Soleno Therapeutics Provides Corporate Update and Reports First Quarter 2021 Financial Results

May 5, 2021 8:01 PM EDT

REDWOOD CITY, Calif., May 05, 2021 (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 three months ended March 31, 2021.

"We are continuing our dialogue with the U.S. Food and Drug Administration (FDA) to evaluate the appropriate next steps in our DCCR program for the treatment of Prader-Willi Syndrome (PWS) and work towards obtaining regulatory approval as expeditiously as possible," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "The Soleno team remains committed to the development of DCCR and building an appropriate data set to support its development. To this end, we were excited to recently present behavioral outcomes data from caregiver interviews that summarized individual patient experiences during treatment with DCCR. We were also pleased to speak to the PWS community directly during the recent PWS DCCR Town Hall meeting where we reiterated our continued focus on DCCR and outlined the proposed necessary steps for submitting a marketing application to the FDA in the U.S. More importantly, we were able to listen to the stories about the individual study participants' experiences during our completed Phase III clinical trial of DCCR, DESTINY PWS, and the ongoing long-term safety extension study."

Dr. Bhatnagar continued, "We are grateful for the work completed by the Foundation for Prader-Willi Research and Prader-Willi Syndrome Association | USA in collecting the experiences of PWS patients and caregivers treated with DCCR. This petition, which was submitted to the FDA, was signed by more than 26,000 individuals in support of DCCR."

First Quarter 2021 and Recent Corporate Highlights

- Continued discussions with FDA and currently evaluating appropriate next steps for DCCR program in PWS
- Presented behavioral outcomes data from the Company's ongoing open-label extension study (C602) of DCCR in PWS at the Pediatric Academic Societies (PAS) 2021 Virtual Annual Meeting (poster available here)
  - A majority of patients (83%) reported positive changes in multiple behavioral outcome domains, including food-seeking behaviors, mealtime behaviors and daily life behaviors in a preliminary analysis of data from interviews of caregivers of participants in C602
- Presented assessment of baseline renal function in PWS patients enrolled in clinical study C601 at the Endocrinology Society (ENDO) 2021 Virtual Annual Meeting (poster available here)
- With researchers from the U.S. National Institutes of Health, presented resting energy expenditure data for a limited number of subjects enrolled in clinical studies C601 and C602 at the Pediatric Academic Societies (PAS) 2021 Virtual Annual Meeting (poster available here)
  - DCCR treated subjects showed progressive increases in resting energy expenditure
- Presented a post-hoc analysis of C601 taking into account data prior to the 'COVID impact' (defined as 1 March 2020) at the PES 2021 Virtual Annual Meeting (poster available here)
  - The primary endpoint, change in hyperphagia using HQ-CT, and all key secondary endpoints showed significant improvements in DCCR treated subjects compared with placebo
  - There were significant improvements in a number of behavioral and cardiometabolic endpoints in DCCR treated subjects compared with placebo
- Participated in PWS DCCR Town Hall
  - Highlighted the proposed necessary steps to submit a marketing application for DCCR in the U.S. and reaffirmed the Company's commitment to this process
  - Listened to individual patient and caregiver experiences with DCCR
- Participated in a fireside chat at the 31st Annual Oppenheimer Healthcare Conference

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.

First Quarter Ended March 31, 2021 Financial Results

Research and development expenses were $7.2 million for the quarter ended March 31, 2021, compared to $6.7 million in the same period of 2020. The increase was primarily due to increased activities related to the DCCR development program. General and administrative expense was $3.0 million for the quarter ended March 31, 2021, compared to $2.0 million in the same period of 2020.

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 DCCR in accordance with the terms of the Essentialis merger agreement. The fair value was estimated to be approximately $9.3 million at March 31, 2021, resulting in a decrease in expense of approximately $1.0 million from the estimate at December 31, 2020.

Total other income was $0.2 million for the quarter ended March 31, 2021, compared to $3.4 million in the same period of 2020, and consisted primarily of the change in the fair value of our outstanding warrants.

Net loss for the quarter ended March 31, 2021, was approximately $9.0 million, or a net loss of $0.11 per basic and diluted share, compared to a net

loss of approximately $5.9 million, or $0.13 per basic and diluted share, for the quarter ended March 31, 2020.

As of March 31, 2021, Soleno had cash and cash equivalents of approximately $41.6 million, compared to $49.2 million at December 31, 2020.

About PWS
The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births in the U.S. 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., obesity, diabetes, cardiovascular disease) and mortality (e.g., stomach rupture, 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 EU, and Fast Track Designation in the U.S.

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 extended-release tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase 3 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 timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of 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)

	March 31, 2021	December 31, 2020
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 41,607	$ 49,224
Prepaid expenses and other current assets	921	1,019
Total current assets	42,528	50,243
Long-term assets		
Property and equipment, net	20	19
Operating lease right-of-use assets	50	124
Finance lease right-of-use assets	13	15
Intangible assets, net	14,095	14,581
Total assets	$ 56,706	$ 64,982
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 4,669	$ 3,489
Accrued compensation	411	1,005
Accrued clinical trial site costs	4,140	3,789
Operating lease liabilities	57	139
Other current liabilities	232	196
Total current liabilities	9,509	8,618
Long-term liabilities		
2018 PIPE Warrant liability	338	539
Contingent liability for Essentialis purchase price	9,291	10,278
Total liabilities	19,138	19,435
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 250,000,000 shares authorized, 79,723,680 and 79,615,692 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively.	80	80
Additional paid-in-capital	228,887	227,912
Accumulated deficit	(191,399)	(182,445)
Total stockholders' equity	37,568	45,547
Total liabilities and stockholders' equity	$ 56,706	$ 64,982

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

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses		
Research and development	$ 7,164	$ 6,695
General and administrative	2,979	2,003
Change in fair value of contingent consideration	(987)	584
Total operating expenses	9,156	9,282
Operating loss	(9,156)	(9,282)
Other income		
Change in fair value of warrants liabilities	201	3,413
Interest income	1	11
Total other income	202	3,424
Net loss	$ (8,954)	$ (5,858)
Net loss per common share, basic and diluted	$ (0.11)	$ (0.13)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	79,694,781	44,679,858

Source: Soleno Therapeutics