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

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REDWOOD CITY, Calif., Aug. 08, 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 second quarter ended June 30, 2023.

Second Quarter 2023 and Recent Corporate Highlights

- Completed enrollment in the randomized withdrawal period of Study C602, a long-term treatment study of DCCR (Diazoxide Choline) Extended-Release tablets for the treatment of Prader-Willi syndrome (PWS).
- Top-line data expected around the end of third quarter 2023.
- Received $10 million in connection with closing of December 2022 Securities Purchase Agreement (SPA) for up to $60 million with Nantahala Capital Management, Abingworth and Vivo Capital, triggered by announcement of enrollment completion.

"We are eagerly awaiting top-line results from the fully-enrolled randomized withdrawal period of Study C602, which remain on track for the third quarter of 2023," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "If successful, results have the potential to support a planned New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA). We continue to believe in the significant potential of DCCR as an effective and safe therapy for patients with 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.

Second Quarter 2023 Financial Results

As of June 30, 2023, Soleno had cash and cash equivalents of approximately $19.4 million, which includes $10 million received during the quarter from the sale of warrants pursuant to the terms of the SPA. The warrants issued during the quarter are immediately exercisable for up to an additional $50 million of gross proceeds to the Soleno; $15 million are required to be exercised within 30 days of the announcement of positive top-line data and $35 million of the warrants will expire if not exercised within 30 days of receipt of FDA approval of DCCR for the treatment of PWS.

Research and development expenses for the three and six months ended June 30, 2023, were $5.1 million and $10.5 million, compared to $3.7 million and $7.7 million for the same periods of 2022. Soleno's research and development expenditures will 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, 2023, were $3.2 million and $6.0 million, compared to $2.5 million and $5.1 million for the same periods of 2022. The increase was mainly attributable to an increase in stock-based compensation and professional services expenses.

Soleno is obligated to make cash payments of up to a maximum of $21.2 million to the former Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sales of DCCR in accordance with the terms of Soleno's merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us was estimated to be $9.4 million as of June 30, 2023, a $0.3 million increase from the estimate as of March 31, 2023.

Total other income was $0.15 million and $0.26 in the three and six months ended June 30, 2023, compared to other income of $0.05 million and $0.10 million for the same periods of 2022. The increase was primarily due to an increase in interest income during the three and six months ended June 30, 2023 compared to the same periods of 2022.

Net loss for the three and six months ended June 30, 2023, was $8.5 million and $16.8 million, or a net loss of $0.81 and $1.69 per basic and diluted share, compared to $6.7 million and $12.4 million, or $0.72 and $1.69 per basic and diluted share, for the same periods in 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)

	June 30, 2023	December 31, 2022
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 19,368	$ 14,602
Prepaid expenses and other current assets	1,130	1,045
Total current assets	20,498	15,647
Long-term assets		
Property and equipment, net	19	26
Operating lease right-of-use assets	541	131
Intangible assets, net	9,721	10,693
Other long-term assets	165	-
Total assets	$ 30,944	$ 26,497
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,442	$ 1,777
Accrued compensation	1,165	1,675
Accrued clinical trial site costs	3,466	3,222
Operating lease liabilities - current	212	155
Other current liabilities	513	484
Total current liabilities	8,798	7,313
Long-term liabilities		
2018 PIPE Warrant liability	-	1
Operating lease liabilities - noncurrent	273	-
Contingent liability for Essentialis purchase price	9,447	8,835
Total liabilities	18,518	16,149
Commitments and contingencies (Note 6)		
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, 9,141,185 and 8,159,382 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	10	8

Additional paid-in-capital	266,669	247,762
Accumulated deficit	(254,253)	(237,422)
Accumulated other comprehensive income	-	-
Total stockholders' equity	12,426	10,348
Total liabilities and stockholders' equity	$ 30,944	$ 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 5,141	$ 3,696	$ 10,457	$ 7,684
General and administrative	3,169	2,467	6,023	5,110
Change in fair value of contingent consideration	313	616	612	(242)
Total operating expenses	8,623	6,779	17,092	12,552
Operating loss	(8,623)	(6,779)	(17,092)	(12,552)
Other income				
Change in fair value of warrants liabilities	1	2	1	29
Interest income	147	52	260	74
Total other income	148	54	261	103
Net loss	$ (8,475)	$ (6,725)	$ (16,831)	$ (12,449)
Other comprehensive income (loss)				
Foreign currency translation adjustment	(16)	1	-	(1)
Total comprehensive loss	$ (8,491)	$ (6,724)	$ (16,831)	$ (12,450)
Net loss per common share, basic and diluted	$ (0.81)	$ (0.72)	$ (1.69)	$ (1.69)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	10,423,598	9,339,254	9,938,171	7,348,045

Source: Soleno Therapeutics