Soleno Therapeutics Provides Corporate Update and Reports Second Quarter 2024 Financial Results

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REDWOOD CITY, Calif., Aug. 07, 2024 (GLOBE NEWSWIRE) -- Soleno Therapeutics, Inc. (Soleno) (NASDAQ: SLNO), a clinical-stage biopharmaceutical company developing novel therapeutics for the treatment of rare diseases, today provided a corporate update, and reported financial results for the second quarter ended June 30, 2024.

Second Quarter 2024 and Recent Corporate Highlights

- Submitted New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Diazoxide Choline Extended-Release (DCCR) for the treatment of Prader-Willi Syndrome (PWS) in individuals four years and older who have hyperphagia.
- Closed on an 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.
- 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.
- Presented data from the randomized withdrawal period of Study C602 of DCCR in PWS in an oral presentation at the Annual Meeting of the Endocrine Society (ENDO 2024), held June 1-4, 2024 in Boston, Massachusetts.
- Joined the broad-market Russell 3000® Index at the conclusion of the 2024 Russell US Indexes annual reconstitution, effective July 1, 2024.

“The second quarter of 2024 saw substantial progress for Soleno, highlighted by submission of an NDA to the FDA for DCCR. We look forward to continuing to work with the FDA,” said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. “Our launch teams are diligently preparing for a potential launch of DCCR, including development of market access strategies, sales force sizing, and identifying medical education needs. With a strong balance sheet, we are well-positioned to commercialize DCCR and deliver a much-needed new therapy to patients with PWS.”

Financial Results

Soleno’s current research and development efforts are primarily focused on advancing its lead product candidate, DCCR, for the treatment of PWS, through late-stage clinical development.

Second Quarter Ended June 30, 2024 Financial Results

As of June 30, 2024, Soleno had $294.6 million of cash, cash equivalents and marketable securities.

Research and development expense was $12.3 and $26.9 million for the three and six months ended June 30, 2024, compared to $5.1 and $10.5 million in the same periods of 2023. The increase was primarily due to increased personnel costs, expenditures in support of our NDA submission and investments in supply chain activities in preparation for commercial launch.

General and administrative expense was $10.9 and $19.4 million for the three and six months ended June 30, 2024, compared to $3.2 and $6.0 million in the same periods of 2023. The increase was primarily related to higher non-cash stock-based compensation expense (see table), higher costs due to an increase in personnel and higher professional services expenses and costs associated with preparation for commercial launch.

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 our merger agreement with Essentialis. The fair value of the liability for the contingent consideration payable by us achieving two commercial sales milestones of $100 million and $200 million in cumulative revenue in future years was estimated to be $13.6 million as of June 30, 2024, a $2.0 million increase from the estimate as of December 31, 2023. During the six months ended June 30, 2023, the estimate increased by $0.6 million from the $8.8 million estimate as of December 31, 2022.

Total other income, net, was $3.0 and $5.1 million for the three and six months ended June 30, 2024, and $0.2 and $0.3 million in the same periods of 2023. The increase was primarily due to an increase in interest income driven by higher cash and cash equivalents and marketable securities during the six months ended June 30, 2024, compared to the six months ended June 30, 2023.

Net loss was approximately $21.9 million and $43.3 million, or $0.57 and $1.16 per basic and diluted share, for the three and six months ended June 30, 2024, and $8.5 and $16.8 million, or $0.81 and $1.69 per basic and diluted share, in the same periods of 2023.

About PWS
The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births. The hallmark 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 DCCR (Diazoxide Choline) Extended-Release Tablets
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 hallmark 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. The company recently submitted an NDA to the FDA, supported by its Phase 3 development program, for its lead candidate, DCCR (diazoxide choline) extended-release tablets, a once-daily oral tablet for the treatment of Prader-Willi syndrome (PWS). 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, filing of an NDA, 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 projected timeline of our NDA submission, whether FDA will agree with our interpretation of the data or the adequacy of data to support an NDA, the FDA's review of our 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)

	June 30, 2024	December 31, 2023
Assets	**(Unaudited)**	
Current assets		
Cash and cash equivalents	$ 57,024	$ 169,681
Marketable securities	209,099	—
Prepaid expenses and other current assets	1,379	1,677
Total current assets	267,502	171,358
Long-term assets		
Property and equipment, net	19	12
Operating lease right-of-use assets	268	407
Intangible assets, net	7,777	8,749
Long-term marketable securities	28,482	-
Other long-term assets	83	165
Total assets	$ 304,131	$ 180,691
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,716	$ 3,149
Accrued compensation	2,149	3,135
Accrued clinical trial site costs	1,863	3,393
Operating lease liabilities	296	273
Other current liabilities	1,126	1,555
Total current liabilities	9,150	11,505
Long-term liabilities		
Contingent liability for Essentialis purchase price	13,587	11,549
Common stock purchase liability	637	—
Long-term lease liabilities	—	130
Total liabilities	23,374	23,184
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, 38,386,779 and 31,678,159 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	38	32

Additional paid-in-capital	600,534	433,885
Accumulated other comprehensive loss	(153)	-
Accumulated deficit	(319,662)	(276,410)
Total stockholders' equity	280,757	157,507
Total liabilities and stockholders' equity	$ 304,131	$ 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 12,342	$ 5,141	$ 26,944	$ 10,457
General and administrative	10,889	3,169	19,361	6,023
Change in fair value of contingent consideration	1,637	313	2,038	612
Total operating expenses	24,868	8,623	48,343	17,092
Operating loss	(24,868)	(8,623)	(48,343)	(17,092)
Other income, net				
Change in fair value of warrants liabilities	—	1	—	1
Interest income, net	3,014	147	5,091	260
Total other income, net	3,014	148	5,091	261
Net loss	$ (21,854)	$ (8,475)	$ (43,252)	$ (16,831)
Other comprehensive income (loss)				
Net unrealized loss on marketable securities	(46)	—	(151)	—
Foreign currency translation adjustment	(1)	(16)	(2)	—
Total comprehensive loss	$ (21,901)	$ (8,491)	$ (43,405)	$ (16,831)
Net loss per common share, basic and diluted	$ (0.57)	$ (0.81)	$ (1.16)	$ (1.69)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	38,631,565	10,423,598	37,419,968	9,938,171

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 2,705	$ 470	$ 5,166	$ 652
General and administrative	4,455	734	8,439	1,183
Total	$ 7,160	$ 1,204	$ 13,605	$ 1,835

Source: Soleno Therapeutics