Soleno Therapeutics Provides Corporate Update and Reports Third Quarter 2020 Financial Results

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REDWOOD CITY, Calif., Nov. 10, 2020 (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, 2020.

Third Quarter 2020 and Recent Corporate Highlights

- Announced updated top-line results from Phase III DESTINY PWS (C601) study evaluating once-daily Diazoxide Choline Controlled-Release (DCCR) tablets for patients with Prader Willi Syndrome (PWS)
  - Significant DCCR exposure response relationship between DCCR plasma concentrations and change from baseline in hyperphagia supporting the therapeutic benefit of DCCR treatment on hyperphagia
  - Significant improvements in leptin and adiponectin, adipokines that are differentially expressed in obesity and cardiovascular diseases, deepening the company’s insight into the mechanism of action in PWS
  - Significant reductions in fat mass and a trend towards increased lean body mass were observed
  - Interim analysis of the change in HQ-CT from C601 baseline at week 13 of C602, the open-label extension study, indicated that nearly all subjects treated with DCCR showed improvement in hyperphagia, supporting the long-term clinical benefit of treatment with DCCR in PWS
  - More than 100 subjects continue to be treated with DCCR in C602, with 20 having been treated for more than a year
  - The safety profile of DCCR remains generally consistent with the known profile of diazoxide and prior experience with DCCR, with no serious unexpected adverse events related to DCCR reported
  - Soleno reaffirms plan to meet with the FDA before the end of this calendar quarter to determine next steps
- Body composition data from C601 were highlighted in a late-breaking oral presentation at The Obesity Society’s ObesityWeek ® 2020 meeting

“We continue to be encouraged by the improvements in hyperphagia and other PWS associated behaviors, as well as positive body composition and metabolic data seen in the updated results from our Phase III program evaluating DCCR for PWS, a disease with life-threatening comorbidities,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We remain confident in the potential of DCCR to address the unmet need for a safe and effective treatment option for PWS patients.”

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, 2020 Financial Results
Research and development expenses were $4.8 million for the quarter ended September 30, 2020, compared to $4.5 million in the same period of 2019. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $2.3 million for the quarter ended September 30, 2020, compared to $1.6 million in the same period of 2019. The increase was primarily related to increased personnel-related costs, costs for intellectual property, and corporate business development expenses.

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 $10.1 million as of September 30, 2020, a $0.8 million increase from the estimate at June 30, 2020.

Total other expense was $0.7 million in the three months ended September 30, 2020, compared to other income of $7.0 million during the three months ended September 30, 2019. The change was primarily due to a change in the value of outstanding warrants.

Net loss for the quarter ended September 30, 2020, was approximately $8.5 million, or a net loss of $0.11 per basic and diluted share, compared to net income of approximately $0.9 million, or $0.03 per basic share, and a net loss of $0.19 per diluted share, for the quarter ended September 30, 2019.

Nine Months Ended September 30, 2020 Financial Results for Continuing Operations
Research and development expenses were $17.6 million for the nine months ended September 30, 2020, compared to $11.0 million in the same period of 2019. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $6.5 million for the nine months ended September 30, 2020, compared to $5.3 million in the same period of 2019. The increase was primarily related to increased personnel-related costs and costs for intellectual property.

Total other income was $6.5 million in the nine months ended September 30, 2020, compared to other income of $0.6 million during the nine months ended September 30, 2019. The increase was primarily due to a $6.5 million decrease in the fair value of Soleno’s outstanding warrants during the nine months ended September 30, 2020, compared to a decrease of $0.9 million during the nine months ended September 30, 2019.

Net loss for the nine months ended September 30, 2020, was approximately $21.8 million, or $0.38 per basic and diluted share, compared to a net

loss of approximately $16.1 million, or $0.51 per basic share, and $0.53 per diluted share, for the nine months ended September 30, 2019.

As of September 30, 2020, Soleno had cash and cash equivalents of approximately $56.1 million, as compared to $20.7 million at December 31, 2019.

About PWS
The Prader-Willi Syndrome Association USA estimates that one 15,000 live births 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 EU, and Fast Track Designation in the U.S.

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 III 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 other metabolic parameters.

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 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, 2020	December 31, 2019
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 56,137	$ 20,733
Prepaid expenses and other current assets	348	411
Total current assets	56,485	21,144
Long-term assets		
Property and equipment, net	20	22
Operating lease right-of-use assets	195	398
Finance lease right-of-use assets	17	24
Intangible assets, net	15,067	16,525
Other long-term assets	—	59
Total assets	$ 71,784	$ 38,172
Liabilities and stockholders’ equity		
Current liabilities		
Accounts payable	$ 3,213	$ 1,995
Accrued compensation	756	283
Accrued clinical trial site costs	3,399	1,999
Operating lease liabilities	220	305

Other current liabilities	408	382
Total current liabilities	7,996	4,964
Long-term liabilities		
2017 PIPE Warrant liability	4,777	10,822
2018 PIPE Warrant liability	867	1,354
Contingent liability for Essentialis purchase price	10,138	5,938
Other long-term liabilities	—	147
Total liabilities	23,778	23,225
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 100,000,000 shares authorized, 79,593,621 and 44,658,054 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively.	80	45
Additional paid-in-capital	227,519	172,708
Accumulated deficit	(179,593)	(157,806)
Total stockholders' equity	48,006	14,947
Total liabilities and stockholders' equity	$ 71,784	$ 38,172

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,	
	2020	**2019**	**2020**	**2019**
Operating expenses				
Research and development	$ 4,827	$ 4,490	$ 17,625	$ 10,995
General and administrative	2,256	1,615	6,507	5,322
Change in fair value of contingent consideration	774	28	4,200	417
Total operating expenses	7,857	6,133	28,332	16,734
Operating loss	(7,857)	(6,133)	(28,332)	(16,734)
Other income (expense)				
Change in fair value of warrants liabilities	(689)	7,116	6,532	930
Loss from minority interest investment	—	(123)	—	(478)
Interest income	1	29	13	133
Total other income (expense)	(688)	7,022	6,545	585
Net income (loss)	$ (8,545)	$ 889	$ (21,787)	$ (16,149)
Net income (loss) per common share:				
Basic	$ (0.11)	$ 0.03	$ (0.38)	$ (0.51)
Diluted	$ (0.11)	$ (0.19)	$ (0.38)	$ (0.53)
Weighted-average common shares outstanding used in per-share calculation:				
Basic	79,583,254	31,793,292	56,916,137	31,775,590
Diluted	79,583,254	32,443,647	56,916,137	32,235,528

Source: Soleno Therapeutics