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): May 12, 2020

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 May 12, 2020, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 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 May 12, 2020
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: May 12, 2020

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

Soleno Therapeutics Provides Corporate Update and Reports First Quarter 2020 Financial Results

REDWOOD CITY, Calif., May 12, 2020 — 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 three months ended March 31, 2020.

First Quarter 2020 and Recent Corporate Highlights

- Completed enrollment for Phase III DESTINY PWS study evaluating once-daily Diazoxide Choline Controlled-Release (DCCR) tablets for patients with Prader Willi Syndrome (PWS) in the first quarter 2020 and reconfirming top-line data anticipated before the end of the current quarter
    - A total of 127 subjects were randomized at 29 sites in the U.S. and the UK.
    - Subjects who have completed DESTINY PWS continue to be treated in the open-label extension study (C602), the duration of which has been increased from 12 months to up to 36 months.
    - No new safety signals associated with DCCR have been identified to date and no serious, unexpected adverse events related to DCCR have been reported.
- Published paper authored by Soleno's researchers, entitled "*The Potential Role of Activating the ATP-Sensitive Potassium Channel in the Treatment of Hyperphagic Obesity,*" in the peer-reviewed journal, *Genes*
    - The article was included in the journal's special supplement on the genetics of PWS and can be accessed at: https://www.mdpi.com/2073-4425/11/4/450/htm.

"Following the completion of enrollment in our ongoing DESTINY PWS study earlier this year, we remain on track to announce top-line data during the current quarter," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "Simultaneously, we continue to build upon the scientific evidence for the potential of DCCR to safely and effectively treat PWS. As such, a paper authored by Soleno's researchers was recently published in the peer-reviewed journal, *Genes*, describing the rationale for the use of DCCR to treat hyperphagic obesity syndromes, such as 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.

First Quarter Ended March 31, 2020 Financial Results

Research and development expenses were $6.7 million for the quarter ended March 31, 2020, compared to $2.8 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 $2.0 million for the quarter ended March 31, 2020, essentially flat as compared to the same period of 2019.

The change in 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. The fair value of the liability for the contingent consideration payable by Soleno was initially established as approximately $2.6 million at the time of the merger in March 2017, and was estimated at approximately $5.1 million at December 31, 2017, and is remeasured at the end of each of our reporting periods, including quarterly and at the end of each year. The fair value was estimated to be approximately $6.5 million at March 31, 2020, resulting in an increase in expense of approximately $0.6 million from the estimate at December 31, 2019.

Total Other income was income of $3.4 million and expense of $2.1 million in 2020 and 2019, respectively, and consisted primarily of the change in the fair value of the liability for warrants of approximately an increase of $3.4 million and a decrease of $1.9 million in 2020 and 2019, respectively.

Net loss for the quarter ended March 31, 2020, was approximately $5.9 million, or a net loss of $0.13 per basic and diluted share, compared to a net loss of approximately $7.0 million, or $0.22 per basic and diluted share, for the quarter ended March 31, 2019.

As of March 31, 2020, Soleno had cash and cash equivalents of approximately $15.1 million, compared to $20.7 million at December 31, 2019.

COVID-19 Impact

In conformance with local public health orders, Soleno has instituted a work from home policy for all employees to protect their health and well-being. While there has been no meaningful impact on the anticipated timeline for the availability of top-line data from the Phase III DCCR program, there have been certain changes in the conduct of Soleno's clinical trials, depending on institution-, state- and country-specific restrictions, such as stay at home requirements. The changes align with the guidance provided by the U.S. Food and Drug Administration (FDA) and the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) regarding the conduct of clinical trials during the COVID-19 public health emergency.

About PWS

The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the U.S. have PWS. 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., stomach rupture, obesity, diabetes, cardiovascular disease) and mortality (e.g., 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 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 E.U., and Fast Track Designation in the U.S.

About DESTINY PWS

DESTINY PWS is a randomized, double-blind, placebo-controlled study of once-daily oral administration of DCCR versus placebo in 127 randomized subjects. Patients who complete DESTINY PWS have the option to enroll into an open-label extension study (C602) and continue treatment with DCCR.

For further information about DESTINY PWS (NCT03440814), please visit: www.clinicaltrials.gov.

About Diazoxide Choline Controlled-Release (DCCR) Tablet

Diazoxide Choline Controlled-Release tablet is a novel, proprietary extended-release, crystalline salt formulation of diazoxide, which 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 on the therapeutic use of diazoxide and DCCR in patients with PWS. The DCCR development program is supported by data from five completed Phase I clinical studies in healthy volunteers and three completed Phase II clinical studies, one of which was in PWS patients. In the PWS Phase II study, 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 abnormal lipid profiles.

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 the Company's expectations concerning, among other things, our ability to receive top-line data in the first half of 2020 from Phase III DESTINY PWS and the impact of the COVID-19 pandemic on our operations and clinical trial. 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:

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LifeSci Advisors, LLC
212-915-2578

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

	March 31, 2020	December 31, 2019
Assets	(Unaudited)	
Current assets		
Cash and cash equivalents	$ 15,070	$ 20,733
Prepaid expenses and other current assets	572	411
Total current assets	15,642	21,144
Long-term assets		
Property and equipment, net	19	22
Operating lease right-of-use assets	332	398
Finance lease right-of-use assets	22	24
Intangible assets, net	16,039	16,525
Other long-term assets	59	59
Total assets	$ 32,113	$ 38,172
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,480	$ 1,995
Accrued compensation	338	283
Accrued clinical trial site costs	2,846	1,999
Operating lease liabilities	315	305
Other current liabilities	308	382
Total current liabilities	7,287	4,964
Long-term liabilities		
2017 PIPE Warrant liability	7,656	10,822
2018 PIPE Warrant liability	1,107	1,354
Contingent liability for Essentialis purchase price	6,522	5,938
Other long-term liabilities	60	147
Total liabilities	22,632	23,225
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, $0.001 par value, 100,000,000 shares authorized, 44,686,811 and 44,658,054 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively.	45	45
Additional paid-in-capital	173,100	172,708
Accumulated deficit	(163,664)	(157,806)
Total stockholders' equity	9,481	14,947
Total liabilities and stockholders' equity	$ 32,113	$ 38,172

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

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 6,695	$ 2,760
General and administrative	2,003	2,012
Change in fair value of contingent consideration	584	206
Total operating expenses	9,282	4,978
Operating loss	(9,282)	(4,978)
Other income (expense)		
Change in fair value of warrants liabilities	3,413	(1,919)
Loss from minority interest investment	—	(190)
Interest income	11	57
Total other income (expense)	3,424	(2,052)
Net loss	$ (5,858)	$ (7,030)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.22)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	44,679,858	31,756,120