



Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2020 Financial Results

March 3, 2021

REDWOOD CITY, Calif., March 03, 2021 (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 announced financial results for the fourth quarter and year ended December 31, 2020.

Fourth Quarter 2020 and Recent Corporate Highlights

- Announced analysis of Phase 3 DESTINY PWS (C601) study evaluating once-daily Diazoxide Choline Controlled-Release (DCCR) tablets for patients with Prader Willi Syndrome (PWS), limited to data collected through March 1, 2020, before the onset of the COVID-19 pandemic
 - Primary endpoint demonstrated a statistically significant change from baseline in hyperphagia
 - Change was measured by the total score of a Hyperphagia Questionnaire for Clinical Trials (HQ-CT, 0-36): p=0.037
 - Statistically significant improvements were noted in all key secondary endpoints
 - Clinical Global Impression of Improvement (CGI-I) at Visit 7: p=0.015
 - Change from Baseline in Body Fat Mass (DXA) at Visit 7: p=0.004
 - Caregiver Global Impression of Change (Caregiver GI-C) at Visit 7: p=0.031
 - The safety profile of DCCR remains generally consistent with the known profile of diazoxide and prior experience with DCCR, with no serious unexpected adverse events related to DCCR reported
 - Soleno continues its interactions with the FDA around this as well as other analyses of completed and ongoing studies of DCCR
- Hosted key opinion leader (KOL) webinar to discuss the treatment landscape and unmet need in PWS, impact of the COVID-19 pandemic on PWS patients and families, and an analysis of Phase 3 DESTINY PWS evaluating data generated prior to disruptions caused by the COVID-19 pandemic
- Announced collaboration agreement with Vanderbilt University to discover and develop novel ATP-dependent potassium (K_{ATP}) channel activators with the potential to treat rare diseases

"We remain focused on our goal of advancing our late-stage DCCR program in PWS," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Based on the substantial impact of the COVID-19 pandemic on PWS patients and families, we conducted further analysis of our Phase 3 DESTINY PWS study that evaluated data collected prior to the onset of the pandemic, which we highlighted at a recent KOL webinar. We observed statistically significant improvements with DCCR compared with placebo patients for the primary and all key secondary endpoints during the pre-pandemic time period. We are continuing our interactions with the regulatory authorities, including around these most recent results. In addition, we are excited about our collaboration with Vanderbilt University, which has the potential to add additional clinical candidates for PWS and other rare diseases to our product pipeline."

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 Ended December 31, 2020 Financial Results from Operations

Research and development expenses were \$5.6 million for the quarter ended December 31, 2020, compared to \$5.3 million in the same period of 2019. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was \$2.3 million for the quarter ended December 31, 2020, compared to \$1.6 million in the same period of 2019. The increase was due to an increase in personnel related costs.

The fair value of contingent consideration results from Soleno's obligation to make cash payments to 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 and is remeasured at the end of each reporting period. The value increased by \$0.1 million for the quarter ended December 31, 2020 compared to a decrease in value of \$0.1 million in the same period in 2019.

Total other income of \$5.2 million and total other expense of (\$7.9 million) for the quarter ended December 31, 2020 and the same period in 2019, respectively, consisted primarily of the change in the fair value of the liability for the company's outstanding warrants. The other income recorded in the fourth quarter of 2020 was primarily due to the 2017 PIPE warrants expiring unexercised during the quarter.

Net loss for the quarter ended December 31, 2020, was approximately \$2.8 million, or \$0.04 per basic and diluted share, compared to net loss of approximately \$14.6 million, or \$0.36 per basic and diluted share, for the quarter ended December 31, 2019.

Year Ended December 31, 2020 Financial Results from Operations

Research and development expenses were \$23.2 million for the year ended December 31, 2020, compared to \$16.3 million for the year ended December 31, 2019. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was \$8.8 million for the year ended December 31, 2020, compared to \$6.9 million for the year ended December 31, 2019. The increase was primarily related to increased compensation costs, costs for intellectual property, and corporate business development expenses.

The fair value of contingent consideration was estimated to be approximately \$10.3 million at December 31, 2020 up \$4.3 million from \$5.9 million at December 31, 2019.

Total other income of \$11.7 million and total other expense of (\$7.3 million) in 2020 and 2019, respectively, consisted primarily of the change in the fair value of the liability for warrants of approximately \$11.6 million and (\$7.0 million) in 2020 and 2019, respectively.

Net loss for the year ended December 31, 2020, was approximately \$24.6 million, or \$0.39 per basic and diluted share, compared to a net loss of approximately \$30.8 million, or \$0.90 per basic and diluted share, for the year ended December 31, 2019.

As of December 31, 2020, Soleno had cash and cash equivalents of approximately \$49.2 million, as compared to \$20.7 million at December 31, 2019.

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., choking, stomach rupture, 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 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 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, Diazoxide Choline Controlled-Release (DCCR) tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase III 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, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 49,224	\$ 20,733
Prepaid expenses and other current assets	1,019	411
Total current assets	50,243	21,144
Long-term assets		
Property and equipment, net	19	22
Operating lease right-of-use assets	124	398
Finance lease right-of-use assets	15	24
Intangible assets, net	14,581	16,525
Other long-term assets	—	59
Total assets	\$ 64,982	\$ 38,172

Liabilities and stockholders' equity			
Current liabilities			
Accounts payable		\$ 3,489	\$ 1,995
Accrued compensation		1,005	283
Accrued clinical trial site costs		3,789	1,999
Operating lease liabilities		139	305
Other current liabilities		196	382
Total current liabilities		8,618	4,964
Long-term liabilities			
2017 PIPE Warrant liability		—	10,822
2018 PIPE Warrant liability		539	1,354
Contingent liability for Essentialis purchase price		10,278	5,938
Other long-term liabilities		—	147
Total liabilities		19,435	23,225
Commitments and contingencies (Note 8)			
Stockholders' equity			
Common stock, \$0.001 par value, 250,000,000 and 100,000,000 shares authorized at December 31, 2020 and December 31, 2019, respectively, 79,615,692 and 44,658,054 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively.			
		80	45
Additional paid-in-capital		227,912	172,708
Accumulated deficit		(182,445)	(157,806)
Total stockholders' equity		45,547	14,947
Total liabilities and stockholders' equity		\$ 64,982	\$ 38,172

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

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2020	2019	2020	2019
Operating expenses				
Research and development	\$ 5,566	\$ 5,272	\$ 23,191	\$ 16,267
General and administrative	2,251	1,608	8,758	6,930
Change in fair value of contingent consideration	140	(128)	4,340	289
Total operating expenses	7,957	6,752	36,289	23,486
Operating loss	(7,957)	(6,752)	(36,289)	(23,486)
Other (expense) income				
Change in fair value of warrants liabilities	5,105	(7,894)	11,637	(6,964)
Loss from minority interest investment	—	—	—	(478)
Interest and other income	—	21	13	154
Total other income (expense)	5,105	(7,873)	11,650	(7,288)
Net loss	\$ (2,852)	\$ (14,625)	\$ (24,639)	\$ (30,774)
Loss per common share, basic and diluted	\$ (0.04)	\$ (0.36)	\$ (0.39)	\$ (0.90)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share				
	79,608,495	41,165,960	62,620,227	34,142,478



Source: Soleno Therapeutics