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): February 25, 2026

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 February 25, 2026, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 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 February 25, 2026
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: February 25, 2026

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

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

REDWOOD CITY, Calif., February 25, 2026 – Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today reported financial results for the fourth quarter and full-year ended December 31, 2025 and provided an update on the U.S. launch of VYKAT™ XR (diazoxide choline) extended-release tablets.

Fourth Quarter and Full-Year 2025 and Recent Corporate Highlights

- Revenue, net, from the sale of VYKAT XR for the three and twelve months ended December 31, 2025, was $91.7 million and $190.4 million, respectively.
- From approval on March 26, 2025 through December 31, 2025, Soleno reports:
  - 1,250 patient start forms received, including 207 in the fourth quarter
  - 630 unique prescribers, including 136 new prescribers in the fourth quarter
  - 859 active patients on drug as of December 31, 2025
  - Over 185 million lives covered
- Achieved profitability with positive net income of $20.9 million for the year.
- Generated $48.7 million of cash flow from operating activities in the fourth quarter.
- Invested $100 million in accelerated share repurchase program announced in November 2025 and ended the year with $506.1 million of cash, cash equivalents and marketable securities.

“Our first year as a commercial organization has been an outstanding success,” stated Anish Bhatnagar, M.D., Chairman and Chief Executive Officer of Soleno Therapeutics. “In just nine months, we received patient start forms representing over 12% of the U.S. VYKAT XR addressable market, reflecting both the strength of our world-class commercial team as well as the substantial disease burden that is addressed by VYKAT XR. We are very pleased with the positive trajectory of our other leading indicators, including patient start forms, patients on active therapy, unique prescribers, and lives covered.”

“Looking ahead, with the U.S. VYKAT XR launch well underway, we plan to pursue regulatory approval in other territories, starting with the EU. We will also begin to evaluate diazoxide choline extended-release (DCCR) in additional high-need rare diseases as we expand our development pipeline. We have made excellent progress in 2025 and are excited for the year ahead.”

Fourth Quarter and Full-Year Ended December 31, 2025 Financial Results

Product revenue, net, was $91.7 million and $190.4 million for the three and twelve months ended December 31, 2025, respectively. VYKAT XR had not been approved or commercially launched in the three and twelve months ended December 31, 2024, and accordingly, generated no revenue during those periods.

Research and development expense was $9.6 million, which includes $2.8 million of non-cash stock-based compensation, for the three months ended December 31, 2025, compared to $21.5 million, which includes $10.1 million of non-cash stock-based compensation, in the same period of 2024. For the year ended December 31, 2025, research and development expense was $40.6 million, which includes $11.7 million of non-cash stock-based compensation, a decrease of $38.0 million compared to $78.6 million, which includes $33.7 million non-cash stock-based compensation, in the same period of 2024.

For the year, the $15.9 million decrease in expense not related to stock-based compensation was due to a reduction in pre-commercial launch costs in support of the Company's 2024 NDA submission, supply chain, and clinical activities. These expenses decreased $7.5 million, $6.0 million, and $3.8 million, respectively. These decreases were partially offset by the Company incurring an additional $1.4 million of expense towards its MAA submission in Europe, which was submitted in the second quarter of 2025. The cadence of the Company's research and development expenditures will fluctuate depending upon the state of its research activities, clinical programs, and the timing of manufacturing and other projects necessary to support the submission of its regulatory filings.

Selling, general and administrative expense was $40.9 million, which includes $8.7 million of non-cash stock-based compensation, for the three months ended December 31, 2025, compared to $37.3 million, which includes $19.7 million of non-cash stock-based compensation, in the same period of 2024. For the year ended December 31, 2025, selling, general and administrative expense was $132.1 million, which includes $34.1 million of non-cash stock-based compensation, an increase of $26.2 million compared to $105.9 million, which includes $66.2 million of non-cash stock-based compensation, in the same period of 2024.

For the year, personnel costs, including hiring expense and other associated headcount costs, increased $31.3 million as the Company hired additional employees in support of its commercial launch and increased business activities. New program costs associated with commercial launch activities, including disease state education, analytics, other marketing programs, medical affairs and patient advocacy activities, increased $23.4 million. Costs for international expansion increased $3.5 million. These increases were offset by the $32.1 million reduction in stock-based compensation. Selling, general and administrative expenses are anticipated to increase as the Company continues commercialization of VYKAT XR.

The Company 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 DCCR 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 the achievement of commercial sales milestones of $100 million and $200 million in aggregate revenue, respectively, was estimated to be $20.3 million as of December 31, 2025, a $5.5 million increase from the estimate as of December 31, 2024. The first commercial milestone was achieved in the fourth quarter 2025 and $7.0 million will be paid in the first quarter 2026.

Total other income, net, was $3.8 million for the three months ended December 31, 2025, compared to total other income, net, of $3.1 million in the same period of 2024. For the year, total other income, net, was $11.5 million for 2025, compared to $11.8 million for 2024.

For the year ended December 31, 2025, net income was approximately $20.9 million, or $0.40 per basic and $0.39 per diluted share, compared to a net loss of $(175.9) million, or $(4.38) per basic and diluted share, for the same period of 2024.

Conference Call and Webcast Information

Soleno management will host an investor conference call and webcast to discuss its fourth quarter and full-year 2025 financial and operating results and provide an update on the U.S. launch of VYKAT XR today, February 25, 2026, at 4:30pm ET. Details can be found below:

Conference call details:	Toll-free: 800-717-1738 International: 646-307-1865 Conference ID: 55257
Call me™ (avoids waiting for an operator):	Here
Webcast:	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 (diazoxide choline) extended-release tablets 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 including its Annual Report on Form 10-K which it intends to release later today. 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.
Consolidated Balance Sheets
(In thousands except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 70,106	$ 87,928
Marketable securities	235,366	203,509
Accounts receivable, net	28,208	—
Inventory, net	15,024	—
Prepaid expenses and other current assets	7,110	2,452
Total current assets	355,814	293,889
Long-term assets		
Property and equipment, net	185	186
Operating lease right-of-use assets	2,191	2,798
Intangible assets, net	4,861	6,805
Long-term marketable securities	200,616	27,211
Other long-term assets	163	83
Total assets	$ 563,830	$ 330,972
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 12,435	$ 8,882
Accrued compensation	9,677	4,776
Operating lease liabilities	726	526
Contingent liability for Essentialis purchase price	20,327	—
Other current liabilities	18,198	4,563
Total current liabilities	61,363	18,747
Long-term liabilities		
Contingent liability for Essentialis purchase price	—	14,791
Long-term debt, net	49,863	49,828
Long-term lease liabilities	1,964	2,472
Other long-term liabilities	525	21
Total liabilities	113,715	85,859
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, 52,286,881 and 45,703,811 shares issued and outstanding at December 31, 2025 and 2024, respectively	52	46
Additional paid-in-capital	881,018	696,966
Accumulated other comprehensive income	415	361
Accumulated deficit	(431,370)	(452,260)
Total stockholders' equity	450,115	245,113
Total liabilities and stockholders' equity	$ 563,830	$ 330,972

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

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
Product revenue, net	$ 91,730	$ —	$ 190,405	$ —
Operating expenses				
Cost of goods sold	863	—	2,700	—
Research and development	9,558	21,486	40,627	78,568
Selling, general and administrative	40,878	37,303	132,128	105,861
Change in fair value of contingent consideration	854	327	5,536	3,242
Total operating expenses	52,153	59,116	180,991	187,671
Operating income (loss)	39,577	(59,116)	9,414	(187,671)
Other income (expense), net				
Interest income, net	5,130	3,365	16,952	12,052
Interest expense	(1,349)	(231)	(5,476)	(231)
Total other income (expense), net	3,781	3,134	11,476	11,821
Net income (loss)	$ 43,358	$ (55,982)	$ 20,890	$ (175,850)
Other comprehensive income (loss)				
Net unrealized gain (loss) on marketable securities	68	(537)	37	361
Foreign currency translation adjustment	(13)	3	17	—
Total comprehensive income (loss)	$ 43,413	$ (56,516)	$ 20,944	$ (175,489)
Net income (loss)	43,358	(55,982)	20,890	(175,850)
Less: Undistributed earnings attributable to participating securities	(1)	—	(415)	—
Net income (loss) attributable to common stockholders - basic and diluted	$ 43,357	$ (55,982)	$ 20,475	$ (175,850)
Net income (loss) per share - basic	$ 0.82	$ (1.27)	$ 0.40	$ (4.38)
Net income (loss) per share - diluted	$ 0.80	$ (1.27)	$ 0.39	$ (4.38)
Weighted-average common shares outstanding - basic	53,175,700	43,924,831	50,817,586	40,175,926
Weighted-average common shares outstanding - diluted	54,331,407	43,924,831	52,384,886	40,175,926

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

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
Research and development	$ 2,821	$ 10,061	$ 11,722	$ 33,743
Selling, general and administrative	8,650	19,694	34,124	66,215
Total	$ 11,471	$ 29,755	$ 45,846	$ 99,958