Soleno Therapeutics Provides Corporate Update and Reports First Quarter 2023 Financial Results

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REDWOOD CITY, Calif., May 09, 2023 (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 first quarter ended March 31, 2023.

First Quarter 2023 and Recent Corporate Highlights

- Completed enrollment in the randomized withdrawal period of Study C602, a long-term treatment study of Diazoxide Choline (DCCR) Extended-Release tablets for the treatment of Prader-Willi syndrome (PWS).
- The U.S. Food and Drug Administration previously acknowledged that data from the study has the potential to support a New Drug Application (NDA) submission for DCCR.
- Top-line data continue to be expected in the third quarter 2023.
- Received $10 million in connection with closing of December 2022 Securities Purchase Agreement with Nantahala Capital Management, Abingworth and Vivo Capital, triggered by announcement of enrollment completion.

“We are very pleased to have recently completed enrollment in the randomized withdrawal phase of Study C602 and would like to thank the participants, their families and the study sites for helping us reach this important milestone,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We continue to be on track for the availability of top-line data in the third quarter of 2023. Furthermore, completing enrollment satisfied the closing condition on our December 2022 Securities Purchase Agreement, enabling us to receive $10 million that will support clinical operations through top-line data leading to a potential NDA filing and approval of DCCR.”

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.

First Quarter 2023 Financial Results

As of March 31, 2023, Soleno had cash and cash equivalents of approximately $7.9 million. This amount does not include the $10 million recently received following enrollment completion in the randomized withdrawal period of Study C602 and the satisfaction of the closing conditions related to the Company’s December 2022 Securities Purchase Agreement. Soleno continues to believe that, in aggregate, these funds are sufficient to fund operations through top-line data, which is anticipated in the third quarter of 2023.

Research and development expenses for the three months ended March 31, 2023, were $5.3 million, compared to $4.0 million for the same period of 2022. The cadence of Soleno’s research and development expenditures fluctuates depending upon the state of its clinical programs and the timing of CMC and other projects necessary to support the submission of an NDA.

General and administrative expenses for the three months ended March 31, 2023, were $2.9 million, compared to $2.6 million for the same period of 2022. The increase was primarily attributable to an increase in professional services expense.

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 of up to $21.2 million to former Essentialis stockholders upon achievement of certain future commercial milestones associated with the sale of DCCR in accordance with the terms of the Essentialis merger agreement. The fair value of the liability payable was estimated to be $9.1 million as of March 31, 2023, a $0.3 million increase from the estimate as of December 31, 2022. During the three months ended March 31, 2022, the estimate decreased by $0.8 million from the $9.5 million estimate as of December 31, 2021.

Total other income was approximately $113,000 in the three months ended March 31, 2023, compared to $49,000 during the three months ended March 31, 2022. The increase was primarily due to an increase in interest income.

Net loss for the three months ended March 31, 2023, was $8.4 million, or $0.88 per basic and diluted share, compared to a net loss of $5.7 million, or $1.07 per basic and diluted share, in the same period of 2022.

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% rated body composition as either 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 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.

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 the closing of the warrant financing under the Securities Purchase Agreement, the receipt of top-line data from the randomized withdrawal period, and the 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)

	March 31, 2023	December 31, 2022
Assets	(Unaudited)	
Current assets		
Cash and cash equivalents	$ 7,874	$ 14,602
Prepaid expenses and other current assets	1,253	1,045
Total current assets	9,127	15,647
Long-term assets		
Property and equipment, net	22	26
Operating lease right-of-use assets	53	131
Intangible assets, net	10,207	10,693
Other long-term assets	126	-
Total assets	$ 19,535	$ 26,497
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,778	$ 1,777
Accrued compensation	721	1,675
Accrued clinical trial site costs	3,531	3,222
Operating lease liabilities	39	155
Other current liabilities	692	484
Total current liabilities	7,761	7,313
Long-term liabilities		
2018 PIPE Warrant liability	1	1
Contingent liability for Essentialis purchase price	9,134	8,835
Total liabilities	16,896	16,149
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, $0.001 par value, 100,000,000 shares authorized, 8,168,788 and 8,159,382 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	8	8
Additional paid-in-capital	248,393	247,762
Accumulated deficit	(245,778)	(237,422)
Accumulated other comprehensive income	16	-

Total stockholders' equity	2,639	10,348
Total liabilities and stockholders' equity	$ 19,535	$ 26,497

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

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 5,316	$ 3,988
General and administrative	2,854	2,643
Change in fair value of contingent consideration	299	(858)
Total operating expenses	8,469	5,773
Operating loss	(8,469)	(5,773)
Other income		
Change in fair value of warrants liabilities	-	27
Interest income	113	22
Total other income	113	49
Net loss	$ (8,356)	$ (5,724)
Other comprehensive income (loss)		
Foreign currency translation adjustment	16	(2)
Total comprehensive loss	$ (8,340)	$ (5,726)
Net loss per common share, basic and diluted	$ (0.88)	$ (1.07)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	9,447,350	5,334,712

Source: Soleno Therapeutics