Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2022 Financial Results

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REDWOOD CITY, Calif., March 21, 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 fourth quarter and full-year ended December 31, 2022.

Fourth Quarter 2022 and Recent Corporate Highlights

- Enrollment is nearing completion 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):
  - 58/63 (>90% of U.S. participants) have been randomized.
  - 15/83 (18%) participants are in the U.K., where enrollment is expected to start imminently following recent approval of the protocol from the MHRA.
  - 5 of 83 total participants in the study (6%) declined to participate, in line with our expectation of non-participation.
  - Top-line data continue to be expected in third quarter 2023.

- Entered into Securities Purchase Agreement with leading healthcare investors, Nantahala Capital Management, Abingworth, and Vivo Capital for up to $60 million in gross proceeds to Soleno. The first $10 million is contingent upon announcing last patient enrolled in the randomized withdrawal trial; $15 million upon announcement of positive top-line data; and the potential of up to an additional $35 million following U.S. Food and Drug Administration (FDA) approval of DCCR for the treatment of PWS.

- Published two peer-reviewed papers featuring results from the previously completed Phase 3 DESTINY PWS (C601) trial of DCCR for PWS:
  - "Chromosomal Microarray Study in Prader-Willi Syndrome," published in the *International Journal of Molecular Sciences,* reports microarray analysis performed on chromosomes from 154 individuals enrolled in the trial and can be found here.
  - "Diazoxide Choline Extended-Release Tablet in People with Prader-Willi Syndrome: A Double-Blind Placebo-Controlled Trial," published in *The Journal of Clinical Endocrinology and Metabolism* (*JCEM*), presents comprehensive results from the trial and can be found here.

"We are excited that enrollment in the randomized withdrawal phase of Study 602 is nearing completion," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Importantly, reaching this milestone enables the Company to receive $10 million under the Securities Purchase Agreement executed in December 2022 with prominent healthcare investors, strengthening our balance sheet and supporting clinical operations through top-line data leading to a potential NDA filing and approval of DCCR. In addition, we are also pleased to have published two papers in prominent peer-reviewed journals featuring results from our previously completed Phase 3 DESTINY PWS trial, adding to the growing body of clinical evidence supporting DCCR for the treatment 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.

Fourth Quarter and Full Year Ended December 31, 2022 Financial Results

As of December 31, 2022, Soleno had cash and cash equivalents of approximately $14.6 million. In addition, under the terms of the December 2022 Securities Purchase Agreement, investors have committed to pay $10 million in exchange for warrants to purchase common stock upon the Company's announcement of full enrollment in the randomized withdrawal phase of Study 602. The Company expects this announcement will occur in the second quarter of 2023 and believes that in aggregate these funds will be sufficient to fund operations through top line-data anticipated in the third quarter of 2023.

The warrants consist of two Tranches. Tranche A warrants to purchase up to approximately 8.6 million shares of common stock at $1.75 for a total of approximately $15 million are required to be exercised within 30 days of announcement of positive top-line data from the randomized withdrawal period of Study C602. Tranche B warrants to purchase up to 14,000,000 shares of common stock at $2.50 for a total of $35 million expire upon the earlier of 3.5 years from the date of issuance and 30 days following receipt of FDA approval of DCCR for the treatment of PWS. The total possible proceeds raised under this agreement is $60 million for the issuance of 22.6 million shares at an average price of $2.65 per share.

Research and development expenses were $3.8 million for the quarter ended December 31, 2022, compared to $3.7 million in the same period of 2021, and $15.3 million for the year ended December 31, 2022, compared to $21.5 million for the year ended 2021. The decrease is primarily due to decreased spending in clinical trials and manufacturing efforts as Soleno awaited FDA guidance on a path forward to obtaining additional controlled clinical data to support an NDA submission.

General and administrative expense was $2.4 million for the quarter ended December 31, 2022, compared to $2.6 million in the same period of 2021, and $9.8 million for the year ended December 31, 2022, compared to $10.8 million for the year ended 2021. The decrease was primarily related to higher stock-based compensation expense and higher professional and consulting expenses in 2021. These costs did not recur in 2022. These decreases were partially offset by an increase in salary and benefits associated with an increase in headcount.

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 a maximum of $21.2 million to the former Essentialis stockholders upon the 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 was estimated to be $8.8 million as of December 31, 2022, a $0.7 million decrease from the estimate as of December 31, 2021.

Total other income (expense), net, was $0.1 million for the quarter ended December 31, 2022, and $0.2 million in the same period of 2021. For the year, total other income (expense), net, was $0.3 million for 2022, and $0.6 million for 2021. Other income consists of interest income and changes in the fair value of the Company's warrant liability.

Net loss was approximately $5.5 million, or $0.58 per basic and diluted share, for the quarter ended December 31, 2022, and $2.8 million, or $0.53 per basic and diluted share, in the same period of 2021.

Net loss for the year ended December 31, 2022, was approximately $24.1 million, or $2.87 per basic and diluted share, compared to a net loss of approximately $30.9 million, or $5.81 per basic and diluted share, for the year ended December 31, 2021.

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 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 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)

	December 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 14,602	$ 21,304
Prepaid expenses and other current assets	1,045	1,118
Total current assets	15,647	22,422
Long-term assets		
Property and equipment, net	26	33
Operating lease right-of-use assets	131	421
Intangible assets, net	10,693	12,637
Other long-term assets	—	40
Total assets	$ 26,497	$ 35,553

Liabilities and stockholders' equity (deficit)		
Current liabilities		
Accounts payable, net	$ 1,777	$ 3,254
Accrued compensation	1,675	728
Accrued clinical trial site costs	3,222	3,420
Operating lease liabilities	155	282
Other current liabilities	484	323
Total current liabilities	7,313	8,007
Long-term liabilities		
2018 PIPE Warrant liability	1	31
Contingent liability for Essentialis purchase price	8,835	9,547
Long-term lease liabilities	—	175
Total liabilities	16,149	17,760
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit)		
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, 8,159,382 and 5,324,287 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	8	80
Additional paid-in-capital	247,762	231,068
Accumulated deficit	(237,422)	(213,355)
Total stockholders' equity (deficit)	10,348	17,793
Total liabilities and stockholders' equity (deficit)	$ 26,497	$ 35,553

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

	Three Months Ended December 31,		For the Years Ended December 31,	
	2022	**2021**	**2022**	**2021**
Operating expenses				
Research and development	$ 3,810	$ 3,734	$ 15,265	$ 21,453
General and administrative	2,402	2,596	9,844	10,806
Change in fair value of contingent consideration	(602)	(3,329)	(712)	(731)
Total operating expenses	5,610	3,001	24,397	31,528
Operating loss	(5,610)	(3,001)	(24,397)	(31,528)
Other income (expense), net				
Change in fair value of warrant liability	(1)	139	30	508
Interest income	125	34	300	110
Total other income (expense), net	124	173	330	618
Net loss	$ (5,486)	$ (2,828)	$ (24,067)	$ (30,910)
Net loss per common share, basic and diluted	$ (0.58)	$ (0.53)	$ (2.87)	$ (5.81)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	9,440,347	5,323,072	8,397,088	5,318,022

Source: Soleno Therapeutics