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

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REDWOOD CITY, Calif., Aug. 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 second quarter and six months ended June 30, 2020.

Second Quarter 2020 and Recent Corporate Highlights

- Announced 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)
  - Study did not meet statistical significance for primary endpoint, but showed significant improvements in prespecified subgroup with severe hyperphagia
  - Significant positive changes seen in two of three key secondary endpoints in subjects receiving DCCR as compared to placebo
  - Subjects who have completed DESTINY PWS and enrolled in the open-label extension study (C602) continue to be treated for up to 36 months
    - Interim analysis of subjects who have completed three months of treatment on C602 demonstrated continuing improvements in hyperphagia and other behaviors typical of PWS
  - The safety profile of DCCR in C601 was generally consistent with the known profile of diazoxide and prior experience with DCCR, with no serious unexpected adverse events related to DCCR
  - Soleno intends to meet with regulatory authorities later this year to determine next steps
- Closed public offering of common stock in June 2020, with net proceeds of approximately $53.7 million
- Added to Russell 3000® Index

“We are encouraged by the positive trends observed in the top-line results from our Phase III DESTINY PWS trial evaluating DCCR and will continue to analyze the data from this trial and our ongoing open-label, long-term, safety extension study, C602,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We look forward to meeting with the regulatory authorities later this year to determine the next steps for this promising program. With our recently closed $53.7 million public offering, Soleno is well-capitalized and in a strong operating position, going forward.”

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.

Second Quarter Ended June 30, 2020 Financial Results

Research and development expenses were $6.1 million for the quarter ended June 30, 2020, compared to $3.7 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 $2.2 million for the quarter ended June 30, 2020, compared to $1.7 million in the same period of 2019. 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 $9.4 million as of June 30, 2020, a $2.8 million increase from the estimate at March 31, 2020.

Total other income was $3.8 million in the three months ended June 30, 2020, compared to other expense of $4.4 million during the three months ended June 30, 2019. The increase was primarily due to a $3.8 million decrease in the fair value of our outstanding warrants during the three months ended June 30, 2020, compared to an increase of $4.3 million during the three months ended June 30, 2019.

Net loss for the quarter ended June 30, 2020, was approximately $7.4 million, or a net loss of $0.16 per basic and diluted share, compared to a net loss of approximately $10.0 million, or $0.31 per basic and diluted share, for the quarter ended June 30, 2019.

Six Months Ended June 30, 2020 Financial Results for Continuing Operations

Research and development expenses were $12.8 million for the six months ended June 30, 2020, compared to $6.5 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 $4.3 million for the six months ended June 30, 2020, compared to $3.7 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 $7.2 million in the six months ended June 30, 2020, compared to other expense of $6.4 million during the six months ended June 30, 2019. The change was primarily due to a $7.2 million decrease in the fair value of our outstanding warrants during the six months ended June 30, 2020, compared to an increase of $6.2 million during the six months ended June 30, 2019.

Net loss for the six months ended June 30, 2020, was approximately $13.2 million, or $0.29 per share, compared to a net loss of approximately $17.0 million, or $0.54 per share, for the six months ended June 30, 2019.

As of June 30, 2020, Soleno had cash and cash equivalents of approximately $62.5 million, as compared to $20.7 million at December 31, 2019. This cash balance includes the proceeds from the public offering that was closed in June. The net proceeds of the offering were approximately $53.7 million, after deducting the underwriting discount and other offering expenses.

About PWS
The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people 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 E.U., and Fast Track Designation in the U.S.

About DESTINY PWS
DESTINY PWS was a randomized, double-blind, placebo-controlled study of once-daily oral administration of DCCR versus placebo in 127 randomized subjects. Patients who completed DESTINY PWS had the option to enroll into an open-label extension study (C602) and continue treatment with DCCR.

For further information about C602, the open-lab extension study (/NCT03714373), 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, and a Phase III study in PWS patients. In the PWS Phase III study, DCCR showed significant improvements in severe hyperphagia, the hallmark symptom of PWS, several other behavioral symptoms, and body composition.

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 the Company's expectations concerning, among other things, the impact of the COVID-19 pandemic on our operations and clinical trial. 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)

	June 30, 2020	December 31, 2019
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 62,499	$ 20,733
Prepaid expenses and other current assets	505	411
Total current assets	63,004	21,144
Long-term assets		
Property and equipment, net	17	22
Operating lease right-of-use assets	265	398
Finance lease right-of-use assets	20	24
Intangible assets, net	15,553	16,525
Other long-term assets	—	59
Total assets	$ 78,859	$ 38,172

Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,657	$ 1,995
Accrued compensation	520	283
Accrued clinical trial site costs	3,444	1,999
Operating lease liabilities	298	305
Other current liabilities	444	382
Total current liabilities	8,363	4,964
Long-term liabilities		
2017 PIPE Warrant liability	4,230	10,822
2018 PIPE Warrant liability	725	1,354
Contingent liability for Essentialis purchase price	9,364	5,938
Other long-term liabilities	—	147
Total liabilities	22,682	23,225
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 100,000,000 shares authorized, 79,560,274 and 44,658,054 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively.	80	45
Additional paid-in-capital	227,145	172,708
Accumulated deficit	(171,048)	(157,806)
Total stockholders' equity	56,177	14,947
Total liabilities and stockholders' equity	$ 78,859	$ 38,172

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,	
	2020	**2019**	**2020**	**2019**
Operating expenses				
Research and development	$ 6,103	$ 3,745	$ 12,798	$ 6,505
General and administrative	2,248	1,695	4,251	3,707
Change in fair value of contingent consideration	2,842	183	3,426	389
Total operating expenses	11,193	5,623	20,475	10,601
Operating loss	(11,193)	(5,623)	(20,475)	(10,601)
Other income (expense)				
Change in fair value of warrants liabilities	3,808	(4,267)	7,221	(6,186)
Loss from minority interest investment	—	(165)	—	(355)
Interest income	1	47	12	104
Total other income (expense)	3,809	(4,385)	7,233	(6,437)
Net loss	$ (7,384)	$ (10,008)	$ (13,242)	$ (17,038)
Net loss per common share, basic and diluted	$ (0.16)	$ (0.31)	$ (0.29)	$ (0.54)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	46,236,209	31,776,951	45,458,034	31,766,593

SOLENO THERAPEUTICS

Source: Soleno Therapeutics