



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

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REDWOOD CITY, Calif., Nov. 07, 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 third quarter ended September 30, 2023.

Third Quarter 2023 and Recent Corporate Highlights

- Announced positive statistically significant top-line data from 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).
 - The study met its primary endpoint, demonstrating a highly statistically significant difference in change from baseline in HQ-CT total score for DCCR compared to placebo ($p=0.0022$)
 - Secondary endpoints of Clinical Global Impression of Severity (CGI-S) and Clinical Global Impression of Improvement (CGI-I) both showed strong trends towards worsening in the placebo group compared to DCCR ($p=0.08$ and 0.09), respectively.
 - DCCR continued to be generally well-tolerated in the randomized withdrawal period with no new or unexpected safety signals, including no serious adverse events or discontinuations due to adverse events occurring in any participants in the treatment group.
- Presented results from the randomized withdrawal phase of Study C602 at the Foundation for Prader-Willi Research (FPWR) 2023 Research Symposium held on October 5-6, 2023 in Denver, Colorado.
- Closed on gross proceeds of approximately \$129 million from an underwritten public offering of common stock and concurrent private placement of common stock and pre-funded warrants in October 2023.
- Appointed industry veteran Matthew Pauls, J.D., M.B.A. to the Board of Directors. Mr. Pauls currently serves as Chair of the Board of Directors and Chief Executive Officer of Savara, Inc., a biopharmaceutical company focused on rare respiratory diseases. He is also a member of the Board of Directors at Amplo Biotechnology, a private gene therapy company focused on rare neuromuscular disorders. Previously, he was President and Chief Executive Officer and a member of the Board of Directors at Strongbridge Biopharma plc. In addition, Mr. Pauls has significant experience in global commercial roles, including at Insmed, Shire Pharmaceuticals, Bristol-Myers Squibb and Johnson & Johnson.
- Hired Mike Huang, M.D. as Senior Vice President of Clinical Development. Prior to joining Soleno, Dr. Huang held leadership roles at several biopharmaceutical companies, including AmMax Bio, Spruce Biosciences, Regulus Therapeutics, Auspex Pharmaceuticals and Santarus, where he worked on programs advancing small molecules, biologic agents and oligonucleotide therapies through all phases of clinical development and successful marketing authorizations. Dr. Huang's therapeutic experience spans an array of indications, including rare/orphan diseases, endocrinology, neurology and oncology.

"The recent announcement of positive results from the randomized withdrawal phase of Study C602 was a significant milestone for us," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We are continuing our ongoing work preparing a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA), currently planned for mid-2024. Importantly, following our successfully completed public offering and concurrent private placement, we have initiated commercial readiness activities and are well-capitalized to execute on our planned corporate strategy leading up to and beyond potential approval of DCCR for 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.

Third Quarter 2023 Financial Results

As of September 30, 2023, Soleno had cash and cash equivalents of approximately \$52.4 million, which includes \$8.4 million received from exercised warrants issued as part of the Company's March 2022 public offering, and \$15 million received from the exercise of previously issued Tranche A warrants in connection with Soleno's December 2022 Securities Purchase Agreement which were triggered by the announcement of positive top-line data. In addition, \$16.0 million of the \$129 million public and concurrent private financing was received in September 2023. The remaining proceeds were received upon the closing of the transaction in October 2023, together with an additional \$17.5 million from exercised Tranche B warrants in connection with the December 2022 Securities Purchase Agreement. In aggregate, the Company received \$169.9 million in gross proceeds from these financing activities.

Research and development expenses for the three and nine months ended September 30, 2023, were \$6.0 million and \$16.5 million, compared to \$3.8 million and \$11.5 million for the same periods of 2022. Soleno's research and development expenditures 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 nine months ended September 30, 2023, were \$3.3 million and \$9.3 million, compared to \$2.3 million and \$7.4 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 commercial milestones associated with the future 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 achieving two commercial sales milestones of \$100 million and \$200 million in revenue in future years was estimated to be \$10.5 million as of September 30, 2023, a \$1.1 million increase from the estimate as of June 30, 2023.

Total other expense was \$0.5 million and \$0.2 million in the three and nine months ended September 30, 2023, compared to other income of \$0.1 million and \$0.2 million for the same periods of 2022. The decrease was primarily due to the change in fair value of warrants liabilities, partially offset by an increase in interest income during the three and nine months ended September 30, 2023 compared to the three and nine months ended September 30, 2022.

Net loss for the three and nine months ended September 30, 2023, was \$10.9 million and \$27.7 million, or a net loss of \$0.95 and \$2.65 per basic and diluted share, compared to \$6.1 million and \$18.6 million, or \$0.65 and \$2.31 per basic and diluted share, for the same periods in 2022.

The following table summarizes the Soleno's outstanding common stock and common stock warrants as of October 31, 2023:

	As of October 31, 2023	
	Number of Common Shares	Weighted Average Exercise Price per Shares
Common stock outstanding	30,499,352	\$ -
Common stock warrants	7,904	\$ 388.94
2018 PIPE warrants	34,241	\$ 30.00
March 2022 common warrants	2,122,924	\$ 4.50
March 2022 Pre-funded warrants	0	\$ 0.15
May 2023 Tranche A warrants	0	\$ 1.75
May 2023 Tranche A Pre-funded warrants	3,058,837	\$ 0.01
May 2023 Tranche B warrants	7,000,000	\$ 2.50
May 2023 Tranche B Pre-funded warrants	451,632	\$ 0.01
Oct 2023 Pre-funded warrants	1,125,019	\$ 0.01
Total	44,299,909	

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The hallmark symptom of this disorder is hyperphagia, a chronic and life-threatening feeling of intense, persistent hunger, food pre-occupation, extreme drive to food seek and consume food that severely diminish the quality of life for patients with PWS 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.

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, diazoxide choline 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 patients with PWS. In the PWS Phase 3 clinical development program, 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. 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 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 PWS, recently completed its Phase 3 development program to support a planned NDA submission. 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 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.

Corporate Contact:

Brian Ritchie
LifeSci Advisors, LLC

Soleno Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)

	<u>September 30, 2023</u>	<u>December 31, 2022</u>
	<u>(Unaudited)</u>	
Assets		
Current assets		
Cash and cash equivalents	\$ 52,437	\$ 14,602
Prepaid expenses and other current assets	1,222	1,045
Total current assets	<u>53,659</u>	<u>15,647</u>
Long-term assets		
Property and equipment, net	15	26
Operating lease right-of-use assets	474	131
Intangible assets, net	9,235	10,693
Other long-term assets	165	-
Total assets	<u>\$ 63,548</u>	<u>\$ 26,497</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 3,216	\$ 1,777
Accrued compensation	1,498	1,675
Accrued clinical trial site costs	3,237	3,222
Common stock purchase liability	19,938	-
Operating lease liabilities - current	256	155
Other current liabilities	848	484
Total current liabilities	<u>28,993</u>	<u>7,313</u>
Long-term liabilities		
2018 PIPE Warrant liability	653	1
Operating lease liabilities - noncurrent	214	-
Contingent liability for Essentialis purchase price	10,468	8,835
Total liabilities	<u>40,328</u>	<u>16,149</u>
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, 15,467,229 and 8,159,382 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	15	8
Additional paid-in-capital	288,320	247,762
Accumulated deficit	(265,114)	(237,422)
Accumulated other comprehensive loss	(1)	-
Total stockholders' equity	<u>23,220</u>	<u>10,348</u>
Total liabilities and stockholders' equity	<u>\$ 63,548</u>	<u>\$ 26,497</u>

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Operating expenses				
Research and development	\$ 6,043	\$ 3,771	\$ 16,500	\$ 11,455
General and administrative	3,318	2,332	9,341	7,442
Change in fair value of contingent consideration	1,021	132	1,633	(110)
Total operating expenses	<u>10,382</u>	<u>6,235</u>	<u>27,474</u>	<u>18,787</u>
Operating loss	<u>(10,382)</u>	<u>(6,235)</u>	<u>(27,474)</u>	<u>(18,787)</u>
Other income (expense), net				
Change in fair value of warrants liabilities	(653)	2	(652)	31
Interest income	174	101	434	175
Total other income (expense), net	<u>(479)</u>	<u>103</u>	<u>(218)</u>	<u>206</u>
Net loss	<u>\$ (10,861)</u>	<u>\$ (6,132)</u>	<u>\$ (27,692)</u>	<u>\$ (18,581)</u>
Other comprehensive loss				
Foreign currency translation adjustment	(1)	(1)	(1)	(2)
Total comprehensive loss	<u>\$ (10,862)</u>	<u>\$ (6,133)</u>	<u>\$ (27,693)</u>	<u>\$ (18,583)</u>

Net loss per common share, basic and diluted	<u>\$ (0.95)</u>	<u>\$ (0.65)</u>	<u>\$ (2.65)</u>	<u>\$ (2.31)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>11,436,748</u>	<u>9,417,705</u>	<u>10,443,186</u>	<u>8,045,513</u>



Source: Soleno Therapeutics