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): May 9, 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)**

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 2.02 Results of Operations and Financial Conditions

On May 9, 2024, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

This information is intended to be furnished under Item 2.02 and Item 9.01 of Form 8-K, "Results of Operations and Financial Condition" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Soleno Therapeutics, Inc. dated May 9, 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: May 10, 2024

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

Soleno Therapeutics Provides Corporate Update and Reports First Quarter 2024 Financial Results

REDWOOD CITY, Calif., May 9, 2024 – 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 first quarter ended March 31, 2024.

First Quarter 2024 and Recent Corporate Highlights

- Closed on approximately $158.7 million underwritten public offering of 3,450,000 shares of common stock at a public offering price of $46.00 per share, which includes the exercise in full by the underwriters of their overallotment option to purchase additional shares.
- Granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for Diazoxide Choline Extended-Release (DCCR) for the treatment of adults and children ages four years and older with genetically confirmed Prader-Willi syndrome (PWS) who have hyperphagia.
- Planned submission of a New Drug Application (NDA) for DCCR in PWS remains on track for mid-2024.
- Published peer-reviewed paper featuring the comparison of results from the Company's Phase 3 placebo-controlled study (C601) and open-label extension study (C602) evaluating DCCR in patients with PWS to data from the PATH for PWS (PATH) natural history study in the *Journal of Neurodevelopmental Disorders*. The article, entitled, *Behavioral Changes in Patients with Prader-Willi Syndrome Receiving Diazoxide Choline Extended-Release Tablets Compared to the PATH for PWS Natural History Study* showed there to be significant improvements in hyperphagia and other PWS-associated behaviors with DCCR compared with natural history, and can be found here.
- Strengthened leadership team with appointments of Meredith Manning, M.B.A. as Chief Commercial Officer, Dairine Dempsey, Ph.D. as Vice President, Europe and Lauren Budesheim, M.S. as Vice President of Human Resources.

"Soleno's top priority remains NDA submission for DCCR in PWS," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Receiving Breakthrough Therapy Designation from the FDA for DCCR was a significant milestone and we are working diligently to ensure a timely NDA submission. In parallel, our commercial team has begun preparations for a potential commercial launch of DCCR. We believe DCCR has the potential to significantly improve the lives of people living with PWS, and, if approved, could be a foundational therapy in the treatment of PWS."

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.

First Quarter Ended March 31, 2024 Financial Results

As of March 31, 2024, Soleno had $42.8 million of cash and cash equivalents, $106.8 million of short-term investments, and $8.8 million of long-term investments. In addition, in May 2024, the Company received $148.8 million in net proceeds from the Closing of a public offering, bringing pro forma cash reserves to a total of $307.2 million.

Research and development expense was $14.6 million for the three months ended March 31, 2024, compared to $5.3 million in the same period of 2023. The increase was primarily due to increased headcount cost, expenditures in support of our NDA submission and CMC project investment in preparation for commercial launch.

General and administrative expense was $8.5 million for the three months ended March 31, 2024, compared to $2.9 million in the same period of 2023. The increase was primarily related to higher stock-based compensation expense, higher costs because of an increase in headcount and higher professional and consulting expenses.

Soleno is obligated to make cash payments of up to a maximum of $21.2 million to the former Essentialis stockholders upon the achievement of certain commercial milestones associated with the future sales of DCCR in accordance with the terms of Soleno's 2016 merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by the Company upon achieving two commercial sales milestones of $100 million and $200 million in revenue in future years was estimated to be $12.0 million as of March 31, 2024, a $0.4 million increase from the estimate as of December 31, 2023.

Total other income, net, was $2.1 million for the three months ended March 31, 2024, and $0.1 million in the same period of 2023. The increase was primarily due to an increase in interest income driven by higher cash and cash equivalents, short-term and long-term investments during the three months ended March 31, 2024, compared to the three months ended March 31, 2023.

Net loss was approximately $21.4 million, or $0.59 per basic and diluted share, for the quarter ended March 31, 2024, and $8.4 million, or $0.88 per basic and diluted share, in the same period of 2023.

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 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 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 for the treatment of PWS, recently completed its Phase 3 development program 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, filing of an NDA, 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.

Corporate Contact:
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LifeSci Advisors, LLC
212-915-2578

Soleno Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands except share and per share data)

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 42,847	$ 169,681
Short-term investments	106,780	—
Prepaid expenses and other current assets	1,596	1,677
Total current assets	151,223	171,358
Long-term assets		
Property and equipment, net	27	12
Operating lease right-of-use assets	338	407
Intangible assets, net	8,263	8,749
Long-term investments	8,821	—
Other long-term assets	165	165
Total assets	$168,837	$ 180,691
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,022	$ 3,149
Accrued compensation	1,226	3,135
Accrued clinical trial site costs	2,395	3,393
Operating lease liabilities	310	273
Other current liabilities	1,511	1,555
Total current liabilities	13,464	11,505
Long-term liabilities		
Contingent liability for Essentialis purchase price	11,950	11,549
Long-term lease liabilities	37	130
Total liabilities	25,451	23,184
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 33,337,079 and 31,678,159 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	33	32
Additional paid-in-capital	441,267	433,885
Accumulated other comprehensive loss	(106)	—
Accumulated deficit	(297,808)	(276,410)
Total stockholders' equity	143,386	157,507
Total liabilities and stockholders' equity	$168,837	$ 180,691

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Operating expenses		
Research and development	$ 14,602	$ 5,316
General and administrative	8,472	2,854
Change in fair value of contingent consideration	401	299
Total operating expenses	23,475	8,469
Operating loss	(23,475)	(8,469)
Other income, net		
Interest income, net	2,077	113
Total other income, net	2,077	113
Net loss	$ (21,398)	$ (8,356)
Other comprehensive income (loss)		
Net unrealized loss on marketable securities	(105)	—
Foreign currency translation adjustment	(1)	16
Total comprehensive loss	$ (21,504)	$ (8,340)
Net loss per common share, basic and diluted	$ (0.59)	$ (0.88)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	36,208,371	9,447,350