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 7, 2025

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 May 7, 2025, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2025. 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 7, 2025
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 7, 2025

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

Soleno Therapeutics Provides Update on U.S. Launch of VYKAT(TM) XR and Reports First Quarter 2025 Financial Results

REDWOOD CITY, Calif., May 7, 2025 – Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided an update on the U.S. launch of VYKAT™ XR and reported financial results for the first quarter ended March 31, 2025.

First Quarter 2025 and Recent Corporate Highlights

- Announced U.S. Food and Drug Administration (FDA) approval of VYKAT XR (diazoxide choline) extended-release tablets, previously referred to as DCCR, for the treatment of hyperphagia in adults and children four years of age and older with Prader-Willi syndrome (PWS).
    - Announced launch and commencement of patient treatments on April 14th, 2025.
- From approval through May 6th, 2025 Soleno reports:
    - 268 patient start forms received
    - 131 unique prescribers of VYKAT XR
- Continued to engage with leading payers regarding the value proposition of VYKAT XR with the goal of establishing broad access for patients.
- Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) seeking marketing approval of DCCR (marketed in the U.S. as VYKAT XR) to patients with PWS in the E.U. on track for second quarter of 2025.

“During the first quarter of 2025, we achieved the most significant milestone in the history of our company with FDA approval of VYKAT XR for the treatment of hyperphagia in patients four years and older with Prader-Willi syndrome,” stated Anish Bhatnagar, M.D., Chairman and Chief Executive Officer of Soleno Therapeutics. “While it has only been a few weeks since we announced approval and commercial availability, the high level of interest that we are experiencing, as reflected in both patient start forms and unique prescribers, reflects the significant unmet need that VYKAT XR can address as a first-to-market treatment for this debilitating condition. With a strong balance sheet and a world class team, I believe we are very well positioned to sustain our current momentum, delivering VYKAT XR to the patients who need it while creating significant long-term value for our company.”

Financial Results

Soleno’s efforts are primarily focused on executing a robust commercial launch of VYKAT XR following FDA approval on March 26th, 2025.

First Quarter Ended March 31, 2025 Financial Results

Soleno used $32.8 million of cash in its operating activities during the three months ended March 31, 2025, and had $290.0 million of cash, cash equivalents and marketable securities as of the end of the quarter.

The Company had not commenced commercialization of VYKAT XR in the three months ended March 31, 2025, and accordingly generated no revenue during this period.

Research and development expense was $13.5 million, which includes $4.3 million of non-cash stock-based compensation, for the three months ended March 31, 2025, compared to $14.6 million, which includes $2.4 million of non-cash stock-based compensation, in the same period of 2024. Personnel and other associated costs increased $1.9 million as the Company continued to hire additional employees in support of its research and development activities. Costs in support of its June 2024 NDA submission decreased $1.3 million. Pre-launch supply chain activities and clinical activities decreased $1.2 million and $3.1 million, respectively, between comparable periods. The Company incurred $0.7 million in the three months ended March 31, 2025, related to its MAA filing with the EMA, which is expected to be filed in the second quarter of 2025. The cadence of the Company's research and development expenditures will fluctuate depending upon the state of its clinical programs, the timing of manufacturing and other projects necessary to support its ongoing regulatory requirements and commercial launch. The $1.9 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which vested upon the approval of the Company's NDA for VYKAT XR by the FDA in March 2025.

Selling, general and administrative expense was $29.3 million, which includes $10.4 million of non-cash stock-based compensation, for the three months ended March 31, 2025, compared to $8.5 million, which includes $4.0 million of non-cash stock-based compensation, in the same period of 2024. Personnel and associated costs increased $7.7 million as the Company hired additional employees in preparation for commercial launch and in support of its increased business activities. New program costs associated with preparation for commercial launch, including disease state education, analytics, other marketing programs, medical affairs activities and patient advocacy activities increased by $5.8 million. The $6.4 million of additional non-cash stock-based compensation being recognized in the period is predominantly due to performance-based RSU grants which vested upon approval of the Company's NDA for VYKAT XR by the FDA in March 2025.

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 sales of VYKAT XR in accordance with the terms of the Company's 2017 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 cumulative revenue in future years was estimated to be $17.8 million as of March 31, 2025, a $3.0 million increase from the estimate as of December 31, 2024, driven primarily by the FDA approval of VYKAT XR.

Other income (expense), net was approximately $2.0 million in the three months ended March 31, 2025, compared to approximately $2.1 million during the three months ended March 31, 2024. The decrease was primarily due to interest expense associated with the long-term debt, partially offset an increase in interest income driven by higher cash, cash equivalents and marketable securities during the three months ended March 31, 2025, compared to the three months ended March 31, 2024.

Net loss was approximately $(43.8) million, or $(0.95) per basic and diluted share, for the three months ended March 31, 2025, and $(21.4) million, or $(0.59) per basic and diluted share, for the same period in 2024.

Conference Call and Webcast Information

Soleno management will host an investor conference call and webcast to discuss its first quarter 2025 financial and operating results and provide an update on the U.S. launch of VYKAT XR today, May 7th, 2025 at 4:30pm ET. Details can be found below:

Conference call details:	Toll-free: 1-800-717-1738 International: 1-646-307-1865 Conference ID: 57643
Call me™ (avoids waiting for an operator):	Click here
Webcast:	Click here

About PWS

Prader-Willi syndrome (PWS) is a rare genetic neurodevelopmental disorder caused by an abnormality in the gene expression on chromosome 15. The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The defining symptom of PWS is hyperphagia, a chronic and life-threatening condition characterized by an intense persistent sensation of hunger accompanied by food preoccupations, an extreme drive to consume food, food-related behavior problems, and a lack of normal satiety, which can severely diminish the quality of life for individuals with PWS and their families. 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.

INDICATION

VYKAT XR is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

IMPORTANT SAFETY INFORMATION

Contraindications

Use of VYKAT XR is contraindicated in patients who have a known hypersensitivity to diazoxide, other components of VYKAT XR, or to thiazides.

Warnings and Precautions

Hyperglycemia

Hyperglycemia, including diabetic ketoacidosis, has been reported. Before initiating VYKAT XR, test fasting plasma glucose (FPG) and HbA1c; optimize blood glucose in patients who have hyperglycemia. During treatment, regularly monitor fasting glucose (FPG or fasting blood glucose) and HbA1c. Monitor fasting glucose more frequently during the first few weeks of treatment in patients with risk factors for hyperglycemia.

Risk of Fluid Overload

Edema, including severe reactions associated with fluid overload, has been reported. Monitor for signs or symptoms of edema or fluid overload. VYKAT XR has not been studied in patients with compromised cardiac reserve and should be used with caution in these patients.

Adverse Reactions

The most common adverse reactions (incidence ≥10% and at least 2% greater than placebo) included hypertrichosis, edema, hyperglycemia, and rash.

Please see the full Prescribing Information, including Medication Guide**.**

About Soleno Therapeutics, Inc.

Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. The Company's first commercial product, VYKAT XR (diazoxide choline) extended-release tablets, formerly known as DCCR, is a once-daily oral treatment for hyperphagia in adults and children 4 years of age and older with Prader-Willi syndrome. 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. 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 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)

Assets	March 31, 2025 (unaudited)	December 31, 2024
Current assets		
Cash and cash equivalents	$ 81,331	$ 87,928
Marketable securities	208,619	203,509
Prepaid expenses and other current assets	18,965	2,452
Total current assets	308,915	293,889
Long-term assets		
Property and equipment, net	173	186
Operating lease right-of-use assets	2,603	2,798
Intangible assets, net	6,318	6,805
Long-term marketable securities	—	27,211
Other long-term assets	83	83
Total assets	$ 318,092	$ 330,972
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 5,483	$ 8,882
Accrued compensation	4,277	4,776
Accrued clinical trial site costs	1,824	1,826
Operating lease liabilities	597	526
Accrued interest payable	423	—
Other current liabilities	3,127	2,737
Total current liabilities	15,731	18,747
Long-term liabilities		
Contingent liability for Essentialis purchase price	17,758	14,791
Long-term debt, net	49,836	49,828
Long-term lease liabilities	2,361	2,472
Other long-term liabilities	145	21
Total liabilities	85,831	85,859
Commitments and contingencies (Note 5)		
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, 48,527,469 and 45,703,811 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	49	46
Additional paid-in-capital	728,019	696,966
Accumulated other comprehensive gain	226	361
Accumulated deficit	(496,033)	(452,260)
Total stockholders' equity	232,261	245,113
Total liabilities and stockholders' equity	$ 318,092	$ 330,972

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,	
	2025	2024
Operating expenses		
Research and development	$ 13,517	$ 14,602
Selling, general and administrative	29,259	8,472
Change in fair value of contingent consideration	2,967	401
Total operating expenses	45,743	23,475
Operating loss	(45,743)	(23,475)
Other income (expense), net		
Interest income, net	3,331	2,077
Interest expense	(1,361)	—
Total other income (expense), net	1,970	2,077
Net loss	$ (43,773)	$ (21,398)
Other comprehensive income (loss)		
Net unrealized loss on marketable securities	(139)	(105)
Foreign currency translation adjustment	4	(1)
Total comprehensive loss	$ (43,908)	$ (21,504)
Net loss per common share, basic and diluted	$ (0.95)	$ (0.59)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	46,178,793	36,208,371

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

	Three Months Ended March 31,	
	2025	2024
Research and development	$ 4,314	$ 2,461
Selling, general and administrative	10,365	3,984
Total	$ 14,679	$ 6,445