Soleno Therapeutics Provides Corporate Update and Reports Second Quarter 2022 Financial Results

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REDWOOD CITY, Calif., Aug. 10, 2022 (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, 2022.

Second Quarter 2022 and Recent Corporate Highlights

- U.S. Food and Drug Administration (FDA) acknowledged that data from a proposed randomized withdrawal phase of Study C602 would have the potential to address its concerns regarding the adequacy of the overall efficacy data supportive of a New Drug Application (NDA) submission for DCCR. Study C602 is an ongoing open-label extension study comprised of patients who completed DESTINY PWS, an international, multi-center, randomized, double-blind, placebo-controlled study of DCCR.
    - The randomized withdrawal phase would consist only of participants currently enrolled in Study C602 and not include any new patients.
    - The Company continues to work collaboratively with the FDA to finalize specific details of the study design and plans to initiate the randomized withdrawal period in the current quarter, with top-line data expected in the first quarter of 2023.
- Results from the analysis of caregiver interviews conducted after at least 12 months of investigational, open-label DCCR treatment showing positive changes across food- and non-food-related behaviors, as well as daily life, presented at the 11th International Prader-Willi Syndrome Organisation (IPWSO) Conference.
- Long-term clinical data showing improvement in metabolic parameters and body composition following treatment with DCCR tablets in patients with PWS presented at ENDO 2022.
- Data on the ongoing safety and efficacy of DCCR in PWS patients at presented the 2022 European Congress of Endocrinology.

“We are pleased to report on a productive period, underscored by positive feedback received from the FDA regarding the planned randomized withdrawal phase of Study C602 that has the potential to support an NDA submission for DCCR ,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “Our recent presentations at scientific conferences continue to emphasize the significant potential of DCCR to be an effective and safe therapy for patients and families struggling to manage the symptoms of PWS.”

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. Cash as the end of June 30, 2022 was $24.1million which the Company believes is sufficient to fund operations at least through top line-data expected in first quarter 2023.

Second Quarter Ended June 30, 2022 Financial Results

Research and development expenses for the three and six months ended June 30, 2022, were $3.7 million and $7.7 million, compared to $5.6 million and $12.8 million for the same periods of 2021. Soleno’s research and development spending continues to fluctuate depending upon the state of its clinical programs and the timing of CMC costs and other projects necessary to support the submission of an NDA.

General and administrative expenses for the three and six months ended June 30, 2022, were $2.5 million and $5.1 million, compared to $2.5 million and $5.4 million for the same periods of 2021. The decrease was primarily due to a reduction in stock-based compensation.

The change in fair value of contingent consideration is a result of Soleno remeasuring at the end of each reporting period its obligation to make cash payments to Essentialis stockholders upon the achievement of certain future commercial milestones associated with the acquisition of DCCR in accordance with the terms of the Essentialis merger agreement. The fair value was estimated to be approximately $9.3 million as of June 30, 2022, a $0.2 million decrease from the estimate as of December 31, 2021.

Total other income was $0.05 million in the three months ended June 30, 2022, compared to other income of $0.1 million during the three months ended June 30, 2021. The decrease was primarily due to a smaller decrease in the fair value of our outstanding warrants during the three months ended June 30, 2022 compared to the three months ended June 30, 2021.

Net loss for the three and six months ended June 30, 2022, was $6.7 million and $12.4 million, or a net loss of $0.06 and $0.12 per basic and diluted share, compared to $11.0 million and $19.9 million, or $0.14 and $0.25 per basic and diluted share, for the same periods in 2021, respectively.

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, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS), is currently being evaluated in an ongoing Phase 3 clinical development program. For more information, please visit www.soleno.life.

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 DCCR (Diazoxide Choline) Extended-Release Tablets
DCCR is a novel, proprietary extended-release dosage form containing the crystalline salt of diazoxide and 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 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in PWS patients. In the PWS Phase 3 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. Soleno has been in ongoing discussions with the FDA regarding additional data needed to support the submission of an NDA.

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, 2022	December 31, 2021
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 24,065	$ 21,304
Prepaid expenses and other current assets	824	1,118
Total current assets	24,889	22,422
Long-term assets		
Property and equipment, net	28	33
Operating lease right-of-use assets	279	421
Intangible assets, net	11,665	12,637
Other long-term assets	-	40
Total assets	$ 36,861	$ 35,553
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,406	$ 3,254
Accrued compensation	932	728
Accrued clinical trial site costs	3,156	3,420
Operating lease liabilities	337	282
Other current liabilities	415	323
Total current liabilities	7,246	8,007
Long-term liabilities		
2018 PIPE Warrant liability	2	31
Contingent liability for Essentialis purchase price	9,305	9,547
Long-term lease liabilities	—	175
Total liabilities	16,553	17,760
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $ par value, shares authorized, and shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively.	120	80
Additional paid-in-capital	245,993	231,068

Accumulated deficit	(225,804)	(213,355)
Accumulated other comprehensive loss	(1)	—
Total stockholders' equity	20,308	17,793
Total liabilities and stockholders' equity	$ 36,861	$ 35,553

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses				
Research and development	$ 3,696	$ 5,587	$ 7,684	$ 12,751
General and administrative	2,467	2,464	5,110	5,443
Change in fair value of contingent consideration	616	3,034	(242)	2,047
Total operating expenses	6,779	11,085	12,552	20,241
Operating loss	(6,779)	(11,085)	(12,552)	(20,241)
Other income				
Change in fair value of warrants liabilities	2	56	29	257
Interest income	52	41	74	42
Total other income	54	97	103	299
Net loss	$ (6,725)	$ (10,988)	$ (12,449)	$ (19,942)
Other comprehensive loss				
Foreign currency translation adjustment	1	—	(1)	—
Total comprehensive loss	$ (6,724)	$ (10,988)	$ (12,450)	$ (19,942)
Net loss per common share, basic and diluted	$ (0.06)	$ (0.14)	$ (0.12)	$ (0.25)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	120,088,816	79,747,506	100,165,432	79,721,290

Source: Soleno Therapeutics