

**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): April 29, 2024

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))

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

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.

ITEM 8.01 Other Events

On April 29, 2024, Soleno Therapeutics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing that it had received Breakthrough Therapy Designation from the U.S. Food and Drug Administration for DCCR (Diazoxide Choline) Extended-Release Tablets in Prader-Willi Syndrome (“PWS”). A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 8.01 (including Exhibit 99.1) is being furnished pursuant to Item 8.01 and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Soleno Therapeutics, Inc. dated April 29, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: April 29, 2024

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

Soleno Therapeutics Receives Breakthrough Therapy Designation from U.S. FDA for DCCR (Diazoxide Choline) Extended-Release Tablets in Prader-Willi Syndrome (PWS)

First Ever Breakthrough Designation for a Drug Being Developed for PWS

Designation is Based on Data from the Phase 3 Program for DCCR

Planned Submission of a New Drug Application (NDA) for DCCR Remains on Track for Mid-2024

REDWOOD CITY, Calif., April 29, 2024 (GLOBE NEWSWIRE) — Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to diazoxide choline for the treatment of adults and children ages 4 years and older with genetically confirmed Prader-Willi syndrome (PWS) who have hyperphagia. The designation reflects the Agency’s determination that, based on an assessment of the preliminary data from the Phase 3 clinical development program, diazoxide choline may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.

“The granting of Breakthrough Therapy Designation, the first for a drug being developed for the treatment of PWS, marks another important milestone for our DCCR clinical development program,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “This important designation is confirmation that the FDA views PWS as a serious condition and is an indication of DCCR’s potential to be a safe and effective treatment for PWS. We remain focused on preparing our NDA submission for DCCR in PWS, which we continue to expect will occur in mid-2024.”

The FDA’s Breakthrough Therapy Designation is intended to expedite the development and review of drugs in the U.S. that are intended to treat a serious condition, when preliminary clinical evidence indicates the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). With Breakthrough Therapy Designation, FDA provides intensive guidance and organizational commitment involving senior managers in a proactive, collaborative, cross-disciplinary review, and may also allow for priority review and other actions to expedite review.

Diazoxide choline has Orphan Drug Designation for PWS in the U.S. and E.U., as well as Fast Track Designation in the U.S.

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The hallmark symptom of this disorder is hyperphagia, a chronic and life-threatening feeling of intense, persistent hunger, food pre-occupation, extreme drive to food seek and consume food that severely diminish the quality of life for patients with PWS 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% rated body composition as either 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.

About DCCR (Diazoxide Choline) Extended-Release Tablets

DCCR is a novel, proprietary extended-release dosage form containing diazoxide choline, the crystalline salt of diazoxide, and is administered once-daily. Soleno conceived of and established extensive patent protection for the therapeutic use of diazoxide, diazoxide choline 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 patients with PWS. In the PWS Phase 3 clinical development program, 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. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the U.S. and E.U., and Fast Track and Breakthrough Designations in the U.S.

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, recently completed its Phase 3 development program in patients with PWS to support a planned NDA submission. 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 the 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 the projected timeline of our NDA submission, whether FDA will agree with our interpretation of the data or the adequacy of data to support an NDA, the FDA's review of our NDA, 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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