in 2019 and 2018, respectively, consisted primarily of the change in the fair value of the liability for

warrants of approximately \$6.2 million and \$3.1 million in 2019 and 2018, respectively.

Net loss for the six months ended June 30, 2019, was approximately \$17.0 million, or (\$0.54) per share, compared to a net loss of approximately \$10.9 million, or (\$0.55) per share, for the six months ended June 30, 2018, which includes a Loss from Discontinued Operations of \$0.9 million.

As of June 30, 2019, Soleno had cash and cash equivalents of approximately \$15.5 million, as compared to \$23.1 million at December 31, 2018.

About PWS

The Prader-Willi Syndrome Association USA estimates that approximately one in 15,000 people in the US 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 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, 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 enrollment of the Phase III C601 study in PWS during 2019 and receive top-line data in the first half of 2020. 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.
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)

	June 30, 2019	December 31, 2018
Assets	(Unaudited)	
Current assets		
Cash and cash equivalents	\$ 15,503	\$ 23,099
Prepaid expenses and other current assets	471	529
Due from related party	18	64
Minority interest investment in former subsidiary	623	978
Total current assets	16,615	24,670
Long-term assets		
Property and equipment, net	22	12
Intangible assets, net	17,497	18,469
Total assets	\$ 34,134	\$ 43,151

Liabilities and stockholders' equity

Current liabilities			
Accounts payable	\$	1,740	\$ 934
Accrued compensation and other current liabilities		1,115	943
Total current liabilities		2,855	1,877
Long-term liabilities			
Series A warrant liability		51	49
2017 PIPE Warrant liability		10,202	4,563
2018 PIPE Warrant liability		1,145	600
Contingent liability for Essentialis purchase price		6,038	5,649
Total liabilities		20,291	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 June 30, 2019 and December 31, 2018; zero shares issued and outstanding at June 30, 2019 and at December 31, 2018.			
Liquidation value of zero.			
Common stock, \$.001 par value, 100,000,000 shares authorized, 31,793,292 and 31,755,169 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively.			
		32	32
Additional paid-in-capital		157,881	157,413
Accumulated deficit		(144,070)	(127,032)
Total stockholders' equity		13,843	30,413
Total liabilities and stockholders' equity	\$	34,134	\$ 43,151

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses				
Research and development	\$ 3,745	\$ 1,714	\$ 6,505	\$ 2,894
General and administrative	1,695	1,766	3,707	3,633
Change in fair value of contingent consideration	183	(67)	389	361
Total operating expenses	5,623	3,413	10,601	6,888
Operating loss	(5,623)	(3,413)	(10,601)	(6,888)
Other income (expense)				
Cease-use income	—	3	—	6
Change in fair value of warrants liabilities	(4,267)	(3,255)	(6,186)	(3,092)
Loss from minority interest investment	(165)	—	(355)	—
Interest income	47	30	104	49
Total other income (expense)	(4,385)	(3,222)	(6,437)	(3,037)
Loss from continuing operations	(10,008)	(6,635)	(17,038)	(9,925)
Loss from discontinued operations	—	(423)	—	(937)
Net loss	\$ (10,008)	\$ (7,058)	\$ (17,038)	\$ (10,862)
Loss per common share from continuing operations, basic and diluted	\$ (0.31)	\$ (0.33)	\$ (0.54)	\$ (0.50)
Loss per common share from discontinued operations, basic and diluted	—	(0.02)	—	(0.05)
Net loss per common share, basic and diluted	\$ (0.31)	\$ (0.35)	\$ (0.54)	\$ (0.55)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	31,776,951	20,345,437	31,766,593	19,940,126



Source: Soleno Therapeutics