Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2024 Financial Results

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REDWOOD CITY, Calif., Feb. 27, 2025 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided a corporate update, and reported financial results for the fourth quarter and full-year ended December 31, 2024.

Full Year 2024 and Recent Corporate Highlights

Regulatory

- New Drug Application (NDA) for diazoxide choline extended-release tablets (DCCR) for the treatment of Prader-Willi syndrome (PWS) accepted by the U.S. Food and Drug Administration (FDA) and granted Priority Review in August 2024. The FDA extended the review period and assigned an updated Prescription Drug User Fee Act (PDUFA) target action date of March 27, 2025.
- Granted Breakthrough Therapy Designation by the FDA for DCCR for the treatment of adults and children ages four years and older with genetically confirmed PWS who have hyperphagia in April 2024.

Commercial Readiness

- Continued strengthening commercial organization in preparation for anticipated U.S. launch of DCCR. All leadership and majority of other positions within Commercial and Medical Affairs organizations hired, and remaining roles contingent upon PDUFA outcome. Strategic investments in key commercial and medical affairs programs, including disease state and payor education, data analytics, and supporting infrastructure well underway.

Publications and Presentations

- Data from the DCCR clinical development program, including positive results from the randomized withdrawal period of Study C602 were presented at medical meetings throughout 2024, including at the Annual Meeting of the Endocrine Society (ENDO 2024) in June 2024 and the 62nd Annual European Society for Paediatric Endocrinology (ESPE) Meeting in November 2024.
- Published peer-reviewed paper featuring the comparison of results from the Company's Phase 3 placebo-controlled study (C601) and open-label extension study (C602) evaluating DCCR in patients with PWS to data from the PATH for PWS (PATH) natural history study in the *Journal of Neurodevelopmental Disorders*. The article, entitled, *Behavioral Changes in Patients with Prader-Willi Syndrome Receiving Diazoxide Choline Extended-Release Tablets Compared to the PATH for PWS Natural History Study*, can be found here.

Corporate

- Entered into loan and security agreement with Oxford Finance LLC and its affiliates (Oxford) for up to $200 million, including $50 million up front, in December 2024. $100 million will be available in three additional tranches, with tranches of $50 million and $25 million contingent on FDA approval of DCCR for PWS and one tranche of $25 million on certain commercial milestones. The final $50 million may be made available upon the mutual consent of Soleno and Oxford.
- Closed on approximately $158.7 million underwritten public offering of 3,450,000 shares of common stock at a public offering price of $46.00 per share, which includes the exercise in full by the underwriters of their overallotment option to purchase additional shares, in May 2024.
- Appointed Dawn Carter Bir, a seasoned biotechnology executive with over 30 years of industry executive leadership and strategic experience, to Soleno's Board of Directors. In addition, current Board member Matthew Pauls assumed the role of Lead Independent Director.

"Soleno is entering 2025 with strong momentum. As we await potential approval of DCCR for PWS, our team is working diligently to ensure we are ready to bring this important therapy to patients as expeditiously as possible," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We continue to work with the FDA as their review progresses. Our extensive commercial preparations, supported by a strong balance sheet, will enable a successful launch of DCCR, if approved, and ultimately allow us to make a meaningful difference in the lives of those with PWS."

Fourth Quarter and Full Year Ended December 31, 2024 Financial Results

Soleno used $69.1 million of cash in its operating activities during the full year ended December 31, 2024, and had $318.6 million of cash, cash equivalents and marketable securities as of December 31, 2024.

Research and development expense was $21.5 million, which includes $10.1 million of non-cash stock-based compensation, for the three months ended December 31, 2024, compared to $8.7 million, which includes $0.8 million of non-cash stock-based compensation in the same period of 2023.

For the year ended December 31, 2024, research and development expense was $78.6 million, which includes $33.7 million of non-cash stock-based compensation, compared to $25.2 million, including $2.4 million non-cash stock-based compensation in the same period of 2023.

For the year, personnel and associated headcount costs increased $6.4 million as the Company hired additional employees in support of its research and development activities and increased potential commercialization activities. Consulting costs in support of its NDA submission and preparation for a submission to the European Medicines Agency increased $9.0 million, and it invested an additional $6.5 million in supply chain and related activities in preparation for commercial launch. The cadence of research and development expenditures will fluctuate depending upon the state of the Company's clinical programs, the timing of manufacturing and other projects necessary to support the submission of Soleno's NDA and the preparation for commercial launch. The $31.3 million of additional non-cash stock-based compensation being recognized in the year is predominantly due to performance-based RSU grants which partially vested upon the acceptance by the FDA of the NDA submission and will fully vest upon the approval by the FDA (see table below).

General and administrative expense was $37.3 million, which includes $19.7 million of non-cash stock-based compensation, for the three months ended December 31, 2024, compared to $4.1 million, which includes $1.1 million of non-cash stock-based compensation, in the same period of 2023. For the year ended December 31, 2024, general and administrative expense was $105.9 million, which includes $66.2 million of non-cash stock-based compensation, compared to $13.5 million, which includes $3.5 million of non-cash stock-based compensation, in the same period of 2023.

For the year, personnel costs, including hiring expense and other associated headcount costs, increased $10.7 million as the Company hired additional employees in preparation for commercial launch and in support of our increased business activities. New program costs associated with preparation for commercial launch, including disease state education, analytics, other marketing programs, medical affairs and patient advocacy activities, totaled $15.8 million and professional services and consulting costs increased $2.9 million. The $62.7 million of additional non-cash stock-based compensation being recognized in the year is predominantly due to performance-based RSU grants which partially vested upon acceptance by the FDA of the NDA submission and fully vest upon approval by the FDA (see table below).

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 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 achieving two commercial sales milestones of $100 million and $200 million in cumulative revenue in future years was estimated to be $14.8 million as of December 31, 2024, a $3.2 million increase from the estimate as of December 31, 2023.

Total other income, net, was $3.1 million for the three months ended December 31, 2024, compared to total other income, net, of $2.6 million in the same period of 2023. For the year, total other income, net, was $11.8 million for 2024, and $2.4 million for 2023. The year over year increase was primarily due to an increase in interest income driven by higher cash and cash equivalents, and marketable securities.

Net loss was approximately $(175.9) million, or $(4.38) per basic and diluted share, for the year ended December 31, 2024, and $(39.0) million, or $(2.36) per basic and diluted share, in the same period of 2023.

About PWS
The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The defining symptom of this disorder is hyperphagia, a chronic and life-threatening feeling of intense, persistent hunger, food pre-occupation, extreme drive to food seek and consume food that severely diminish the quality of life for patients with PWS and their families. Additional characteristics of PWS include behavioral problems, cognitive disabilities, low muscle tone, short stature (when not treated with growth hormone), the accumulation of excess body fat, developmental delays, and incomplete sexual development. Hyperphagia can lead to significant morbidities (e.g., obesity, diabetes, cardiovascular disease) and mortality (e.g., stomach rupture, choking, accidental death due to food seeking behavior). In a global survey conducted by the Foundation for Prader-Willi Research, 96.5% of respondents (parent and caregivers) rated hyperphagia and 92.9% rated body composition as either the most important or a very important symptom to be relieved by a new medicine. There are currently no approved therapies to treat the hyperphagia/appetite, metabolic, cognitive function, or behavioral aspects of the disorder.

About Diazoxide Choline Extended-Release Tablets (DCCR)
DCCR is a novel, proprietary extended-release dosage form containing the crystalline salt of diazoxide and is administered once-daily. The parent molecule, diazoxide, has been used for decades in thousands of patients in a few rare diseases in neonates, infants, children and adults, but has not been approved for use in PWS. Soleno conceived of and established extensive patent protection for the therapeutic use of diazoxide, diazoxide choline and DCCR in patients with PWS. The DCCR development program is supported by data from five completed Phase 1 clinical studies in healthy volunteers and three completed Phase 2 clinical studies, one of which was in patients with PWS. In the PWS Phase 3 clinical development program, DCCR showed promise in addressing hyperphagia, the defining symptom of PWS, as well as several other symptoms such as aggressive/destructive behaviors, fat mass and other metabolic parameters. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the U.S. and E.U., and Fast Track and Breakthrough Designations in the U.S.

About Soleno Therapeutics, Inc.
Soleno is focused on the development and commercialization of novel therapeutics for the treatment of rare diseases. An NDA for its lead candidate, diazoxide choline extended-release tablets (DCCR), a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS) is currently under review by the FDA and was granted Priority Review. 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, including statements regarding the timing of any regulatory process or ultimate approvals and determining a path forward for DCCR for the treatment of PWS. 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 the risks and uncertainties associated with the FDA's review of Soleno's NDA, market conditions, as well as risks and uncertainties inherent in Soleno's business, 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)

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 87,928	$ 169,681
Marketable securities	203,509	—
Prepaid expenses and other current assets	2,452	1,677
Total current assets	293,889	171,358
Long-term assets		
Property and equipment, net	186	12
Operating lease right-of-use assets	2,798	407
Intangible assets, net	6,805	8,749
Long-term marketable securities	27,211	—
Other long-term assets	83	165
Total assets	$ 330,972	$ 180,691
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 8,882	$ 3,149
Accrued compensation	4,776	3,135
Accrued clinical trial site costs	1,826	3,393
Operating lease liabilities	526	273
Other current liabilities	2,737	1,555
Total current liabilities	18,747	11,505
Long-term liabilities		
Contingent liability for Essentialis purchase price	14,791	11,549
Long-term debt, net	49,828	—
Long-term lease liabilities	2,472	130
Other long-term liabilities	21	—
Total liabilities	85,859	23,184
Commitments and contingencies (Note 7)		
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, 45,703,811 and 31,678,159 shares issued and outstanding at December 31, 2024 and 2023, respectively	46	32
Additional paid-in-capital	696,966	433,885
Accumulated other comprehensive gain	361	—
Accumulated deficit	(452,260)	(276,410)
Total stockholders' equity	245,113	157,507
Total liabilities and stockholders' equity	$ 330,972	$ 180,691

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

	Three Months Ended December 31,		For the Years Ended December 31,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 21,486	$ 8,689	$ 78,568	$ 25,189
General and administrative	37,303	4,410	105,861	13,481
Change in fair value of contingent consideration	327	1,081	3,242	2,714)
Total operating expenses	59,116	13,910	187,671	41,384
Operating loss	(59,116)	(13,910)	(187,671)	(41,384)
Other income (expense), net				
Change in fair value of warrant liability		470	-	(182)
Interest income, net	3,365	2,144	12,052	2,578
Interest expense	(231)	-	(231)	-
Total other income (expense), net	3,134	2,614	11,821	2,396
Net loss	$ (55,982)	$ (11,296)	$ (175,850)	$ (38,988)

Other comprehensive income (loss)				
Net unrealized gain (loss) on marketable securities	(537)	-	361	-
Foreign currency translation adjustment	3	1	-	-
Total comprehensive loss	$ (56,516)	$ (11,295)	$ (175,489)	$ (38,988)
Net loss per common share, basic and diluted	$ (1.27)	$ (0.33)	$ (4.38)	$ (2.36)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	43,924,831	34,441,721	40,175,926	16,492,132

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Research and development	$ 10,061	$ 847	$ 33,743	$ 2,434
General and administrative	19,694	1,062	66,215	3,511
Total	$ 29,755	$ 1,909	$ 99,958	$ 5,945

Source: Soleno Therapeutics