# Soleno Therapeutics Provides Corporate Update and Reports Third Quarter 2022 Financial Results

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REDWOOD CITY, Calif., Nov. 09, 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 and nine months ended September 30, 2022.

**Third Quarter 2022 and Recent Corporate Highlights**

- Initiated 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)
  - U.S. Food and Drug Administration (FDA) previously acknowledged that data from the study has the potential to support a New Drug Application (NDA) submission for DCCR
  - Randomized withdrawal period consists only of patients currently enrolled in Study C602 and will not enroll any new subjects
  - Top-line data expected in the first half of 2023
- Exposure response analysis of DCCR in PWS was presented at the Foundation For Prader-Willi Research (FPWR) Research Symposium and Family Conference in September 2022
  - Analysis showed that long term hyperphagia change from baseline was significantly associated with circulating drug levels, with greater improvements associated with higher circulating drug levels
  - Significant exposure response relationships were also characterized for leptin and insulin change from baseline and for various safety parameters evaluated

“The initiation of the randomized withdrawal phase of Study C602 is an important step in advancing our late-stage DCCR program towards NDA submission,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “We anticipate top-line data in the first half of 2023, and are confident that these results, together with the robust data generated to date from our DCCR development program, will demonstrate the significant potential of this promising product candidate as an effective and safe therapy for patients with PWS who have limited therapeutic options.”

**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. Cash at the end of September 30, 2022 was $19.8 million, which the Company believes is sufficient to fund operations at least through top line-data expected in the first half of 2023.

**Third Quarter Ended September 30, 2022 Financial Results**

Research and development expenses for the three and nine months ended September 30, 2022, were $3.8 million and $11.5 million, compared to $5.0 million and $17.7 million for the same periods of 2021. The cadence of Soleno’s research and development expenditures will fluctuate depending upon the state of its clinical programs and the timing of CMC and other projects necessary to support the submission of an NDA.

General and administrative expenses for the three and nine months ended September 30, 2022, were $2.3 million and $7.4 million, compared to $2.8 million and $8.2 million for the same periods of 2021. The decrease was primarily due to a decrease in stock-based compensation expense.

The change in fair value of contingent consideration at the end of each reporting period is a result of Soleno remeasuring 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 $9.4 million as of September 30, 2022, a $0.1 million increase from the estimate as of June 30, 2022.

Total other income was $103,000 in the three months ended September 30, 2022, compared to $146,000 during the three months ended September 30, 2021. The decrease of was primarily due to a larger decrease in the fair value of our outstanding warrants, partially offset by an increase in interest income during the three months ended September 30, 2022 compared to the three months ended September 30, 2021.

Net loss for the three and nine months ended September 30, 2022, was $6.1 million and $18.6 million, or a net loss of $0.76 and $2.60 per basic and diluted share, compared to $8.1 million and $28.1 million, or $1.53 and $5.28 per basic and diluted share, for the same periods in 2021, respectively.

**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)*

| | September 30, 2022 | December 31, 2021 |
|---|---|---|
| **Assets** | **(Unaudited)** | |
| Current assets | | |
| Cash and cash equivalents | $ 19,751 | $ 21,304 |
| Prepaid expenses and other current assets | 821 | 1,118 |
| Total current assets | 20,572 | 22,422 |
| Long-term assets | | |
| Property and equipment, net | 23 | 33 |
| Operating lease right-of-use assets | 206 | 421 |
| Intangible assets, net | 11,178 | 12,637 |
| Other long-term assets | - | 40 |
| Total assets | $ 31,979 | $ 35,553 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 2,324 | $ 3,254 |
| Accrued compensation | 1,282 | 728 |
| Accrued clinical trial site costs | 2,826 | 3,420 |
| Operating lease liabilities | 239 | 282 |
| Other current liabilities | 671 | 323 |
| Total current liabilities | 7,342 | 8,007 |
| Long-term liabilities | | |
| 2018 PIPE Warrant liability | - | 31 |
| Contingent liability for Essentialis purchase price | 9,437 | 9,547 |
| Long-term lease liabilities | — | 175 |
| Total liabilities | 16,779 | 17,760 |
| Commitments and contingencies (Note 6) | | |
| Stockholders' equity | | |
| Common stock, $0.001 par value, 100,000,000 shares authorized, 8,159,382 and 5,324,287 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively. | 8 | 80 |
| Additional paid-in-capital | 247,130 | 231,068 |
| Accumulated deficit | (231,936) | (213,355) |
| Accumulated other comprehensive loss | (2) | — |

| | | |
|---|---|---|
| Total stockholders' equity | 15,200 | 17,793 |
| Total liabilities and stockholders' equity | $ 31,979 | $ 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses | | | | |
| Research and development | $ 3,771 | $ 4,968 | $ 11,455 | $ 17,719 |
| General and administrative | 2,332 | 2,767 | 7,442 | 8,210 |
| Change in fair value of contingent consideration | 132 | 551 | (110) | 2,598 |
| Total operating expenses | 6,235 | 8,286 | 18,787 | 28,527 |
| Operating loss | (6,235) | (8,286) | (18,787) | (28,527) |
| Other income | | | | |
| Change in fair value of warrants liabilities | 2 | 112 | 31 | 369 |
| Interest income | 101 | 34 | 175 | 76 |
| Total other income | 103 | 146 | 206 | 445 |
| Net loss | $ (6,132) | $ (8,140) | $ (18,581) | $ (28,082) |
| Other comprehensive loss | | | | |
| Foreign currency translation adjustment | (1) | — | (2) | — |
| Total comprehensive loss | $ (6,133) | $ (8,140) | $ (18,583) | $ (28,082) |
| Net loss per common share, basic and diluted | $ (0.76) | $ (1.53) | $ (2.60) | $ (5.28) |
| Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share | 8,093,033 | 5,319,405 | 7,156,344 | 5,316,320 |

Source: Soleno Therapeutics