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 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)**

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 2.02 Results of Operations and Financial Conditions

On November 6, 2024, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 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.

SOLENO THERAPEUTICS, INC.

Date: November 6, 2024

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

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

REDWOOD CITY, Calif., November 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 third quarter ended September 30, 2024.

Third Quarter 2024 and Recent Corporate Highlights

- New Drug Application (NDA) for DCCR (diazoxide choline) extended-release tablets for the treatment of Prader-Willi syndrome (PWS) accepted by the U.S. Food and Drug Administration (FDA) and granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) target action date of December 27, 2024.
    - The FDA Review Division determined that there does not appear to be a need for an advisory committee meeting at this time. However, the Division's review team will continue to consider the potential need for an advisory committee meeting during their ongoing review.
- Announced updates to its Board of Directors:
    - Appointed Dawn Carter Bir, a seasoned biotechnology executive with over 30 years of industry executive leadership and strategic experience, to Soleno's Board of Directors.
    - Current Board member Matthew Pauls, J.D., M.B.A assumed the role of Lead Independent Director.
- Soleno mourned the passing of former Chairman of the Board Ernest Mario, Ph.D. Dr. Mario served as Soleno's (formerly Capnia's) Chairman from 2007 through August 2024.

"In the third quarter of 2024, we achieved a major milestone with FDA acceptance of our NDA seeking approval of DCCR for the treatment of PWS," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Our dialogue with the FDA has been productive to date, and we look forward to continued collaboration as the review process advances. As we look towards potential approval of DCCR, our commercial team continues to prepare for our planned U.S. market launch. Our strong balance sheet supports successful execution of a launch and the delivery of a transformative therapy to people living with PWS, if approved."

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.

Third Quarter Ended September 30, 2024 Financial Results

Soleno used $14.9 million of cash in its operating activities during the three months ended September 30, 2024, and had $284.7 million of cash, cash equivalents and marketable securities.

Research and development expense was $30.1 million, which includes $18.5 million of non-cash stock-based compensation, for the three months ended September 30, 2024, compared to $6.0 million, which includes $0.9 million of non-cash stock-based compensation in the same period of 2023. Personnel and associated costs increased $2.4 million as we hired additional employees in support of our research and development activities. Consulting costs in support of our NDA submission and preparation for a submission to the European Medicines Agency increased $2.7 million, and we invested $1.3 million in supply chain activities in preparation for commercial launch. The cadence of our research and development expenditures will fluctuate depending upon the state of our clinical programs, the timing of manufacturing and other projects necessary to support the submission of our NDA and prepare for commercial launch. The $17.6 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon the acceptance by the FDA of the NDA submission and fully vest upon the approval by the FDA (see table below).

General and administrative expense was $49.2 million, which includes $38.1 million of non-cash stock-based compensation, for the three months ended September 30, 2024, compared to $3.3 million, which includes $1.3 million of non-cash stock-based compensation, in the same period of 2023. Personnel and associated costs increased $3.0 million as we hired additional employees in preparation for commercial launch and in support of our increased business activities. Professional services expenses and other program costs associated with preparation for commercial launch, including medical affairs activities, increased by $5.9 million. The $36.8 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which partially vested upon acceptance by the FDA of the NDA submission and fully vest upon approval by the FDA (see table below).

We are 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 sales of DCCR in accordance with the terms of our merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of $100 million and $200 million in cumulative revenue in future years was estimated to be $14.5 million as of September 30, 2024, a $0.9 million increase from the estimate as of June 30, 2024.

Total other income, net, was $3.6 million for the three months ended September 30, 2024, compared to total other expense, net, of $0.5 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, marketable securities and long-term marketable securities during the three months ended September 30, 2024, compared to the three months ended September 30, 2023.

Net loss was approximately $76.6 million, or $1.83 per basic and diluted share, for the three months ended September 30, 2024, and $10.9 million, or $0.95 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. 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.

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)

	September 30, 2024	December 31, 2023
Assets	**(unaudited)**	
Current assets		
Cash and cash equivalents	$ 48,413	$ 169,681
Marketable securities	208,363	—
Prepaid expenses and other current assets	1,423	1,677
Total current assets	258,199	171,358
Long-term assets		
Property and equipment, net	196	12
Operating lease right-of-use assets	2,992	407
Intangible assets, net	7,291	8,749
Long-term marketable securities	27,945	—
Other long-term assets	83	165
Total assets	$ 296,706	$ 180,691
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 6,243	$ 3,149
Accrued compensation	3,408	3,135
Accrued clinical trial site costs	1,762	3,393
Operating lease liabilities	448	273
Other current liabilities	3,101	1,555
Total current liabilities	14,962	11,505
Long-term liabilities		
Contingent liability for Essentialis purchase price	14,464	11,549
Long-term lease liabilities	2,581	130
Total liabilities	32,007	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, 41,041,216 and 31,678,159 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	41	32
Additional paid-in-capital	660,041	433,885
Accumulated other comprehensive gain	895	—
Accumulated deficit	(396,278)	(276,410)
Total stockholders' equity	264,699	157,507
Total liabilities and stockholders' equity	$ 296,706	$ 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 30,138	$ 6,043	$ 57,082	$ 16,500
General and administrative	49,197	3,318	68,558	9,341
Change in fair value of contingent consideration	877	1,021	2,915	1,633
Total operating expenses	80,212	10,382	128,555	27,474
Operating loss	(80,212)	(10,382)	(128,555)	(27,474)
Other income (expense), net				
Change in fair value of warrants liabilities	—	(653)	—	(652)
Interest income, net	3,596	174	8,687	434
Total other income (expense), net	3,596	(479)	8,687	(218)
Net loss	$ (76,616)	$ (10,861)	$ (119,868)	$ (27,692)
Other comprehensive income (loss)				
Net unrealized gain on marketable securities	1,049	—	898	—
Foreign currency translation adjustment	(1)	(1)	(3)	(1)
Total comprehensive loss	$ (75,568)	$ (10,862)	$ (118,973)	$ (27,693)
Net loss per common share, basic and diluted	$ (1.83)	$ (0.95)	$ (3.08)	$ (2.65)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	41,879,025	11,436,748	38,917,169	10,443,186

Soleno Therapeutics, Inc.
Stock-based Compensation Expense
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	$ 18,516	$ 935	$23,682	$1,587
General and administrative	38,082	1,266	46,521	2,449
Total	$ 56,598	$ 2,201	$70,203	$4,036