Soleno Therapeutics Announces Select Preliminary Fourth Quarter and Full-Year 2025 Results

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REDWOOD CITY, Calif., Jan. 12, 2026 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today announced select preliminary financial and operating results for the fourth quarter and full-year 2025:

- Preliminary unaudited full-year 2025 net revenue related to U.S. sales of VYKAT™ XR since second quarter launch expected to be in a range of $189 million to $191 million.
- Preliminary unaudited fourth quarter 2025 net revenue expected to be in a range of $90 million to $92 million.
- 1,250 total new patient start forms (207 in the fourth quarter) from launch through December 31, 2025, or approximately 12.5% of the total U.S. VYKAT XR addressable market.
- Discontinuation rate of VYKAT XR related to adverse events was approximately 12% as of the end of the fourth quarter.
- 630 unique prescribers, including 136 new prescribers in the fourth quarter.
- Over 185 million lives covered, or approximately 60% of total lives.
- Company has responded to Day 120 questions received from the European Medicines Agency.
- Company has achieved profitability and positive cash flow.
- Year-end 2025 cash, cash equivalents and marketable securities were approximately $500 million, after the $100 million accelerated share repurchase program that the Company announced on November 11, 2025.

“Our strong fourth quarter results cap a truly transformational year for Soleno Therapeutics, driven by the approval and successful launch of VYKAT XR in the U.S.,” said Dr. Anish Bhatnagar, Chief Executive Officer and Chairman of the Board of Soleno Therapeutics. “In less than nine months since launch, we have received patient start forms representing well over 10% of our addressable U.S. Prader-Willi syndrome (PWS) patient population. This reflects the significant unmet medical need that VYKAT XR can address as well as our success in communicating VYKAT XR’s value proposition to payers, providers and caregivers.”

“Looking ahead, as we continue to raise awareness of this first-to-market hyperphagia treatment, we have the opportunity to significantly impact the lives of many more patients and families living with PWS while simultaneously creating sustained value for our company. We are well-funded, our leading indicators are strong, and I am excited for what the future holds in 2026 and beyond,” Dr. Bhatnagar concluded.

The estimates of Soleno’s net revenue, cash, cash equivalents and marketable securities, patient start forms and other metrics above as of December 31, 2025 are preliminary, have not been audited, and do not present all information necessary for an understanding of Soleno’s financial condition as of December 31, 2025. The preliminary select financial information presented in this press release is provided as an approximation in advance of Soleno’s announcement of full fourth quarter and full-year 2025 financial results, which is anticipated to occur in late February 2026.

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.

About VYKAT XR
VYKAT XR was approved by the U.S. Food and Drug Administration (FDA) on March 26, 2025, and is commercially available to U.S. patients.

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 and was approved by the U.S. Food and Drug Administration (FDA) on March 26, 2025. 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:
Brian Ritchie
LifeSci Advisors, LLC
212-915-2578

Media Contact:
media@soleno.life

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