Soleno Therapeutics Provides Corporate Update and Reports First Quarter 2022 Financial Results

May 10, 2022 8:01 PM EDT

REDWOOD CITY, Calif., May 10, 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 reported financial results for the three months ended March 31, 2022.

First Quarter 2022 and Recent Corporate Highlights

- Continuing dialogue with the U.S. Food and Drug Administration (FDA) to obtain alignment on the design of a study to provide additional clinical data to support the potential filing of a New Drug Application for diazoxide choline extended-release (DCCR) for the treatment of Prader-Willi Syndrome (PWS)
- Presented posters highlighting long-term results from the Company’s studies evaluating DCCR tablets for the treatment of patients with PWS who received DCCR for 52 weeks and compared to a matched cohort from the PATH for PWS natural history study (C601/C602) at the Pediatric Academic Societies (PAS) 2022 Virtual Annual Meeting and Pediatric Endocrinology Society (PES) 2022 Virtual Annual Meeting
- Closed $15 million public offering on March 31, 2022

“We look forward to reaching alignment with the FDA on generating additional controlled clinical data,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “Achieving regulatory approval as expeditiously as possible for DCCR continues to be the Soleno team’s core priority. Our recent data presentations at the PAS and PES annual meetings highlight the significant potential of DCCR to improve behavioral and metabolic outcomes for people with PWS who have no current therapeutic options. Our recently closed public offering has strengthened our balance sheet, providing us with financial flexibility as we continue to advance our strategic clinical and operational plans.”

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.

First Quarter Ended March 31, 2022 Financial Results

Research and development expenses were $4.0 million for the quarter ended March 31, 2022, compared to $7.2 million in the same period of 2021. Soleno’s research and development spending continues to 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 expense was $2.6 million for the quarter ended March 31, 2022, compared to $3.0 million in the same period of 2021. The decrease was primarily due to a reduction in stock-based compensation.

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 acquisition of DCCR in accordance with the terms of the Essentialis merger agreement. The fair value was estimated to be approximately $8.7 million as of March 31, 2022, a $0.9 million decrease from the estimate as of December 31, 2021.

Total other income was $0.05 million for the quarter ended March 31, 2022, compared to $0.2 million in the same period of 2021, and consisted of the change in the fair value of Soleno’s outstanding warrants and interest income.

Net loss for the quarter ended March 31, 2022, was approximately $5.7 million, or a net loss of $0.07 per basic and diluted share, compared to a net loss of approximately $9.0 million, or $0.11 per basic and diluted share, for the quarter ended March 31, 2021.

As of March 31, 2022, Soleno had cash and cash equivalents of approximately $29.0 million, compared to $21.3 million as of December 31, 2021.

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 EU, 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. 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)

	March 31, 2022	December 31, 2021
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 28,974	$ 21,304
Prepaid expenses and other current assets	1,004	1,118
Total current assets	29,978	22,422
Long-term assets		
Property and equipment, net	27	33
Operating lease right-of-use assets	350	421
Intangible assets, net	12,151	12,637
Other long-term assets	40	40
Total assets	$ 42,546	$ 35,553
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 2,411	$ 3,254
Accrued compensation	598	728
Accrued clinical trial site costs	3,521	3,420
Operating lease liabilities	344	282
Other current liabilities	439	323
Total current liabilities	7,313	8,007
Long-term liabilities		
2018 PIPE Warrant liability	4	31
Contingent liability for Essentialis purchase price	8,689	9,547
Long-term lease liabilities	79	175
Total liabilities	16,085	17,760
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 250,000,000 shares authorized, 120,088,816 and 79,864,310 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively.	120	80
Additional paid-in-capital	245,422	231,068
Accumulated deficit	(219,079)	(213,355)
Accumulated other comprehensive loss	(2)	—
Total stockholders' equity	26,461	17,793
Total liabilities and stockholders' equity	$ 42,546	$ 35,553

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses		
Research and development	$ 3,988	$ 7,164
General and administrative	2,643	2,979
Change in fair value of contingent consideration	(858)	(987)
Total operating expenses	5,773	9,156
Operating loss	(5,773)	(9,156)
Other income		
Change in fair value of warrants liabilities	27	201
Interest income	22	1
Total other income	49	202
Net loss	$ (5,724)	$ (8,954)
Other comprehensive loss		
Foreign currency translation adjustment	(2)	—
Total comprehensive loss	$ (5,726)	$ (8,954)
Net loss per common share, basic and diluted	$ (0.07)	$ (0.11)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	80,020,677	79,694,781

Source: Soleno Therapeutics