Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2021 Financial Results

March 31, 2022

REDWOOD CITY, Calif., March 31, 2022 (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 full-year ended December 31, 2021.

Fourth Quarter 2021 and Recent Corporate Highlights

- Received official meeting minutes on January 20, 2022, from the December 21, 2021, Type C meeting with the U.S. Food and Drug Administration's (FDA) Division of Psychiatry. The purpose of the meeting was to discuss the adequacy of the data submitted to the FDA by Soleno in October 2021 to support a potential New Drug Application (NDA) submission for diazoxide choline extended-release (DCCR) tablets for the treatment of Prader-Willi syndrome (PWS), as well as possible ways to generate additional controlled clinical data. Soleno recently submitted a study proposal involving participants currently enrolled in Study C602, Soleno's ongoing open-label extension study, and intends to initiate the study after alignment with the FDA is reached.
- Announced that Running for Research - Prader-Willi Syndrome, an organization committed to raising private donations in support of advancing the science around PWS, will fund an investigator-sponsored clinical study to evaluate DCCR in patients with early phase PWS
- Closed $15 million public offering on March 31, 2022
- Participated in the BIO CEO & Investor Conference
    - Participated in the LifeSci Partners 11th Annual Corporate Access Event

"Following our recent discussions with the FDA, the Soleno team remains focused on advancing our late-stage DCCR program to an NDA submission," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Based on the feedback from the FDA, we recently submitted a study proposal to generate additional controlled clinical data involving patients currently enrolled in our ongoing open-label extension study, Study C602. Once alignment with the FDA is reached, we anticipate study initiation shortly thereafter. We remain confident in DCCR's efficacy and safety based on the considerable data we have generated to date and look forward to continuing to work closely with the FDA, providers, patients and the entire PWS community to bring this important therapy to people with PWS. Importantly, we strengthened our balance sheet through the recent successfully completed public offering and are well-positioned to continue executing on our product development and corporate growth initiatives."

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, 2021 Financial Results from Operations

Research and development expenses were $3.8 million for the quarter ended December 31, 2021, compared to $5.6 million in the same period of 2020, and $21.5 million for the year ended December 31, 2021, compared to $23.2 million for the year ended 2020. The decrease was primarily due to the completion of the DESTINY PWS study in June 2020 and the subsequent winding down of associated activities and costs.

General and administrative expense was $2.6 million for the quarter ended December 31, 2021, compared to $2.3 million in the same period of 2020, and $10.8 million for the year ended December 31, 2021, compared to $8.8 million for the year ended 2020. The increase was primarily related to increased compensation costs, professional services and corporate business development expenses.

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 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. In December 2021, in connection with the dissolution of two of the former Essentialis stockholders, the two former stockholders entered into an agreement with Soleno which assigned the right, title and interest to all their future earnout payments to Soleno. As a result of the assignment, as of December 31, 2021, and going forward, the maximum cash earnout payments have been reduced from $30.0 million to $21.2 million. The fair value of the contingent liability as of December 31, 2021, was $9.5 million compared to $10.3 million as of December 31, 2020.

Total other income was $0.2 million and $5.2 million for the fourth quarter ended December 31, 2021, and 2020, respectively, and $0.6 million and $11.7 million for the year ended December 31, 2021, and 2020, respectively. Total other income consisted primarily of the change in the fair value of the liability for Soleno's outstanding warrants and was primarily due to the 2017 PIPE warrants expiring unexercised at the end of 2020.

Net loss was approximately $2.8 million, or $0.04 per basic and diluted share, for both fourth quarters ended December 31, 2021 and 2020.

Net loss for the year ended December 31, 2021, was approximately $30.9 million, or $0.39 per basic and diluted share, compared to a net loss of approximately $24.6 million, or $0.39 per basic and diluted share, for the year ended December 31, 2020.

As of December 31, 2021, Soleno had cash and cash equivalents of approximately $21.3 million, as compared to $49.2 million as of December 31, 2020. On March 31, 2022, the Company completed a public offering of its common stock and, for certain investors, in lieu of common stock, prefunded warrants, and for each share of common stock or pre-funded warrant, one immediately exercisable common warrant. The net proceeds of the offering are expected to be $13.9 million after deducting the underwriting discount and other estimated offering expenses, and assuming that no pre-funded warrants are immediately exercised.

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, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in an ongoing Phase 3 clinical development program. For more information, please visit www.soleno.life.

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. Soleno has been in ongoing discussions with the FDA regarding additional data needed to support the submission of an NDA.

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, including the Annual Report on Form 10-K, which Soleno intends to file with the SEC on March [30], 2022. 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, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 21,304	$ 49,224
Prepaid expenses and other current assets	1,118	1,019
Total current assets	22,422	50,243
Long-term assets		
Property and equipment, net	33	19
Operating lease right-of-use assets	421	124
Finance lease right-of-use assets	—	15
Intangible assets, net	12,637	14,581
Other long-term assets	40	—
Total assets	$ 35,553	$ 64,982
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,254	$ 3,489

Accrued compensation	728	1,005
Accrued clinical trial site costs	3,420	3,789
Operating lease liabilities	282	139
Other current liabilities	323	196
Total current liabilities	8,007	8,618
Long-term liabilities		
2018 PIPE Warrant liability	31	539
Contingent liability for Essentialis purchase price	9,547	10,278
Long-term lease liabilities	175	—
Total liabilities	17,760	19,435
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.001 par value, 250,000,000 shares authorized, 79,864,310 and 79,615,692 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively.	80	80
Additional paid-in-capital	231,068	227,912
Accumulated deficit	(213,355)	(182,445)
Total stockholders' equity	17,793	45,547
Total liabilities and stockholders' equity	$ 35,553	$ 64,982

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,	
	2021	**2020**	**2021**	**2020**
Operating expenses				
Research and development	$ 3,734	$ 5,566	$ 21,453	$ 23,191
General and administrative	2,596	2,251	10,806	8,758
Change in fair value of contingent consideration	(3,329)	140	(731)	4,340
Total operating expenses	3,001	7,957	31,528	36,289
Operating loss	(3,001)	(7,957)	(31,528)	(36,289)
Other income (expense)				
Change in fair value of warrants liabilities	139	5,105	508	11,637
Interest income	34	0	110	13
Total other income (expense)	173	5,105	618	11,650
Net loss	$ (2,828)	$ (2,852)	$ (30,910)	$ (24,639)
Net loss per common share, basic and diluted	$ (0.04)	$ (0.04)	$ (0.39)	$ (0.39)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	79,846,083	79,608,495	79,770,334	62,620,227

Source: Soleno Therapeutics