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 6, 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 March 6, 2024, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2023. 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 7.01 Regulation FD Disclosure.

On March 6, 2024, the Company issued a press release announcing our financial results for the fourth quarter and year ended December 31, 2023, which contained a scrivener's error in the table "Condensed Consolidated Statements of Operations" attached thereto. Specifically, the general and administrative expense line should have read $4,140 instead of $4,410 for the three months ended December 31, 2023. A revised copy of the table, which corrects the scrivener's error, is included in Exhibit 99.1. The information contained in Exhibit 99.1 is incorporated herein by reference.

The information furnished pursuant to this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Soleno Therapeutics, Inc. dated March 6, 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.

Date: March 7, 2024

SOLENO THERAPEUTICS, INC.

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

Exhibit 99.1

Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2023 Financial Results

REDWOOD CITY, Calif., March 6, 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 fourth quarter and full-year ended December 31, 2023.

Full Year 2023 and Recent Corporate Highlights

- Announced positive statistically significant top-line data from the randomized withdrawal period of Study C602, a long-term treatment study of DCCR (Diazoxide Choline) Extended-Release tablets for the treatment of Prader-Willi syndrome (PWS) in September 2023.
  - The study met its primary endpoint, demonstrating a highly statistically significant difference in change from baseline in HQ-CT total score for DCCR compared to placebo (p=0.0022).
  - Secondary endpoints of Clinical Global Impression of Severity (CGI-S) and Clinical Global Impression of Improvement (CGI-I) both showed strong trends towards worsening in the placebo group compared to DCCR (p=0.08 and 0.09), respectively.
  - DCCR continued to be generally well-tolerated in the randomized withdrawal period with no new or unexpected safety signals.
- Planned submission of a New Drug Application (NDA) for DCCR in PWS remains on track for mid-2024, after receipt of pre-NDA meeting minutes from the U.S. Food and Drug Administration. The FDA stated that the potential for data from the DCCR clinical program to provide substantial evidence of effectiveness will be a matter of review following the submission of an NDA.
- Closed on gross proceeds of approximately $129 million from an underwritten public offering of common stock and concurrent private placement of common stock and pre-funded warrants in October 2023, and received $43.1 million from the sale and exercise of warrants issued in connection with the December 2022 Securities Purchase Agreement.
- 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.

"Following recent feedback from the FDA, Soleno remains focused on preparing an NDA submission for DCCR in PWS mid-2024," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We believe data from our extensive clinical program, including highly statistically significant top-line results from the randomized withdrawal period of Study C602, supports that DCCR has the potential to be a safe and effective therapy for patients with PWS. With our strengthened leadership team and balance sheet, we are ideally positioned to carry out our corporate strategy and, if approved, deliver a new treatment option for PWS patients."

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.

Fourth Quarter and Full Year Ended December 31, 2023 Financial Results

As of December 31, 2023, Soleno had cash and cash equivalents of approximately $169.7 million, which includes $129 million received upon the closing of the public offering and concurrent private placement in October 2023, and $43.1 million received from the sale and exercise of warrants issued in connection with the December 2022 Securities Purchase Agreement. The Company may receive an additional $16.9 million from the exercise of the remaining warrants issued pursuant to the December 2022 Securities Purchase Agreement.

Research and development expenses were $8.7 million for the quarter ended December 31, 2023, compared to $3.8 million in the same period of 2022, and $25.2 million for the year ended December 31, 2023, compared to $15.3 million for the year ended 2022. The increase was primarily due to increased clinical trials costs, manufacturing efforts, and expenditures in support of our NDA submission.

General and administrative expenses were $4.1 million for the quarter ended December 31, 2023, compared to $2.4 million in the same period of 2022, and $13.5 million for the year ended December 31, 2023, compared to $9.8 million for the year ended 2022. 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 in 2023.

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 $11.5 million as of December 31, 2023, a $1.1 million increase from the estimate as of September 30, 2023.

Total other income (expense), net, was $2.6 million for the quarter ended December 31, 2023, and $0.1 million in the same period of 2022. For the year, total other income (expense), net, was $2.4 million for 2023, and $0.3 million for 2022. Other income (expense) consists of interest income and changes in the fair value of the Company's warrant liability.

Net loss was approximately $11.3 million, or $0.33 per basic and diluted share, for the quarter ended December 31, 2023, and $5.5 million, or $0.58 per basic and diluted share, in the same period of 2022.

Net loss for the year ended December 31, 2023, was approximately $39.0 million, or $2.36 per basic and diluted share, compared to a net loss of approximately $24.1 million, or $2.87 per basic and diluted share, for the year ended December 31, 2022.

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 Designation 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 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:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

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

	December 31, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 169,681	$ 14,602
Prepaid expenses and other current assets	1,677	1,045
Total current assets	171,358	15,647
Long-term assets		
Property and equipment, net	12	26
Operating lease right-of-use assets	407	131
Intangible assets, net	8,749	10,693
Other long-term assets	165	—
Total assets	$ 180,691	$ 26,497
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable, net	$ 3,149	$ 1,777
Accrued compensation	3,135	1,675
Accrued clinical trial site costs	3,393	3,222
Operating lease liabilities	273	155
Other current liabilities	1,555	484
Total current liabilities	11,505	7,313
Long-term liabilities		
2018 PIPE Warrant liability	—	1
Contingent liability for Essentialis purchase price	11,549	8,835
Long-term lease liabilities	130	—
Total liabilities	23,184	16,149
Commitments and contingencies (Note 8)		
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, 31,678,159 and 8,159,382 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	32	8
Additional paid-in-capital	433,885	247,762
Accumulated deficit	(276,410)	(237,422)
Total stockholders' equity	157,507	10,348
Total liabilities and stockholders' equity	$ 180,691	$ 26,497

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

	Three Months Ended December 31,		For the Years Ended December 31,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 8,689	$ 3,810	$ 25,189	$ 15,265
General and administrative	4,140	2,402	13,481	9,844
Change in fair value of contingent consideration	1,081	(602)	2,714	(712)
Total operating expenses	13,910	5,610	41,384	24,397
Operating loss	(13,910)	(5,610)	(41,384)	(24,397)
Other income (expense), net				
Change in fair value of warrant liability	470	(1)	(182)	30
Interest income	2,144	125	2,578	300
Total other income (expense), net	2,614	124	2,396	330
Net loss	$ (11,296)	$ (5,486)	$ (38,988)	$ (24,067)
Net loss per common share, basic and diluted	$ (0.33)	$ (0.58)	$ (2.36)	$ (2.87)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	34,441,721	9,440,347	16,492,132	8,397,088