



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

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REDWOOD CITY, Calif., Aug. 06, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Solenio) (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 second quarter ended June 30, 2025.

Second Quarter 2025 and Recent Corporate Highlights

- Announced launch of VYKAT XR and commencement of patient treatments on April 14, 2025.
- From approval on March 26, 2025 through June 30, 2025, Soleno reports:
 - 646 patient start forms received
 - 295 unique prescribers of VYKAT XR
 - Over 100 million lives covered
- Announced submission and validation of 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.
- Subsequent to the end of the second quarter, raised \$230 million in gross proceeds through an underwritten offering of common stock.
- Continued to raise awareness of VYKAT XR's efficacy and safety profile with data presentations at leading medical meetings, including:
 - The Annual Meeting of the Endocrine Society (ENDO 2025), July 12-15, 2025, in San Francisco, CA
 - The 2025 United in Hope: International Prader-Willi Syndrome Conference, June 24-28, 2025, in Phoenix, AZ
 - The Pediatric Endocrine Society (PES) Meeting 2025, May 15-18, in National Harbor, MD
 - The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Meeting 2025, May 13-16, in Montreal, Canada
 - The Joint Congress of European Society for Pediatric Endocrinology (ESPE) and the European Society of Endocrinology (ESE) Meeting 2025, May 10-13, 2025, in Copenhagen, Denmark

"Our commercial launch of VYKAT XR following the FDA approval in March was a truly transformative milestone for our company, and more importantly, for individuals with PWS and their physicians and caregivers," stated Anish Bhatnagar, M.D., Chairman and Chief Executive Officer of Soleno Therapeutics. "We are pleased with the initial reception that we are seeing for VYKAT XR, reflecting its position as the very first FDA-approved therapy and the unmet need to treat the hallmark symptom of PWS: hyperphagia. I am very optimistic about our current trajectory and believe that we are well-positioned to address the needs of the PWS community while in parallel creating significant and long-lasting value for our company and our shareholders."

Financial Results

Solenio announced FDA approval of VYKAT XR on March 26, 2025 and commercial availability in the U.S. on April 14, 2025.

Second Quarter Ended June 30, 2025 Financial Results

Solenio used \$12.6 million of cash in its operating activities during the three months ended June 30, 2025, and had \$293.8 million of cash, cash equivalents and marketable securities as of the end of the quarter. Cash as of the end of the second quarter excludes \$230 million of gross proceeds that the company raised in July through an underwritten offering of common stock.

Product revenue, net was \$32.7 million for the three months ended June 30, 2025. VYKAT XR had not been approved or commercially launched in the three months ended June 30, 2024, and accordingly, generated no revenue during this period.

Cost of goods sold was \$0.7 million for the three months ended June 30, 2025 due to sales of VYKAT XR, compared to zero for the three months ended June 30, 2024. Prior to receiving FDA approval for VYKAT XR in March 2025, 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 \$9.1 million, which includes \$2.4 million of non-cash stock-based compensation, for the three months ended June 30, 2025, compared to \$12.3 million, which includes \$2.7 million of non-cash stock-based compensation, in the same period of 2024. Costs in support of our June 2024 New Drug Application (NDA) submission, supply chain activities, and clinical activities decreased \$2.6 million, \$0.3 million, and \$0.5 million, respectively, between comparable periods. Soleno incurred \$0.6 million in the three months ended, June 30, 2025 towards its Marketing Authorization Application (MAA) submission in Europe, which was submitted in the second quarter of 2025. 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 \$28.2 million, which includes \$7.3 million of non-cash stock-based compensation, for the three months ended June 30, 2025, compared to \$10.9 million, which includes \$4.5 million of non-cash stock-based compensation, in the same period of 2024. Personnel and associated costs increased \$7.6 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 \$6.8 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 the former Essentialis stockholders 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 achieving two commercial sales milestones of \$100 million and \$200 million in cumulative revenue in future years was estimated to be \$18.9 million as of June 30, 2025, a \$1.1 million increase from the estimate as of March 31, 2025, primarily due to the approval of the NDA for VYKAT XR by the FDA in March 2025 and recording product revenue from sales of VYKAT XR subsequent to the approval. During the three months ended June 30, 2024, the estimate increased by \$1.6 million from the \$12.0 million estimate as of March 31, 2024.

Other income (expense), net was approximately \$1.8 million in the three months ended June 30, 2025, compared to approximately \$3.0 million during the three months ended June 30, 2024. The decrease was primarily due to interest expense associated with the long-term debt, partially offset by an increase in interest income driven by higher cash and cash equivalents and marketable securities during the three months ended June 30, 2025, compared to the three months ended June 30, 2024.

Net loss was approximately \$(4.7) million, or \$(0.09) per basic and diluted share, for the three months ended June 30, 2025, and \$(21.9) million, or \$(0.57) 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 second quarter 2025 financial and operating results and provide an update on the U.S. launch of VYKAT XR today, August 6, 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: 96180

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 $\geq 10\%$ 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:
 Brian Ritchie
 LifeSci Advisors, LLC
 212-915-2578

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

	June 30, 2025	December 31, 2024
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	\$ 76,497	\$ 87,928
Marketable securities	210,344	203,509
Accounts receivable, net	24,624	-
Inventory	2,355	-
Prepaid expenses and other current assets	2,969	2,452
Total current assets	316,789	293,889
Long-term assets		
Property and equipment, net	166	186
Operating lease right-of-use assets	2,434	2,798
Intangible assets, net	5,832	6,805
Long-term marketable securities	7,002	27,211
Other long-term assets	83	83
Total assets	\$ 332,306	\$ 330,972
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	\$ 6,216	\$ 8,882
Accrued compensation	6,267	4,776
Accrued clinical trial site costs	1,863	1,826
Operating lease liabilities	676	526
Accrued interest payable	409	-
Other current liabilities	5,512	2,737
Total current liabilities	20,943	18,747
Long-term liabilities		
Contingent liability for Essentialis purchase price	18,859	14,791
Long-term debt, net	49,845	49,828
Long-term lease liabilities	2,248	2,472
Other long-term liabilities	271	21
Total liabilities	92,166	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, 50,437,066 and 45,703,811 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	50	46
Additional paid-in-capital	740,746	696,966
Accumulated other comprehensive income	85	361
Accumulated deficit	(500,741)	(452,260)
Total stockholders' equity	240,140	245,113
Total liabilities and stockholders' equity	\$ 332,306	\$ 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue				
Product revenue, net	\$ 32,657	\$ —	\$ 32,657	\$ —

Total revenue	32,657	—	32,657	—
Operating expenses				
Cost of goods sold	696	—	696	—
Research and development	9,147	12,342	22,664	26,944
Selling, general and administrative	28,238	10,889	57,497	19,361
Change in fair value of contingent consideration	1,101	1,637	4,068	2,038
Total operating expenses	39,182	24,868	84,925	48,343
Operating loss	(6,525)	(24,868)	(52,268)	(48,343)
Other income (expense), net				
Interest income, net	3,193	3,014	6,524	5,091
Interest expense	(1,376)	-	(2,737)	-
Total other income (expense), net	1,817	3,014	3,787	5,091
Net loss	<u>\$ (4,708)</u>	<u>\$ (21,854)</u>	<u>\$ (48,481)</u>	<u>\$ (43,252)</u>
Other comprehensive income (loss)				
Net unrealized loss on marketable securities	(153)	(46)	(292)	(151)
Foreign currency translation adjustment	12	(1)	16	(2)
Total comprehensive loss	<u>\$ (4,849)</u>	<u>\$ (21,901)</u>	<u>\$ (48,757)</u>	<u>\$ (43,405)</u>
Net loss per common share, basic and diluted	<u>\$ (0.09)</u>	<u>\$ (0.57)</u>	<u>\$ (1.00)</u>	<u>\$ (1.16)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>50,483,281</u>	<u>38,631,565</u>	<u>48,342,928</u>	<u>37,419,968</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	\$ 2,368	\$ 2,705	\$ 6,682	\$ 5,166
Selling, general and administrative	7,330	4,455	17,695	8,439
Total	<u>\$ 9,698</u>	<u>\$ 7,160</u>	<u>\$ 24,377</u>	<u>\$ 13,605</u>



Source: Soleno Therapeutics