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

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REDWOOD CITY, Calif., Nov. 10, 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 nine months ended September 30, 2021.

"The recently announced top-line results from Soleno's ongoing open-label extension study evaluating DCCR for the treatment of Prader-Willi syndrome (PWS), and the comparison of these data to matched subjects from the PATH for PWS (PfPWS) natural history study, highlight the compelling potential of this promising therapy in addressing the myriad physical and behavioral challenges faced by PWS patients and families," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We have submitted these collective results to the U.S. Food and Drug Administration (FDA) as part of an ongoing discussion with the agency regarding the clinical data necessary to support the submission of a New Drug Application (NDA) to market DCCR for the treatment of PWS. We remain firmly committed to obtaining regulatory approval for DCCR as a new treatment for people with PWS as quickly as possible."

Third Quarter 2021 and Recent Corporate Highlights

- Submitted to the FDA top-line results from the company's ongoing open-label extension study, C602, evaluating investigational, once-daily DCCR (Diazoxide Choline) Extended-Release tablets for patients with PWS and its comparison to data from the PfPWS, an ongoing study sponsored by the Foundation for Prader-Willi Research (FPWR) to advance the understanding of the natural history in individuals with PWS.
  - A total of 115 subjects were enrolled into C602, the extension study in PWS patients who completed DESTINY PWS, an international, multi-center, randomized, double-blind, placebo-controlled study of DCCR.
    - Key top-line results of Study C602
      - Hyperphagia: There was a progressive improvement in hyperphagia, the primary endpoint in the DESTINY PWS study, represented by a decrease in the HQ-CT total score, which was highly significant ($p<0.0001$) after receiving DCCR for 52 weeks.
      - PWS related behaviors: Behaviors related to PWS were measured using the PWS Profile Questionnaire (PWS-P). After 52 weeks, there were statistically significant improvements in all behavioral domains (all $p<0.0001$).
      - The safety profile of DCCR remains consistent with the known safety profile of diazoxide and the prior experience with DCCR. No serious, unexpected, related adverse events have occurred with DCCR in the program to date.
  - Key top-line results of Study C602 compared to matched subjects from PfPWS
    - **Hyperphagia:** Statistically significant improvement with DCCR was seen compared with PfPWS subjects at 52 weeks ($p<0.001$).
    - **PWS related behaviors:** As with hyperphagia, statistically significant improvements with DCCR in C602 subjects compared with subjects in the PfPWS study were seen in all behavioral domains of the PWS-P at 52 weeks ($p<0.003$ for all).
- Presented the above data from C602 and the comparison to PfPWS at the FPWR Annual Scientific Conference.
- Presented a DCCR clinical program overview at the FPWR Annual Family Conference, Presentation can be viewed here.
- Participated in the Oppenheimer Fall Healthcare Life Sciences and MedTech Summit.
- Participated in the 2021 Cantor Virtual Global 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.

Financial Results for Three and Nine Months Ended September 30, 2021

Research and development expenses for the three and nine months ended September 30, 2021, were $5.0 million and $17.7 million, compared to $4.8 million and $17.6 million for the same periods of 2020, respectively. 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 nine months ended September 30, 2021, were $2.8 million and $8.2 million, compared to $2.3 million and $6.5 million for the same periods of 2020, respectively. The increases were primarily related to increased compensation costs due to headcount growth and increased stock-based compensation expense.

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 $12.9 million as of September 30, 2021, a $0.6 million increase from the estimate on June 30, 2021, and a $2.6 million increase from the estimate on December 31, 2020.

Total other income (expense) was $0.1 million in the three months ended September 30, 2021, compared to other expense of $0.7 million during the three months ended September 30, 2020, and consisted primarily of the change in the fair value of the company's outstanding warrants.

Net loss for the three and nine months ended September 30, 2021, was $8.1 million and $28.1 million, or a net loss of $0.10 and $0.35 per basic and diluted share, compared to net loss of $8.5 million and $21.8 million, or $0.11 and $0.38 per basic and diluted share, for the same periods in 2020,

respectively.

As of September 30, 2021, Soleno had cash and cash equivalents of approximately $28.2 million, as compared to $49.2 million as of 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)

	September 30, 2021	December 31, 2020
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 28,185	$ 49,224
Prepaid expenses and other current assets	702	1,019
Total current assets	28,887	50,243
Long-term assets		
Property and equipment, net	26	19
Operating lease right-of-use assets	489	124
Other long-term assets	40	15
Intangible assets, net	13,123	14,581
Total assets	$ 42,565	$ 64,982
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,858	$ 3,489
Accrued compensation	809	1,005
Accrued clinical trial site costs	3,593	3,789
Operating lease liabilities	290	139
Other current liabilities	492	196
Total current liabilities	9,042	8,618
Long-term liabilities		
2018 PIPE Warrant liability	170	539
Contingent liability for Essentialis purchase price	12,876	10,278
Operating lease liabilities, net of current	274	-
Total liabilities	22,362	19,435
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.001 par value, 250,000,000 shares authorized, 79,806,487 and 79,615,692 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively.	80	80
Additional paid-in-capital	230,650	227,912

Accumulated deficit	(210,527)	(182,445)
Total stockholders' equity	20,203	45,547
Total liabilities and stockholders' equity	$ 42,565	$ 64,982

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,	
	2021	**2020**	**2021**	**2020**
Operating expenses				
Research and development	$ 4,968	$ 4,827	$ 17,719	$ 17,625
General and administrative	2,767	2,256	8,210	6,507
Change in fair value of contingent consideration	551	774	2,598	4,200
Total operating expenses	8,286	7,857	28,527	28,332
Operating loss	(8,286)	(7,857)	(28,527)	(28,332)
Other income (expense)				
Change in fair value of warrants liabilities	112	(689)	369	6,532
Interest income	34	1	76	13
Total other income (expense)	146	(688)	445	6,545
Net loss	$ (8,140)	$ (8,545)	$ (28,082)	$ (21,787)
Net loss per common share, basic and diluted	$ (0.10)	$ (0.11)	$ (0.35)	$ (0.38)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	79,791,075	79,583,254	79,744,807	56,916,137

Source: Soleno Therapeutics