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): November 26, 2024

SOLENO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36593**	**77-0523891**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification Number)**

100 Marine Parkway, Suite 400
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 November 26, 2024, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") extended the target action date of its review of the New Drug Application ("NDA") for DCCR (diazoxide choline) extended-release tablets by three months. The new target date is March 27, 2025, revised from the original target action date of December 27, 2024.

The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Soleno Therapeutics, Inc. dated November 26, 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: November 26, 2024

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

Soleno Therapeutics Announces FDA Extension of Review Period for DCCR (Diazoxide Choline) Extended-Release Tablets in Prader-Willi Syndrome

PDUFA target action date extended by three months to March 27, 2025

REDWOOD CITY, Calif., November 26, 2024 – 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 extended the review period for the New Drug Application (NDA) for DCCR (diazoxide choline) extended-release tablets for the treatment of Prader-Willi syndrome (PWS) in individuals four years and older who have hyperphagia. The new Prescription Drug User Fee Act (PDUFA) target action date is March 27, 2025.

The FDA determined that responses to recent information requests constituted a major amendment to the NDA, resulting in the extension of the PDUFA goal date by three months. The extension allows the FDA time to complete their review, including that of the recently submitted information. The FDA did not cite any safety, efficacy or manufacturing concerns in their correspondence.

Soleno submitted the NDA to the FDA on June 27, 2024. The FDA accepted the NDA and granted Priority Review in August 2024. Diazoxide choline has been granted Breakthrough and Fast Track Designations in the U.S., as well as Orphan Drug Designation in the U.S. and E.U. for the treatment of patients with PWS.

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 condition characterized by feelings of intense, persistent hunger, food pre-occupation, and an extreme drive to seek and consume food, which can severely diminish the quality of life for individuals 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 mortality (e.g., stomach rupture, choking, accidental death due to food seeking behavior) and longer term, co-morbidities such as diabetes, obesity, and cardiovascular disease. In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parents 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. The parent molecule, diazoxide, has been used for decades in thousands of individuals in a few rare diseases in neonates, infants, children and adults, but is not approved for use in PWS. Soleno conceived of and established extensive patent protection for the therapeutic use of diazoxide, diazoxide choline and DCCR in individuals 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 individuals 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.

About Soleno Therapeutics, Inc.

Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. An NDA for its lead candidate, DCCR (diazoxide choline) extended-release tablets, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS) is currently under review by the FDA and was granted Priority Review. 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 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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