# 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): August 14, 2018**

# 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)** |

**1235 Radio Road, Suite 110**
**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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 August 14, 2018, Soleno Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2018. 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 August 14, 2018 |

**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: August 14, 2018

By: /s/ Jonathan Wolter
Jonathan Wolter
Chief Financial Officer

**Soleno Therapeutics Provides Corporate Update and Reports Second Quarter 2018 Financial Results**

**REDWOOD CITY, Calif., August 14, 2018** — 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 second quarter and six months ended June 30, 2018.

"Our Phase III clinical program for Diazoxide Choline Controlled-Release (DCCR) in Prader-Willi Syndrome (PWS) continues to advance according to plan," said Anish Bhatnagar, M.D., Chief Executive Officer of Soleno Therapeutics. "We enrolled the first patient in our ongoing Phase III clinical trial in the second quarter, and have activated several clinical sites across the country to advance enrollment over the next few months. Most recently, we were granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for DCCR in PWS. This significant regulatory milestone provides us with multiple benefits, including increased collaboration with the FDA."

**Recent Corporate Highlights**

- Initiated Phase III clinical trial of DCCR in PWS
    - Phase III trial is a randomized, double-blind, placebo-controlled study that will treat approximately 100 patients
- Granted Fast Track designation for DCCR for the treatment of PWS
    - Fast Track designation allows additional meetings with the FDA to discuss Soleno's development plan to ensure the appropriate data are collected and encourages frequent written communication with the FDA regarding design of clinical trials and use of biomarkers
    - If certain criteria are met, the drug will be eligible for Accelerated Approval and Priority Review and also Rolling Review, which allows Soleno to submit to the FDA sections of its New Drug Application as they are finished instead of waiting for all sections to be completed before submitting the marketing application
- Presented a corporate overview at the BIO International Convention

**Second Quarter Ended June 30, 2018 Financial Results for Continuing Operations**

As a result of the decision to sell NeoForce, partner the CoSense business and divest the Serenz business, all revenue and expenses of these businesses have been excluded from continuing operations for all periods herein and reported as discontinued operations. All assets and liabilities of these businesses have been classified as assets and liabilities held for sale on the balance sheet. All prior period information has been recast to conform to this presentation.

Research and development expense was $1.7 million for the three months ended June 30, 2018, compared to $0.8 million in the same period of 2017. The increase was primarily due to spending in preparation for the recently initiated Phase III trial of DCCR in PWS.

General and administrative expense was $1.8 million for the three months ended June 30, 2018, compared to $2.2 million in the same period of 2017. The decrease was due primarily to incurring lower professional fees in 2018 compared to those incurred in 2017 associated with the acquisition of Essentialis, and to a decrease in personnel-related expenses reflecting a reduction in full-time headcount in 2018 compared to 2017.

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 Essentialis' product 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 as approximately $5.1 million at December 31, 2017, and at $5.5 million at March 31, 2018. The fair value was estimated as approximately $5.4 million at June 30, 2018, resulting in a decrease in expense of approximately $0.1 million in the quarter ended June 30, 2018.

The loss from continuing operations for the second quarter of 2018 was $7.2 million, or ($0.36) per share.

The loss from discontinued operations for the second quarter of 2018 was $0.4 million, or ($0.02) per share.

The net loss for the second quarter of 2018 was $7.6 million, or ($0.38) per share, compared to a net loss of $4.0 million, or ($0.42) per share, for the second quarter of 2017.

**Six Months Ended June 30, 2018 Financial Results for Continuing Operations**

As a result of the decision to sell NeoForce, partner the CoSense business and divest the Serenz business, all revenue and expenses of these businesses have been excluded from continuing operations for all periods herein and reported as discontinued operations. All assets and liabilities of these businesses have been classified as assets and liabilities held for sale on the balance sheet. All prior period information has been recast to conform to this presentation.

Research and development expense was $2.9 million for the six months ended June 30, 2018, compared to $1.1 million in the same period of 2017. The increase was primarily due to spending in preparation for the recently initiated Phase III trial of DCCR in PWS.

General and administrative expense was $3.6 million for the six months ended June 30, 2018, compared to $3.2 million in the same period of 2017. The increase was primarily due to amortization of the intangible asset acquired in the Essentialis merger.

The loss from continuing operations for the six months ended June 30, 2018, was $10.5 million, or ($0.52) per share.

The loss from discontinued operations for the six months ended June 30, 2018, was $0.9 million, or ($0.05) per share.

The net loss for the six months ended June 30, 2018, was $11.4 million, or ($0.57) per share, compared to a net loss of $6.9 million, or ($0.94) per share, for the same six month period of 2017.

At June 30, 2018, Soleno had cash and cash equivalents of $12.6 million, compared to $17.1 million at December 31, 2017.

**About PWS**

The Prader-Willi Syndrome Association USA estimates that one in 12,000 to 15,000 people in the US 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.

**About Diazoxide Choline Controlled-Release 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 positive data from five completed Phase I clinical studies in various metabolic indications or 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, DCCR, a once-daily oral tablet for the treatment of 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 that are subject to many risks and uncertainties. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ability to complete the Phase III clinical development program of DCCR in PWS in 2019.

We may use terms such as “believes,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” “approximately” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained herein,

we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation. As a result of these factors, we cannot assure you that the forward-looking statements in this press release will prove to be accurate. Additional factors that could materially affect actual results can be found in Soleno's Form 10-K filed with the Securities and Exchange Commission on April 2, 2018, including under the caption titled "Risk Factors." Soleno expressly disclaims any intent or obligation to update these forward-looking statements, except as required by law.

**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)*

| Assets | June 30, 2018 (Unaudited) | December 31, 2017 |
|---|---|---|
| Current assets | | |
| Cash and cash equivalents | $ 12,593 | $ 17,100 |
| Restricted cash | — | 35 |
| Prepaid expenses and other current assets | 248 | 343 |
| Current assets held for sale | 470 | 516 |
| Total current assets | 13,311 | 17,994 |
| Long-term assets | | |
| Property and equipment, net | 13 | 23 |
| Other assets | 126 | 126 |
| Intangible assets, net | 19,441 | 20,413 |
| Long-term assets held for sale | 453 | 466 |
| Total assets | $ 33,344 | $ 39,022 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 981 | $ 633 |
| Accrued compensation and other current liabilities | 862 | 973 |
| Current liabilities held for sale | 102 | 127 |
| Total current liabilities | 1,945 | 1,733 |
| Long-term liabilities | | |
| Series A warrant liability | 1,015 | 352 |
| Series C warrant liability | 5 | 6 |
| 2017 PIPE warrant liability | 8,036 | 5,076 |
| Contingent liability for Essentialis purchase price | 5,443 | 5,082 |
| Other liabilities | 13 | 13 |
| Long-term liabilities held for sale | 1,050 | 225 |
| Total liabilities | 17,507 | 12,487 |
| Commitments and contingencies (Note 7) | | |
| Stockholders' equity | | |
| Preferred Stock, $0.001 par value, 10,000,000 shares authorized: | | |
| Series B convertible preferred stock, 13,780 are designated at June 30, 2018 and December 31, 2017; nil and 4,571 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively. Liquidation value of zero. | — | — |
| Common stock, $0.001 par value, 100,000,000 shares authorized, 21,413,867 and 19,238,972 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively. | 21 | 19 |
| Additional paid-in-capital | 141,187 | 140,495 |
| Accumulated deficit | (125,371) | (113,979) |
| Total stockholders' equity | 15,837 | 26,535 |
| Total liabilities and stockholders' equity | $ 33,344 | $ 39,022 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Operating expenses | | | | |
| Research and development | $ 1,714 | $ 773 | $ 2,894 | $ 1,100 |
| Sales and marketing | — | — | — | 27 |
| General and administrative | 1,766 | 2,195 | 3,633 | 3,214 |
| Change in fair value of contingent consideration | (67) | — | 361 | — |
| Total operating expenses | 3,413 | 2,968 | 6,888 | 4,341 |
| Operating loss | (3,413) | (2,968) | (6,888) | (4,341) |
| Other income (expense) | | | | |
| Cease-use income (expense) | 3 | — | 6 | (2) |
| Change in fair value of warrants liabilities | (3,834) | (91) | (3,622) | (160) |
| Interest and other income (expense) | 30 | 3 | 49 | (598) |
| Total other income (expense) | (3,801) | (88) | (3,567) | (760) |
| Loss from continuing operations | (7,214) | (3,056) | (10,455) | (5,101) |
| Loss from discontinued operations | (423) | (913) | (937) | (1,755) |
| Net loss | $ (7,637) | $ (3,969) | $ (11,392) | $ (6,856) |
| Loss per common share from continuing operations, basic and diluted | $ (0.36) | $ (0.32) | $ (0.52) | $ (0.70) |
| Loss per common share from discontinued operations, basic and diluted | (0.02) | (0.10) | (0.05) | (0.24) |
| Net loss per common share, basic and diluted | $ (0.38) | $ (0.42) | $ (0.57) | $ (0.94) |
| Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share | 20,345,437 | 9,516,108 | 19,940,126 | 7,315,569 |