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

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REDWOOD CITY, Calif., Nov. 04, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today reported financial results for the third quarter ended September 30, 2025 and provided an update on the U.S. launch of VYKAT^{TM} XR.

Third Quarter 2025 and Recent Corporate Highlights

- Revenue, net, from the sale of VYKAT XR for the three months ended September 30, 2025 was $66.0 million and the Company achieved profitability with positive net income of $26.0 million for the third quarter.
- From approval on March 26, 2025 through September 30, 2025, Soleno reports:
  - 1,043 patient start forms received, including 397 in the third quarter
  - 494 unique prescribers, including 199 in the third quarter
  - 764 active patients on drug as of September 30, 2025
  - Over 132 million lives covered
- Appointed biopharma executive Mark W. Hahn to its Board of Directors and as a member of the Audit Committee.
- Raised $230 million in gross proceeds through an underwritten offering of common stock.

“Our strong third quarter results reflect growing awareness of the compelling efficacy and safety profile of VYKAT XR within the PWS community,” stated Anish Bhatnagar, M.D., Chairman and Chief Executive Officer of Soleno Therapeutics. “As the first and only FDA-approved therapy to treat the hallmark symptom of PWS – hyperphagia – in patients 4 years and older, VYKAT XR can offer a new option to this fragile and complex patient population that often suffers from a multitude of serious co-morbidities. The favorable efficacy and safety profile of VYKAT XR from our clinical program includes over 100 patients on therapy for greater than one year, and many patients who have been on continuous therapy for greater than six years. We believe VYKAT XR has the potential to become a foundational therapy for patients with hyperphagia associated with PWS, and we are working tirelessly to make it as broadly accessible as possible.”

Third Quarter Ended September 30, 2025 Financial Results

Soleno generated $43.5 million of cash from its operating activities during the three months ended September 30, 2025, and had $556.1 million of cash, cash equivalents and marketable securities as of the end of the quarter. Cash as of the end of the third quarter includes $230 million of gross proceeds that the company raised in July through an underwritten offering of common stock.

Product revenue, net, was $66.0 million for the three months ended September 30, 2025. VYKAT XR had not been approved or commercially launched in the three months ended September 30, 2024, and accordingly, generated no revenue during this period. Third quarter 2025 product revenue increased more than 100% sequentially from $32.7 million for the three months ended June 30, 2025.

Cost of goods sold was $1.1 million for the three months ended September 30, 2025 due to sales of VYKAT XR, compared to zero for the three months ended September 30, 2024. Prior to receiving FDA approval, costs associated with the manufacturing of VYKAT XR were expensed as research and development expense. As such, a portion of the cost of inventory sold during the period was expensed prior to FDA approval.

Research and development expense was $8.4 million, which includes $2.2 million of non-cash stock-based compensation, for the three months ended September 30, 2025, compared to $30.1 million, which includes $18.5 million of non-cash stock-based compensation, in the same period of 2024. Costs in support of the Company’s June 2024 New Drug Application (NDA) submission and second quarter 2025 Marketing Authorization Application (MAA), supply chain activities, and clinical activities decreased $3.5 million, $0.8 million, and $0.5 million, respectively, between comparable periods. The cadence of Soleno’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 the submission of its regulatory filings and activities for commercial launch.

Selling, general and administrative expense was $33.8 million, which includes $7.8 million of non-cash stock-based compensation, for the three months ended September 30, 2025, compared to $49.2 million, which includes $38.1 million of non-cash stock-based compensation, in the same period of 2024. Personnel and associated costs increased $6.4 million as Soleno hired additional employees for commercial launch and in support of its increased business activities. New program costs associated with commercial launch, including disease state education, analytics, other marketing programs, medical affairs activities and patient advocacy activities increased by $8.6 million. Soleno expects selling, general and administrative expenses to continue to increase following commercialization of VYKAT XR.

Soleno is obligated to make cash payments up to a maximum of $21.2 million to certain former stockholders of Essentialis upon the achievement of certain future commercial milestones associated with the sales of VYKAT XR in accordance with the terms of its 2017 merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by Soleno upon achieving the two commercial sales milestones of

$100 million and $200 million in cumulative revenue was estimated to be $19.5 million as of September 30, 2025, a $0.6 million increase from the estimate as of June 30, 2025, primarily due to increasing sales of VYKAT XR.

Other income (expense), net was approximately $3.9 million in the three months ended September 30, 2025, compared to approximately $3.6 million during the three months ended September 30, 2024.

Net income was approximately $26.0 million, or $0.47 per diluted share, for the three months ended September 30, 2025, compared to a net loss of $(76.6) million, or $(1.83) per 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 third quarter 2025 financial and operating results and provide an update on the U.S. launch of VYKAT XR today, November 4, 2025, at 4:30pm ET. Details can be found below:

Conference call details:	Toll-free: 800-717-1738 International: 646-307-1865 Conference ID: 48794
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. 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.

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

	September 30, 2025	December 31, 2024

Assets	**(unaudited)**	
Current assets		
Cash and cash equivalents	$ 246,662	$ 87,928
Marketable securities	252,272	203,509
Accounts receivable, net	25,506	-
Inventory, net	6,674	-
Prepaid expenses and other current assets	3,739	2,452
Total current assets	534,853	293,889
Long-term assets		
Property and equipment, net	150	186
Operating lease right-of-use assets	2,314	2,798
Intangible assets, net	5,347	6,805
Long-term marketable securities	57,148	27,211
Other long-term assets	83	83
Total assets	$ 599,895	$ 330,972
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,145	$ 8,882
Accrued compensation	7,248	4,776
Operating lease liabilities	697	526
Other current liabilities	17,163	4,563
Total current liabilities	33,253	18,747
Long-term liabilities		
Contingent liability for Essentialis purchase price	19,473	14,791
Long-term debt, net	49,854	49,828
Long-term lease liabilities	2,112	2,472
Other long-term liabilities	398	21
Total liabilities	105,090	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, 53,703,675 and 45,703,811 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	54	46
Additional paid-in-capital	969,119	696,966
Accumulated other comprehensive income	360	361
Accumulated deficit	(474,728)	(452,260)
Total stockholders' equity	494,805	245,113
Total liabilities and stockholders' equity	$ 599,895	$ 330,972

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Product revenue, net	$ 66,018	$ —	$ 98,675	$ —
Operating expenses				
Cost of goods sold	1,141	—	1,837	—
Research and development	8,405	30,138	31,069	57,082
Selling, general and administrative	33,753	49,197	91,250	68,558
Change in fair value of contingent consideration	614	877	4,682	2,915
Total operating expenses	43,913	80,212	128,838	128,555
Operating income (loss)	22,105	(80,212)	(30,163)	(128,555)
Other income (expense), net				
Interest income, net	5,298	3,596	11,822	8,687
Interest expense	(1,390)	-	(4,127)	-
Total other income (expense), net	3,908	3,596	7,695	8,687
Net income (loss)	$ 26,013	$ (76,616)	$ (22,468)	$ (119,868)
Other comprehensive income (loss)				
Net unrealized gain (loss) on marketable securities	261	1,049	(31)	898
Foreign currency translation adjustment	14	(1)	30	(3)

Total comprehensive income (loss)	$ 26,288	$ (75,568)	$ (22,469)	$ (118,973)
Net income (loss) per share - basic	$ 0.49	$ (1.83)	$ (0.45)	$ (3.08)
Net income (loss) per share - diluted	$ 0.47	$ (1.83)	$ (0.45)	$ (3.08)
Weighted-average common shares outstanding - basic	53,328,094	41,879,025	50,022,910	38,917,169
Weighted-average common shares outstanding - diluted	54,921,916	41,879,025	50,022,910	38,917,169

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Research and development	$ 2,219	$ 18,516	$ 8,901	$ 23,682
Selling, general and administrative	7,779	38,082	25,474	46,521
Total	$ 9,998	$ 56,598	$ 34,375	$ 70,203

Source: Soleno Therapeutics