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

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REDWOOD CITY, Calif., July 28, 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 and six months ended June 30, 2021.

“The Soleno team remains focused on achieving regulatory approval for DCCR for the treatment of Prader-Willi syndrome, or PWS,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We are continuing our dialogue with the U.S. Food and Drug Administration (FDA) and, as recently announced, intend to submit the clinical study reports from DESTINY PWS and the C602 extension study, as well as additional data, to the Agency before the end of the third quarter. The FDA has agreed to review these clinical study reports and data to determine if the totality of data generated to date for DCCR are sufficient to support a potential New Drug Application (NDA) submission.”

Second Quarter 2021 and Recent Corporate Highlights

- Continued discussions with FDA and currently evaluating appropriate next steps for DCCR program in PWS
  - On July 2, 2021, the Company received official meeting minutes from the June 11, 2021, Type B meeting with the Division of Diabetes, Lipid Disorders and Obesity. The FDA continued to assert that based on the data the Agency has seen to date, an additional clinical trial is necessary for the submission of an NDA. However, the FDA strongly encouraged Soleno to submit the available data and clinical study reports for the Company’s Phase 3 trial, DESTINY PWS (C601), and its long-term, open-label extension study (C602), to allow FDA to assess if these studies may provide adequate evidence of safety and efficacy to support the submission of an NDA.
  - As of June 2021, 97 patients in study C602 have completed one year in the study
- Expanded patent protection for DCCR for the treatment of PWS
  - Received notice of allowance of patents covering the use of diazoxide choline and diazoxide to treat behavioral, metabolic and body composition complications of PWS in New Zealand, Mexico and Canada. Soleno has already successfully prosecuted this patent filing to issuance of three U.S. patents (9,757,384, 10,058,557, and 10,456,408), and corresponding patents in the EU, Japan, China, Australia, Malaysia, Indonesia and Eurasia. These patents extend protection of DCCR in the treatment of PWS to at least 2035 in all of these regions.
- A manuscript titled, “A Qualitative Methodology for Evaluating Novel Treatments for Hyperphagia in People with Prader-Willi Syndrome” published online in the *International Journal of Rare Diseases and Disorders*
  - Highlighted collaboration with Casimir Inc. to capture individual patient experience data from participants in the DESTINY PWS study and its long-term extension study. The publication summarizes the methodology utilized to collect these patient experience data that might not otherwise be captured by existing caregiver reported outcome tools.
  - Subset of interviews conducted from this study were analyzed utilizing natural language processing to better understand the complexities of PWS behaviors and outcomes. Results presented at the Pediatric Academic Societies (PAS) 2021 Virtual Annual Meeting.
- Hosted webinar highlighting DCCR for the treatment of Prader-Willi syndrome at the European Congress on Endocrinology 202
  - Webinar, titled “Results from DESTINY PWS, a Randomized Double-Blind Placebo-Controlled Phase 3 Study in Subjects with Prader-Willi Syndrome,” featured presentations by PWS key opinion leaders from France and the UK.
- Participated in the Oppenheimer Rare & Orphan Disease Summit
- Received Orphan Drug Designation from the FDA for DCCR for the treatment of Glycogen Storage Disease Type 1a (GSD 1a), or von Gierke disease

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.

Financial Results for Three and Six Months Ended June 30, 2021

Research and development expenses for the three and six months ended June 30, 2021, were $5.6 million and $12.8 million, compared to $6.1 million and $12.8 million for the same periods of 2020. The fluctuations in expenses were primarily due to the cadence of activities related to the DCCR development program.

General and administrative expenses for the three and six months ended June 30, 2021, were $2.5 million and $5.4 million, compared to $2.2 million and $4.3 million for the same periods of 2020. The increase was primarily related to increased personnel-related costs.

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 commercial sales of DCCR in accordance with the terms of the Essentialis merger agreement. The fair value was estimated to be approximately $12.3 million as of June 30, 2021, a $3.0 million increase from the estimate on March 31, 2021, and a $2.0 million increase from the estimate on December 31, 2020.

Total other income was $0.1 million in the three months ended June 30, 2021, compared to other income of $3.8 million during the three months ended June 30, 2020, and consisted primarily of the change in the fair value of the Company’s outstanding warrants.

Net loss for the three and six months ended June 30, 2021, was $11.0 million and $19.9 million, or a net loss of $0.14 and $0.25 per basic and diluted share, compared to $7.4 million and $13.2 million, or $0.16 and $0.29 per basic and diluted share, for the same periods in 2020, respectively.

As of June 30, 2021, Soleno had cash and cash equivalents of approximately $33.6 million, as compared to $49.2 million on 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 and 92.9 % body composition 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.

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

	June 30, 2021	December 31, 2020
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 33,596	$ 49,224
Prepaid expenses and other current assets	948	1,019
Total current assets	34,544	50,243
Long-term assets		
Property and equipment, net	27	19
Operating lease right-of-use assets	558	124
Other long term assets	40	15
Intangible assets, net	13,609	14,581
Total assets	$ 48,778	$ 64,982
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,348	$ 3,489
Accrued compensation	652	1,005
Accrued clinical trial site costs	3,927	3,789
Operating lease liabilities	180	139
Other current liabilities	255	196
Total current liabilities	8,362	8,618
Long-term liabilities		
2018 PIPE Warrant liability	282	539
Contingent liability for Essentialis purchase price	12,325	10,278
Operating lease liabilities, net of current	372	-
Total liabilities	21,341	19,435

Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 250,000,000 shares authorized, 79,759,225 and 79,615,692 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively.	80	80
Additional paid-in-capital	229,744	227,912
Accumulated deficit	(202,387)	(182,445)
Total stockholders' equity	27,437	45,547
Total liabilities and stockholders' equity	$ 48,778	$ 64,982

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,	
	2021	**2020**	**2021**	**2020**
Operating expenses				
Research and development	$ 5,587	$ 6,103	$ 12,751	$ 12,798
General and administrative	2,464	2,248	5,443	4,251
Change in fair value of contingent consideration	3,034	2,842	2,047	3,426
Total operating expenses	11,085	11,193	20,241	20,475
Operating loss	(11,085)	(11,193)	(20,241)	(20,475)
Other income				
Change in fair value of warrants liabilities	56	3,808	257	7,221
Interest income	41	1	42	12
Total other income	97	3,809	299	7,233
Net loss	$ (10,988)	$ (7,384)	$ (19,942)	$ (13,242)
Net loss per common share, basic and diluted	$ (0.14)	$ (0.16)	$ (0.25)	$ (0.29)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	79,747,506	46,236,209	79,721,290	45,458,034