



Soleno Therapeutics Announces Proposed Underwritten Public Offering

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REDWOOD CITY, Calif., March 28, 2022 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, announced today that it intends to offer and sell shares of its common stock in an underwritten public offering and, in lieu of common stock, Soleno intends to offer and sell to certain investors pre-funded warrants to purchase shares of its common stock. Each share of common stock or pre-funded warrant is being sold together with one immediately exercisable common warrant to purchase one share of common stock. All shares of common stock, and accompanying common warrants, and pre-funded warrants, and accompanying common warrants, to be sold in the offering will be offered by the company. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Soleno intends to use the net proceeds from this offering to fund its current research and development efforts primarily focused on advancing its lead candidate, DCCR tablets for the treatment of Prader-Willi Syndrome (PWS), and to provide for general corporate purposes, which may include working capital, capital expenditures, other clinical trials, other corporate expenses and acquisitions of complementary products, technologies or businesses, though the company does not have agreements or commitments for any specific acquisitions at this time.

Oppenheimer & Co. Inc. is acting as the sole book-running manager for the offering.

The securities described above are being offered by Soleno pursuant to a shelf registration statement on Form S-3 (File No. 333-252108) previously filed with, and declared effective by, the Securities and Exchange Commission (SEC) on February 9, 2021. A preliminary prospectus supplement and accompanying prospectus relating to this offering will be filed with the SEC. When available, copies of the preliminary prospectus supplement and the accompanying prospectus relating to this offering may be obtained from Oppenheimer & Co. Inc. Attention: Syndicate Prospectus Department, 85 Broad Street, 26th Floor, New York, NY 10004, or by telephone at (212) 667-8055, or by email at EquityProspectus@opco.com. Electronic copies of the preliminary prospectus supplement and accompanying prospectus will also be available on the website of the SEC at www.sec.gov.

Before investing in this offering, interested parties should read in their entirety the preliminary prospectus supplement and the accompanying prospectus and the other documents that the company has filed with the SEC that are incorporated by reference in such prospectus supplement and the accompanying prospectus, which provide more information about the company and such offering.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction.

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 PWS, is currently being evaluated in an ongoing Phase 3 clinical development program. For more information, please visit www.solenolife.com.

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 the Company's expectations on the completion, timing and size of the proposed public offering and the anticipated use of proceeds therefrom. 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 and the satisfaction of customary closing conditions related to the proposed public offering, 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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Source: Soleno Therapeutics



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