
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **March 28, 2022**

SOLENO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36593
(Commission
File No.)

77-0523891
(IRS Employer
Identification Number)

203 Redwood Shores Pkwy, Suite 500
Redwood City, CA 94065
(Address of principal executive offices)

(650) 213-8444
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbols	Name of each exchange on which registered
Common Stock, \$0.001 par value	SLNO	NASDAQ

Item 2.02 Results of Operations and Financial Condition

On March 28, 2022, Soleno Therapeutics, Inc. (the “**Company**”) filed a preliminary prospectus supplement (the “**Preliminary Prospectus Supplement**”) with the Securities and Exchange Commission (the “**SEC**”) relating to a proposed public offering (the “**Offering**”) of the Company’s common stock and, for certain investors, in lieu of common stock, pre-funded warrants to purchase shares of the Company’s 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 securities issued in the Offering (including the shares of common stock issuable from time to time upon exercise of the pre-funded warrants and the common warrants) are being offered and issued pursuant to a shelf registration statement filed on Form S-3 (File No. 333- 252108) with the SEC, which was declared effective February 9, 2021. The Company included the following disclosure in the Preliminary Prospectus Supplement (the “**Preliminary Estimates**”) under the heading “Recent Developments”:

“We have not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through December 31, 2021, have generated no revenue from operations. We had a net loss of \$30.9 million during the year ended December 31, 2021 and an accumulated deficit of \$213.4 million as of December 31, 2021 as a result of having incurred losses since our inception. We had \$21.3 million in cash and cash equivalents and \$14.4 million of working capital as of December 31, 2021, used \$27.8 million of cash in operating activities during the year ended December 31, 2021 and expect to continue incurring losses for the foreseeable future.”

The Preliminary Estimates are not final or a comprehensive statement of our financial results for the year ended December 31, 2021. We caution that our final results for the year ended December 31, 2021 that we will file with the SEC could vary significantly from these Preliminary Estimates as a result of the completion of our customary year-end closing, review and audit procedures and other developments arising between now and the time that our financial results for the year ended December 31, 2021 are finalized. The Preliminary Estimates should not be viewed as a substitute for complete financial statements prepared in accordance with generally accepted accounting principles in the United States of America and they are not necessarily indicative of the results to be achieved in any future period. Accordingly, you should not place undue reliance on the Preliminary Estimates.

Item 8.01 Other Events.

On March 28, 2022, the Company issued a press release announcing the commencement of the Offering. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, nor shall there be any sale of the Company’s securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Soleno Therapeutics, Inc. dated March 28, 2022.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SOLENO THERAPEUTICS, INC.

Date: March 28, 2022

By: /s/ Anish Bhatnagar
Anish Bhatnagar
Chief Executive Officer

Soleno Therapeutics Announces Proposed Underwritten Public Offering

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.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 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.

Corporate Contact:

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Source: Soleno Therapeutics