UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): March 3, 2021

SOLENO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36593**	**77-0523891**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification Number)**

203 Redwood Shores Pkwy, Suite 500
Redwood City, CA 94065
(Address of principal executive offices)

(650) 213-8444
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbols	Name of each exchange on which registered
Common Stock, $0.001 par value	**SLNO**	**NASDAQ**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 2.02 Results of Operations and Financial Conditions

On March 3, 2021, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2020. The full text of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

This information is intended to be furnished under Item 2.02 and Item 9.01 of Form 8-K, "Results of Operations and Financial Condition" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Soleno Therapeutics, Inc. dated March 3, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SOLENO THERAPEUTICS, INC.

Date: March 3, 2021

By: /s/ Anish Bhatnagar
Anish Bhatnagar
Chief Executive Officer

Soleno Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2020 Financial Results

REDWOOD CITY, Calif., March 3, 2021 – 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 announced financial results for the fourth quarter and year ended December 31, 2020.

Fourth Quarter 2020 and Recent Corporate Highlights

- Announced analysis of Phase 3 DESTINY PWS (C601) study evaluating once-daily Diazoxide Choline Controlled-Release (DCCR) tablets for patients with Prader Willi Syndrome (PWS), limited to data collected through March 1, 2020, before the onset of the COVID-19 pandemic
    - Primary endpoint demonstrated a statistically significant change from baseline in hyperphagia
        - Change was measured by the total score of a Hyperphagia Questionnaire for Clinical Trials (HQ-CT, 0-36): p=0.037
    - Statistically significant improvements were noted in all key secondary endpoints
        - Clinical Global Impression of Improvement (CGI-I) at Visit 7: p=0.015
        - Change from Baseline in Body Fat Mass (DXA) at Visit 7: p=0.004
        - Caregiver Global Impression of Change (Caregiver GI-C) at Visit 7: p=0.031
    - The safety profile of DCCR remains generally consistent with the known profile of diazoxide and prior experience with DCCR, with no serious unexpected adverse events related to DCCR reported
    - Soleno continues its interactions with the FDA around this as well as other analyses of completed and ongoing studies of DCCR
- Hosted key opinion leader (KOL) webinar to discuss the treatment landscape and unmet need in PWS, impact of the COVID-19 pandemic on PWS patients and families, and an analysis of Phase 3 DESTINY PWS evaluating data generated prior to disruptions caused by the COVID-19 pandemic
- Announced collaboration agreement with Vanderbilt University to discover and develop novel ATP-dependent potassium (K_{ATP}) channel activators with the potential to treat rare diseases

"We remain focused on our goal of advancing our late-stage DCCR program in PWS," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Based on the substantial impact of the COVID-19 pandemic on PWS patients and families, we conducted further analysis of our Phase 3 DESTINY PWS study that evaluated data collected prior to the onset of the pandemic, which we highlighted at a recent KOL webinar. We observed statistically significant improvements with DCCR compared with placebo patients for the primary and all key secondary endpoints during the pre-pandemic time period. We are continuing our interactions with the regulatory authorities, including around these most recent results. In addition, we are excited about our collaboration with Vanderbilt University which has the potential to add additional clinical candidates for PWS and other rare diseases to our product pipeline."

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.

Fourth Quarter Ended December 31, 2020 Financial Results from Operations

Research and development expenses were $5.6 million for the quarter ended December 31, 2020, compared to $5.3 million in the same period of 2019. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $2.3 million for the quarter ended December 31, 2020, compared to $1.6 million in the same period of 2019. The increase was due to an increase in personnel related costs.

The fair value of contingent consideration results from Soleno's obligation to make cash payments to Essentialis stockholders upon the achievement of certain future commercial milestones associated with the sale of DCCR in accordance with the terms of the Essentialis merger agreement and is remeasured at the end of each reporting period. The value increased by $0.1 million for the quarter ended December 31, 2020 compared to a decrease in value of $0.1 million in the same period in 2019.

Total other income of $5.2 million and total other expense of ($7.9 million) for the quarter ended December 31, 2020 and the same period in 2019, respectively, consisted primarily of the change in the fair value of the liability for the company's outstanding warrants. The other income recorded in the fourth quarter of 2020 was primarily due to the 2017 PIPE warrants expiring unexercised during the quarter.

Net loss for the quarter ended December 31, 2020, was approximately $2.8 million, or $0.04 per basic and diluted share, compared to net loss of approximately $14.6 million, or $0.36 per basic and diluted share, for the quarter ended December 31, 2019.

Year Ended December 31, 2020 Financial Results from Operations

Research and development expenses were $23.2 million for the year ended December 31, 2020, compared to $16.3 million for the year ended December 31, 2019. The increase was primarily due to increased activities related to the DCCR development program.

General and administrative expense was $8.8 million for the year ended December 31, 2020, compared to $6.9 million for the year ended December 31, 2019. The increase was primarily related to increased compensation costs, costs for intellectual property, and corporate business development expenses.

The fair value of contingent consideration was estimated to be approximately $10.3 million at December 31, 2020 up $4.3 million from $5.9 million at December 31, 2019.

Total other income of $11.7 million and total other expense of ($7.3 million) in 2020 and 2019, respectively, consisted primarily of the change in the fair value of the liability for warrants of approximately $11.6 million and ($7.0 million) in 2020 and 2019, respectively.

Net loss for the year ended December 31, 2020, was approximately $24.6 million, or $0.39 per basic and diluted share, compared to a net loss of approximately $30.8 million, or $0.90 per basic and diluted share, for the year ended December 31, 2019.

As of December 31, 2020, Soleno had cash and cash equivalents of approximately $49.2 million, as compared to $20.7 million at December 31, 2019.

About PWS

The Prader-Willi Syndrome Association USA estimates that PWS occurs in one in every 15,000 live births in the U.S. The hallmark symptom of this disorder is hyperphagia, a chronic feeling of insatiable hunger that severely diminishes the quality of life for PWS patients 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., choking, stomach rupture, 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 as 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. Diazoxide choline has received Orphan Drug Designation for the treatment of PWS in the U.S. and EU, and Fast Track Designation 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’s lead candidate, Diazoxide Choline Controlled-Release (DCCR) tablets, a once-daily oral tablet for the treatment of Prader-Willi Syndrome (PWS), is currently being evaluated in a Phase III clinical development program. 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 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 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.

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)

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 49,224	$ 20,733
Prepaid expenses and other current assets	1,019	411
Total current assets	50,243	21,144
Long-term assets		
Property and equipment, net	19	22
Operating lease right-of-use assets	124	398
Finance lease right-of-use assets	15	24
Intangible assets, net	14,581	16,525
Other long-term assets	—	59
Total assets	$ 64,982	$ 38,172
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,489	$ 1,995
Accrued compensation	1,005	283
Accrued clinical trial site costs	3,789	1,999
Operating lease liabilities	139	305
Other current liabilities	196	382
Total current liabilities	8,618	4,964
Long-term liabilities		
2017 PIPE Warrant liability	—	10,822
2018 PIPE Warrant liability	539	1,354
Contingent liability for Essentialis purchase price	10,278	5,938
Other long-term liabilities	—	147
Total liabilities	19,435	23,225
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.001 par value, 250,000,000 and 100,000,000 shares authorized at December 31, 2020 and December 31, 2019, respectively, 79,615,692 and 44,658,054 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively.	80	45
Additional paid-in-capital	227,912	172,708
Accumulated deficit	(182,445)	(157,806)
Total stockholders' equity	45,547	14,947
Total liabilities and stockholders' equity	$ 64,982	$ 38,172

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

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 5,566	$ 5,272	$ 23,191	$ 16,267
General and administrative	2,251	1,608	8,758	6,930
Change in fair value of contingent consideration	140	(128)	4,340	289
Total operating expenses	7,957	6,752	36,289	23,486
Operating loss	(7,957)	(6,752)	(36,289)	(23,486)
Other (expense) income				
Change in fair value of warrants liabilities	5,105	(7,894)	11,637	(6,964)
Loss from minority interest investment	—	—	—	(478)
Interest and other income	—	21	13	154
Total other income (expense)	5,105	(7,873)	11,650	(7,288)
Net loss	$ (2,852)	$ (14,625)	$ (24,639)	$ (30,774)
Loss per common share, basic and diluted	$ (0.04)	$ (0.36)	$ (0.39)	$ (0.90)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	79,608,495	41,165,960	62,620,227	34,142,478