

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2020

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-36593

SOLENO THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

77-0523891
(I.R.S. Employer
Identification No.)

203 Redwood Shores Parkway, Suite 500
Redwood City, California
(Address of principal executive offices)

94065
(Zip Code)

(650) 213-8444

(Registrant's telephone number, including area code)

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------------------|-------------------|---|
| Common Stock, \$0.001 par value | SLNO | NASDAQ |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 8, 2020, there were 44,710,790 shares of the registrant's Common Stock, par value \$0.001 per share, outstanding.

TABLE OF CONTENTS

| | Page |
|--|------|
| <u>PART I—FINANCIAL INFORMATION</u> | |
| <u>Item 1. Financial Statements</u> | 3 |
| <u>Condensed Consolidated Balance Sheets</u> | 3 |
| <u>Condensed Consolidated Statements of Operations (unaudited)</u> | 3 |
| <u>Condensed Consolidated Statements of Stockholders' Equity (unaudited)</u> | 4 |
| <u>Condensed Consolidated Statements of Cash Flows (unaudited)</u> | 5 |
| <u>Notes to Condensed Consolidated Financial Statements (unaudited)</u> | 6 |
| <u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 7 |
| <u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u> | 17 |
| <u>Item 4. Controls and Procedures</u> | 20 |
| <u>PART II—OTHER INFORMATION</u> | 20 |
| <u>Item 1. Legal Proceedings</u> | 21 |
| <u>Item 1A. Risk Factors</u> | 21 |
| <u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u> | 21 |
| <u>Item 3. Defaults Upon Senior Securities</u> | 22 |
| <u>Item 4. Mine Safety Disclosures</u> | 22 |
| <u>Item 5. Other Information</u> | 22 |
| <u>Item 6. Exhibits</u> | 22 |
| <u>EXHIBIT INDEX</u> | 22 |
| <u>SIGNATURES</u> | 23 |
| | 24 |

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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 |

See accompanying notes to condensed consolidated financial statements

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 |

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
For the Three Months Ended March 31, 2020 and 2019
(unaudited)
(In thousands except share data)

| | <u>Common Stock</u> | | <u>Additional Paid-In Capital</u> | <u>Accumulated Deficit</u> | <u>Total Stockholders' Equity</u> |
|---|---------------------|---------------|---|--------------------------------|---|
| | <u>Shares</u> | <u>Amount</u> | | | |
| Balances at January 1, 2020 | 44,658,054 | \$ 45 | \$ 172,708 | \$ (157,806) | \$ 14,947 |
| Stock-based compensation | | | 296 | | 296 |
| Issuance of restricted stock units under equity incentive plans | 28,757 | — | 96 | | 96 |
| Net loss | | | | (5,858) | (5,858) |
| Balances at March 31, 2020 | <u>44,686,811</u> | <u>\$ 45</u> | <u>\$ 173,100</u> | <u>\$ (163,664)</u> | <u>\$ 9,481</u> |

| | <u>Common Stock</u> | | <u>Additional Paid-In Capital</u> | <u>Accumulated Deficit</u> | <u>Total Stockholders' Equity</u> |
|---|---------------------|---------------|---|--------------------------------|---|
| | <u>Shares</u> | <u>Amount</u> | | | |
| Balances at January 1, 2019 | 31,755,169 | \$ 32 | \$ 157,413 | \$ (127,032) | \$ 30,413 |
| Stock-based compensation | | | 202 | | 202 |
| Issuance of restricted stock units under equity incentive plans | 21,415 | — | 46 | | 46 |
| Net loss | | | | (7,030) | (7,030) |
| Balances at March 31, 2019 | <u>31,776,584</u> | <u>\$ 32</u> | <u>\$ 157,661</u> | <u>\$ (134,062)</u> | <u>\$ 23,631</u> |

See accompanying notes to condensed consolidated financial statements

Soleno Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

| | Three Months Ended March 31, | |
|---|-------------------------------------|------------------|
| | 2020 | 2019 |
| Cash flows from operating activities: | | |
| Net loss | \$ (5,858) | \$ (7,030) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 489 | 489 |
| Noncash lease expense | 68 | 110 |
| Stock-based compensation expense | 392 | 248 |
| Change in fair value of stock warrants | (3,413) | 1,919 |
| Change in fair value of contingent consideration | 584 | 206 |
| Operating loss on minority interest investment | — | 190 |
| Change in operating assets and liabilities: | | |
| Prepaid expenses, other current assets and other assets | (161) | (74) |
| Due from related party | — | (8) |
| Accounts payable | 1,485 | 324 |
| Accrued compensation | 55 | (92) |
| Accrued clinical trial site costs | 847 | 188 |
| Operating lease liabilities | 10 | (117) |
| Other liabilities | (157) | (40) |
| Net cash used in operating activities | (5,659) | (3,687) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | — | (10) |
| Net cash used in investing activities | — | (10) |
| Cash flows from financing activities: | | |
| Principal paid on finance lease liabilities | (4) | — |
| Net cash used in financing activities | (4) | — |
| Net decrease in cash and cash equivalents | (5,663) | (3,697) |
| Cash and cash equivalents, beginning of period | 20,733 | 23,099 |
| Cash and cash equivalents, end of period | \$ 15,070 | \$ 19,402 |

See accompanying notes to condensed consolidated financial statements.

Soleno Therapeutics, Inc.
March 31, 2020
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 1. Overview

Soleno Therapeutics, Inc. (the “Company” or “Soleno”) was incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. The Company initially established its operations as Capnia, a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs. During 2017, Soleno received stockholder approval to amend its Amended and Restated Certificate of Incorporation to change its name from “Capnia, Inc.” to “Soleno Therapeutics, Inc.” and merged with Essentialis, Inc. After the merger, the Company’s primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases and the Company divested itself of its prior business efforts.

The Company’s lead candidate is Diazoxide Choline Controlled Release tablets, or DCCR, once-daily oral tablets for the treatment of Prader-Willi Syndrome, or PWS. DCCR is currently being evaluated in a Phase III clinical development program. The Phase III study (C601 or DESTINY PWS), a 3-month randomized, double-blind placebo-controlled study, completed enrollment in January 2020 with 127 patients at 29 sites in the US and UK. Patients who complete treatment in DESTINY PWS are eligible to receive DCCR for up to 36 months in C602, an open-label extension study. Top line results from DESTINY PWS are expected in 1H2020. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

Note 2. Going Concern and Management’s Plans

The Company had a net loss of \$5.9 million during the three months ended March 31, 2020 and has an accumulated deficit of \$163.7 million at March 31, 2020 resulting from having incurred losses since its inception. The Company had \$15.1 million of cash on hand at March 31, 2020 and used \$5.7 million of cash in its operating activities during the three months ended March 31, 2020. The Company has financed its operations principally through issuances of equity securities.

The accompanying condensed consolidated financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company’s ability to continue as a going concern.

The Company expects to continue incurring losses for the foreseeable future and will be required to raise additional capital to complete its clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the Company’s access to such capital resources is uncertain and is not assured. If the Company is unable to secure additional capital, it may be required to curtail its clinical trials and development of new products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. These measures could cause significant delays in the Company’s efforts to complete its clinical trials and commercialize its products, which is critical to the realization of its business plan and the future operations of the Company. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should it be unable to continue as a going concern.

Management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company’s expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company’s access to such resources is not assured. Accordingly, management believes that there is substantial doubt regarding the Company’s ability to continue operating as a going concern within one year from the date of filing these financial statements.

Note 3. Summary of Significant Accounting Policies

There have been no material changes to the significant accounting policies during the three months ended March 31, 2020 as compared to the significant accounting policies described in Note 3 of the “Notes to Consolidated Financial Statements” in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019. Below are those policies with current period updates.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared on a going concern basis in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three months ended March 31, 2020, are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2020. For further information, refer to the financial statements and footnotes included in the Company’s annual financial statements for the fiscal year ended December 31, 2019, which are included in the Company’s annual report on Form 10-K filed with the SEC on March 4, 2020.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of expenses in the financial statements and accompanying notes. Actual results could differ from those estimates. Key estimates included in the financial statements include the valuation of deferred income tax assets, the valuation of financial instruments, stock-based compensation, value and life of acquired intangibles, and the valuation of contingent liabilities. The contingent liability represents the fair value of the contingent consideration arising from the Company’s acquisition of Essentialis in 2017. As part of the purchase price, the Company is obligated to make cash earn out payments to Essentialis stockholders up to a maximum of \$30 million upon the achievement of certain commercial milestones.

Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”) or other standard setting bodies that are adopted by the Company as of the specified effective date.

Recently Adopted Accounting Standards

In August 2018, the FASB issued ASU 2018-13, “*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*”. The ASU modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The Company has adopted this ASU at the beginning of 2020. The adoption did not have a material impact on the Company’s condensed consolidated financial statements disclosures.

Recently Issued Accounting Standards

In December 2019, the FASB issued ASU 2019-12: “*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*”. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this Update are effective for public business entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company has not yet assessed the potential impact of adopting ASU 2019-12 on its condensed consolidated financial statements.

During the three months ended March 31, 2020, other than ASU 2019-12, there have been no new, or existing recently issued, accounting pronouncements that are of significance, or potential significance, that impact the Company’s condensed consolidated interim financial statements.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company’s cash, cash equivalents and accounts payable, approximate fair value due to the short-term nature of these items.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the

measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

- Level I — Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level II — Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and
- Level III — Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The following table sets forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands).

| | Fair Value Measurements at March 31, 2020 | | | |
|---|---|-------------|-------------|------------------|
| | Total | Level 1 | Level 2 | Level 3 |
| Liabilities | | | | |
| 2017 PIPE warrant liability | \$ 7,656 | \$ — | \$ — | \$ 7,656 |
| 2018 PIPE warrant liability | 1,107 | — | — | 1,107 |
| Essentialis purchase price contingency liability | 6,522 | — | — | 6,522 |
| Total common stock warrant and contingent consideration liability | <u>\$ 15,285</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 15,285</u> |

| | Fair Value Measurements at December 31, 2019 | | | |
|---|--|-------------|-------------|------------------|
| | Total | Level 1 | Level 2 | Level 3 |
| Liabilities | | | | |
| 2017 PIPE warrant liability | \$ 10,822 | \$ — | \$ — | \$ 10,822 |
| 2018 PIPE warrant liability | 1,354 | — | — | 1,354 |
| Essentialis purchase price contingency liability | 5,938 | — | — | 5,938 |
| Total common stock warrant and contingent consideration liability | <u>\$ 18,114</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 18,114</u> |

The Company's estimated fair value of the 2017 PIPE Warrants and the 2018 PIPE Warrants was calculated using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation-pricing model requires the input of highly subjective assumptions including the expected stock price volatility, the expected term, the expected dividend yield and the risk-free interest rate. The fair value of the Essentialis purchase price contingent liability is estimated using scenario-based methods based upon the Company's analysis of the likelihood of obtaining specified approvals from the Federal Drug Administration as well as reaching cumulative revenue milestones. The Level 3 estimates are based, in part, on subjective assumptions.

During the periods presented, the Company has not changed the manner in which it values liabilities that are measured at fair value using Level 3 inputs. There were no transfers between levels within the hierarchy during the periods presented.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 liabilities (dollars in thousands).

| | Series C Warrants | | 2017 PIPE Warrants | | 2018 PIPE Warrants | | Purchase Price Contingent Liability |
|---|-----------------------|-----------|-----------------------|-----------|-----------------------|-----------|---|
| | Number of Warrants | Liability | Number of Warrants | Liability | Number of Warrants | Liability | |
| Balance at December 31, 2019 | 118,083 | \$ — | 6,024,425 | \$ 10,822 | 513,617 | \$ 1,354 | \$ 5,938 |
| Expiration of Series C Warrants | (118,083) | — | — | — | — | — | — |
| Change in value of 2017 PIPE Warrants | — | — | — | (3,166) | — | — | — |
| Change in value of 2018 PIPE Warrants | — | — | — | — | — | (247) | — |
| Change in value of contingent liability | — | — | — | — | — | — | 584 |
| Balance at March 31, 2020 | — | \$ — | 6,024,425 | \$ 7,656 | 513,617 | \$ 1,107 | \$ 6,522 |

Note 5. Warrant Liabilities

The Company has issued multiple warrant series, of which the 2017 PIPE Warrants and the 2018 PIPE Warrants (the "Warrants") remain outstanding at March 31, 2020 and are considered liabilities pursuant to the guidance established by *ASC 815 Derivatives and Hedging*.

Accounting Treatment

The Company accounts for the Warrants in accordance with the guidance in *ASC 815*. As indicated below, the Company may be obligated to settle Warrants in cash. The Company classified the Warrants as long-term liabilities at their fair value and will re-measure the warrants at each balance sheet date until they are exercised or expire. Any change in the fair value is recognized as other income (expense) in the Company's condensed consolidated statements of operations.

Series C Warrants

As of March 31, 2020, the fair value of the Series C Warrants was zero as the warrants had expired. This balance is consistent with the balance as of December 31, 2019.

The Company calculated the fair value of the Series C Warrants as of December 31, 2019 using a Black-Scholes pricing model. The Black-Scholes pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The Company used the following inputs.

| | December 31, 2019 |
|--------------------------|----------------------|
| Volatility | 90% |
| Contractual term (years) | 0.17 |
| Expected dividend yield | —% |
| Risk-free rate | 1.52% |

Warrants Issued as Part of the Units in the 2017 PIPE Offering

The 2017 PIPE Warrants were issued on December 15, 2017 in the 2017 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2017 PIPE Offering, and entitle the holder of each of the 8,141,116 units to purchase 0.74 shares of the Company's common stock at an exercise price equal to \$2.00 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the 2017 PIPE Warrants and terminating at the earlier of December 15, 2020 or 30 days following positive Phase III results for the DCCR tablet in PWS.

The exercise price and number of shares of common stock issuable upon exercise of the 2017 PIPE Warrants may be adjusted in certain circumstances, including the event of a stock split, stock dividend, extraordinary dividend, or recapitalization, reorganization, merger or consolidation. However, the exercise price of the 2017 PIPE Warrants will not be reduced below \$1.72.

In the event of a change of control of the Company, the holders of unexercised warrants may present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black Scholes methodology.

As of March 31, 2020, the fair value of the 2017 PIPE Warrants was estimated at \$7.7 million. The decrease in the fair value of the liability for the 2017 PIPE Warrants of approximately \$3.2 million during the three months ended March 31, 2020 was recorded as other income (expense) in the condensed consolidated statements of operations.

The Company has calculated the fair value of the 2017 PIPE Warrants using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The following summarizes certain key assumptions used in estimating the fair values.

| | March 31, 2020 | December 31, 2019 |
|--------------------------|-------------------|----------------------|
| Volatility | 105% | 99% |
| Contractual term (years) | 0.7 | 1.0 |
| Expected dividend yield | —% | —% |
| Risk-free rate | 0.10% | 1.60% |

Warrants Issued as Part of the Units in the 2018 PIPE Offering

The 2018 PIPE Warrants were issued on December 19, 2018 in the 2018 PIPE Offering, pursuant to a Warrant Agreement with each of the investors in the 2018 PIPE Offering, and entitle the holders of each of the 10,272,375 units to purchase 0.05 shares of the Company's common stock at an exercise price equal to \$2.00 per share, subject to adjustment as discussed below, at any time commencing upon issuance of the 2018 PIPE Warrants and terminating on December 21, 2023.

The exercise price and number of shares of common stock issuable upon exercise of the 2018 PIPE Warrants may be adjusted in certain circumstances, including the event of a stock split, stock dividend, extraordinary dividend, or recapitalization, reorganization, merger or consolidation. However, the exercise price of the 2018 PIPE Warrants will not be reduced below \$2.00.

In the event of a change of control of the Company, the holders of unexercised warrants may present their unexercised warrants to the Company, or its successor, to be purchased by the Company, or its successor, in an amount equal to the per share value determined by the Black Scholes methodology.

As of March 31, 2020, the fair value of the 2018 PIPE Warrants was estimated at \$1.1 million. The approximate \$247,000 decrease in the fair value of the liability for the 2018 PIPE Warrants during the three months ended March 31, 2020 was recorded as other income (expense) in the condensed consolidated statements of operations.

The Company has calculated the fair value of the 2018 PIPE Warrants using a Monte Carlo simulation of a geometric Brownian motion model. The Monte Carlo simulation pricing model requires the input of highly subjective assumptions including the expected stock price volatility. The following summarizes certain key assumptions used in estimating the fair values.

| | March 31, 2020 | December 31, 2019 |
|--------------------------|-------------------|----------------------|
| Volatility | 105% | 99% |
| Contractual term (years) | 3.7 | 4.0 |
| Expected dividend yield | —% | —% |
| Risk-free rate | 0.33% | 1.56% |

The Monte Carlo simulation of a geometric Brownian motion model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates.

- *Volatility*: The Company calculates the estimated volatility rate based on the volatilities of common stock of comparable companies in its industry.
- *Contractual term*: The expected life of the warrants, which is based on the contractual term of the warrants.

- *Expected dividend yield:* The Company has never declared or paid any cash dividends and does not currently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.
- *Risk-free rate:* The risk-free interest rate is based on the U.S. Treasury rate for similar periods as those of expected volatility.

Note 6. Commitments and Contingencies

Facility Leases

The Company's previous operating lease for its headquarters facility office space in Redwood City, California, terminated in August 2019, along with the related subleases. One of the subleases was with Capnia, of which the Company was a joint owner until September 2019. Sublease income received from Capnia during the three months ended March 31, 2019 was approximately \$25,000.

In July 2019, the Company executed a non-cancellable lease agreement for 6,368 square feet of new space in Redwood City, California, which began in September 2019 and expires in May 2021. The lease also provides the Company with the right to use office furniture in the space and allows the purchase of this furniture at the end of the lease term for \$1. The lease agreement requires monthly lease payments of approximately \$29,000 beginning in November of 2019, with an increase to approximately \$30,000 per month in September of 2020. The Company has accounted for the new lease as an operating lease for the office space and a finance lease for the office furniture, based on their relative standalone prices.

The components of lease expense during the three months ended March 31, 2019 and 2018 were as follows (in thousands):

| | Three Months Ended March 31, | |
|-------------------------------------|---------------------------------|--------------|
| | 2020 | 2019 |
| Operating lease cost: | | |
| Operating lease cost | \$ 76 | \$ 119 |
| Sublease income | — | (65) |
| Total operating lease cost | <u>\$ 76</u> | <u>\$ 54</u> |
| Finance lease cost: | | |
| Amortization of right-of-use assets | \$ 2 | \$ — |
| Interest on lease liabilities | 1 | — |
| Total finance lease cost | <u>\$ 3</u> | <u>\$ —</u> |

Contingencies

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

Note 7. CoSense Joint Venture Agreement and Discontinued Operations

In December 2017, the Company entered into a joint venture with OptAsia Healthcare Limited, or OAHL, with respect to its CoSense product by agreeing to sell shares of Capnia, its then wholly-owned subsidiary, to OAHL. CoSense was Soleno's first Sensalyze Technology Platform product to receive 510(k) clearances from the FDA and CE Mark certification. The Company's entry into the joint venture resulted from a comprehensive review of strategic alternatives for its legacy products and product candidates following its transition to a primarily therapeutic drug product company. The terms of the Joint Venture Agreement provided that OAHL would invest up to a total of \$2.2 million in Capnia's common shares on an incremental quarterly basis commencing in December 2017. OAHL was also responsible for funding a portion of the Capnia operations. The Joint Venture Agreement provided that Capnia would issue shares of common stock to OAHL based on a negotiated price of \$1.00 per share when the cumulative investment made by OAHL equaled or exceeded \$1.2 million. For financial reporting purposes, Capnia's assets, liabilities and results of operations had historically been consolidated with those of the Company.

During October 2018, the Company and OAHL determined and agreed that the cumulative investment made by OAHL exceeded \$1.2 million during the quarter ended September 30, 2018. Accordingly, on October 16, 2018, Capnia issued 1,690,322 shares of its common stock to OAHL, representing 53% of its outstanding shares. After the share issuance the Company no longer

held a controlling interest in Capnia and resulted in the deconsolidation of Capnia’s financial statements from those of the Company. The remaining 47% investment in Capnia was classified as an equity method investment and was presented as a Minority interest investment in former subsidiary in the condensed consolidated balance sheet. The Company’s share of Capnia’s net losses during the three months ended March 31, 2019 are recorded in the condensed consolidated statements of operations in the line titled “Loss from minority interest investment”. During September 2019, the Company sold its remaining 47% investment in Capnia. Following the transaction, the Company has no interest remaining in Capnia and the previous joint venture agreement with OAHL has been terminated.

Note 8. Stockholders’ Equity

Equity Incentive Plans

The Company has adopted the 2014 Equity Incentive Plan, or the Plan. Under the Plan the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance units or performance shares to employees, directors, advisors, and consultants. Options granted under the Plan may be incentive stock options (“ISOs”) or nonqualified stock options (“NSOs”). ISOs may be granted only to Company employees, including officers and directors.

The Board of Directors has the authority to determine to whom stock options will be granted, the number of options, the term, and the exercise price. Options are to be granted at an exercise price not less than fair value. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. The vesting period is normally monthly over a period of 4 years from the vesting date. The contractual term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options. The terms and conditions governing restricted stock units is at the sole discretion of the Board. As of March 31, 2020, a total of 190,601 shares are available for future grant under the Plan.

The Company recognizes stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants. The compensation expense is allocated on a departmental basis, based on the classification of the award holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements during any of the periods presented.

Stock-based compensation expense was recognized in the condensed consolidated statements of operations as follows (in thousands).

| | Three Months Ended March 31, | |
|----------------------------|------------------------------|---------------|
| | 2020 | 2019 |
| Research and development | \$ 99 | \$ 41 |
| General and administrative | 293 | 207 |
| Total | <u>\$ 392</u> | <u>\$ 248</u> |

Stock Options

The Company granted options to purchase 464,000 of the Company’s common stock during the three months ended March 31, 2019. There were no options granted during the three months ended March 31, 2020. The fair value of each award granted during the three months ended March 31, 2019 was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions.

| | |
|-------------------------|---------|
| Expected life (years) | 6.0-6.1 |
| Risk-free interest rate | 2.6% |
| Volatility | 71% |
| Dividend rate | — % |

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. These assumptions include the following estimates:

- *Expected life:* The expected life of stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. The Company does not believe it is able to rely on historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use

in estimating the fair value-based measurement of stock options. Therefore, it has opted to use the “simplified method” for estimating the expected term of options.

- *Risk-free interest rate:* The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.
- *Volatility:* The estimated volatility rate based on the volatilities of common stock of comparable companies in the Company’s industry.
- *Dividend rate:* The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero.

The following table summarizes stock option transactions for the three months ended March 31, 2020 as issued under the 2014 Plan:

| | Number of Options Outstanding | Weighted- Average Exercise Price per Share | Weighted Average Remaining Contractual Term (in years) |
|---|-------------------------------------|--|---|
| Balance at December 31, 2019 | 2,123,117 | \$ 4.62 | 7.87 |
| Options canceled/forfeited | (38,359) | \$ 2.11 | |
| Balance at March 31, 2020 | <u>2,084,758</u> | <u>\$ 4.66</u> | <u>7.59</u> |
| Options vested at March 31, 2020 | <u>1,220,423</u> | <u>\$ 6.65</u> | <u>7.01</u> |
| Options vested and expected to vest at March 31, 2020 | <u>2,084,758</u> | <u>\$ 4.66</u> | <u>7.59</u> |

The weighted-average grant date fair value of options granted was and \$1.08 per share for the three months ended March 31, 2019. At March 31, 2020 total unrecognized employee stock-based compensation related to stock options was approximately \$919,000, which is expected to be recognized over the weighted-average remaining vesting period of 2.2 years. As of March 31, 2020, the outstanding stock options had an intrinsic value of approximately \$883,000.

Restricted Stock Units

There were 687,257 and 21,415 restricted stock units granted by the Company during the three months ended March 31, 2020 and March 31, 2019, respectively, to employees and directors. The shares granted to directors were 100% vested on the grant date and represent compensation for past board services. The shares granted to employees typically vest annually over a period of four years. The shares were valued based on the Company’s common stock price on the grant date.

The following table summarizes restricted stock unit transactions for the three months ended March 31, 2020 as issued under the Plan:

| | Number of Restricted Stock Units | Weighted- Average Grant-Date Fair Value per Share |
|----------------------------------|--|--|
| Outstanding at December 31, 2019 | - | |
| Restricted stock units granted | 687,257 | \$ 3.83 |
| Restricted stock units vested | (28,757) | \$ 3.35 |
| Outstanding at March 31, 2020 | <u>658,500</u> | <u>\$ 3.85</u> |

The weighted-average grant-date fair value of all restricted stock units granted during the three months ended March 31, 2020 and March 31, 2019 was \$3.83 and \$2.18, respectively. The fair value of all restricted stock units vested during the three months ended March 31, 2020 and March 31, 2019 was approximately \$96,000 and approximately \$46,000, respectively. At March 31, 2020 total unrecognized employee stock-based compensation related to restricted stock units was \$2.4 million, which is expected to be recognized over the weighted-average remaining vesting period of 3.7 years.

2014 Employee Stock Purchase Plan

The Company’s board of directors and stockholders have adopted the 2014 Employee Stock Purchase Plan, or the ESPP. The ESPP has become effective, and the board of directors will implement commencement of offers thereunder in its discretion. A total of

27,967 shares of the Company's common stock has been made available for sale under the ESPP. In addition, the ESPP provides for annual increases in the number of shares available for issuance under the plan on the first day of each year beginning in the year following the initial date that the board of directors authorizes commencement, equal to the least of:

- 1.0% of the outstanding shares of the Company's common stock on the first day of such year;
- 55,936 shares; or
- such amount as determined by the board of directors.

As of March 31, 2020, there were no purchases by employees under this plan.

Series D Warrants

The Company issued 270,270 Series D Warrants in October 2015, which are exercisable into 540,540 shares of the Company's common stock, with an exercise price of \$8.75 and a term of five years expiring on October 15, 2020. The Company's Series D Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. They also contain a cashless exercise feature that provides for their net share settlement at the option of the holder in the event that there is no effective registration statement covering the continuous offer and sale of the warrants and underlying shares. The Company is required to comply with certain requirements to cause or maintain the effectiveness of a registration statement for the offer and sale of these securities. The Series D Warrant agreement further provides for the payment of liquidated damages at an amount per month equal to 1% of the aggregate VWAP of the shares into which each Series D Warrant is convertible in the event that the Company is unable to maintain the effectiveness of a registration statement as described herein. The Company evaluated the registration payment arrangement stipulated in the terms of this securities agreement and determined that it is probable that the Company will maintain an effective registration statement and has therefore not allocated any portion of the proceeds to the registration payment arrangement. The Series D Warrant agreement specifically provides that under no circumstances will the Company be required to settle any Series D Warrant exercise for cash, whether by net settlement or otherwise.

Accounting Treatment

The Company accounts for the Series D Warrants in accordance with the guidance in ASC 815 *Derivatives and Hedging*. As indicated above, the Company is not required under any circumstance to settle any Series D Warrant exercise for cash. The Company has therefore classified the value of the Series D Warrants as permanent equity.

Other Common Stock Warrants

As of March 31, 2020, the Company had 102,070 common stock warrants outstanding from the 2010/2012 convertible notes, with an exercise price of \$24.35 and a term of 10 years expiring in November 2024. The Company also had 16,500 common stock warrants issued to the underwriter in the Company's IPO, with an exercise price of \$35.70 and a term of 10 years, expiring in November 2024.

Note 9. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common stock actually outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding and dilutive potential common stock that would be issued upon the exercise of common stock warrants and options. For the three months ended March 31, 2020 and 2019, the effect of issuing the potential common stock is anti-dilutive due to the net losses in those periods and the number of shares used to compute basic and diluted earnings per share are the same in each of those periods.

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares).

| | <u>As of March 31,</u> | |
|--|------------------------|------------------|
| | <u>2020</u> | <u>2019</u> |
| Warrants issued to 2010/2012 convertible note holders to purchase common stock | 102,070 | 102,070 |
| Options to purchase common stock | 2,084,758 | 2,116,107 |
| Outstanding restricted stock units | 658,500 | — |
| Warrants issued to underwriter to purchase common stock | 16,500 | 16,500 |
| Series A warrants to purchase common stock | — | 485,121 |
| Series C warrants to purchase common stock | — | 118,083 |
| Series D warrants to purchase common stock | 540,540 | 540,540 |
| 2017 PIPE warrants | 6,024,425 | 6,024,425 |
| 2018 PIPE warrants | 513,617 | 513,617 |
| Total | <u>9,940,410</u> | <u>9,916,463</u> |

Note 10. Subsequent Events

The Company has evaluated its subsequent events from March 31, 2020 through the date these condensed consolidated financial statements were issued and has determined that there are no subsequent events requiring disclosure in these condensed consolidated financial statements other than the item noted below.

PPP Term Note

On April 22, 2020, the Company entered into a \$350,000 loan with Silicon Valley Bank (“SVB”) pursuant to the Small Business Administration’s (“SBA”) Paycheck Protection Program (“the PPP”). The loan proceeds were intended to be used for payroll, rent and utilities over the eight- week period following the date of the loan. At the time the Company applied for the PPP loan, it believed in good faith that it met all of the certification requirements for a PPP loan. However, on April 23, 2020, the SBA issued additional guidance with respect to PPP loans. The Company evaluated this new guidance and concluded that currently it may not be able to meet all of the certification requirements. As such, the Company decided to return all of the funds received under the PPP loan (including interest accrued on such funds) to the SBA and on May 6, 2020 the Company instructed SVB to make repayment.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operation

The interim consolidated financial statements included in this Quarterly Report on Form 10-Q and this Management’s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2019, and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, contained in the Company’s Form 10-K for the year ended December 31, 2019. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II – Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Overview

We were incorporated in the State of Delaware on August 25, 1999, and are located in Redwood City, California. We initially established our operations as Capnia, a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs. During 2017, we received stockholder approval to amend our Amended and Restated Certificate of Incorporation to change our name from “Capnia, Inc.” to “Solen Therapeutics, Inc.” and merge with Essentialis, Inc. After the merger, our primary focus has been the development and commercialization of novel therapeutics for the treatment of rare diseases and we divested our self of our prior business efforts.

Our lead candidate is Diazoxide Choline Controlled Release tablets, or DCCR, once-daily oral tablets for the treatment of Prader-Willi Syndrome, or PWS. DCCR is currently being evaluated in a Phase III clinical development program. The Phase III study (C601 or DESTINY PWS), a 3-month randomized, double-blind placebo-controlled study, completed enrollment in January 2020 with 127 patients at 29 sites in the US and UK. Patients who complete treatment in DESTINY PWS are eligible to receive DCCR for up to 36 months in C602, an open-label extension study. Top line results from DESTINY PWS are expected in 1H2020. DCCR has orphan designation for the treatment of PWS in the United States, or U.S., as well as in the European Union, or E.U.

The spread of the COVID-19 virus during the first quarter of 2020 has caused an economic downturn on a global scale, as well as significant volatility in the financial markets. In March 2020, the World Health Organization declared the spread of the COVID-19 virus a pandemic. Due to stay at home orders both in the United States and United Kingdom, we have instituted a work from home policy for all of our employees and other service providers to protect their health and well-being. We have ensured that all of our employees have essential materials to work comfortably and efficiently from home during this time.

We have not experienced a significant financial impact directly related to the pandemic. As of March 31, 2020, we have cash and cash equivalents of \$15.1 million, however management believes that the Company does not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. Additionally, in view of the Company’s expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company’s access to such resources is not assured. We have not experienced a significant operational impact on our primary development program, DCCR for the treatment of PWS, and our ongoing clinical trial DESTINY PWS, although we cannot rule out future delays as authorities fight the spread of the virus. As of March 31, 2020, we had an accumulated deficit of \$163.7 million, primarily as a result of research and development and general and administrative expenses. We may never be successful in commercializing our novel therapeutic-lead candidate DCCR. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 3 of our most recent Form 10-K.

Results of Operations

Comparison of the three months ended March 31, 2020 and 2019

| | Three Months Ended March 31, | | Increase (decrease) | |
|--|------------------------------|----------------|---------------------|-------------|
| | 2020 | 2019 | Amount | Percentage |
| | (in thousands) | | | |
| Operating expenses | | | | |
| Research and development | \$ 6,695 | \$ 2,760 | \$ 3,935 | 143% |
| General and administrative | 2,003 | 2,012 | (9) | 0% |
| Change in fair value of contingent consideration | 584 | 206 | 378 | 183% |
| Total operating expenses | 9,282 | 4,978 | 4,304 | 86% |
| Operating loss | (9,282) | (4,978) | (4,304) | 86% |
| Other income (expense) | | | | |
| Change in fair value of warrants liabilities | 3,413 | (1,919) | 5,332 | 278% |
| Loss from minority interest investment | — | (190) | 190 | 100% |
| Interest income | 11 | 57 | (46) | 81% |
| Total other income (expense) | 3,424 | (2,052) | 5,476 | 267% |
| Net loss | \$ (5,858) | \$ (7,030) | \$ 1,172 | 17% |

Revenue

We have yet not commenced commercialization of DCCR, our current sole product, and accordingly, through March 31, 2020, have generated no revenue from operations.

Research and development expense

Research and development expense of \$6.7 million for the three months ended March 31, 2020 increased by \$3.9 million over the three months ended March 31, 2019. In January 2020 we announced the completion of target enrollment in DESTINY III trial. As of March 31, 2020, we had 29 clinical trial sites initiated compared to 15 as of March 31, 2019. As a result, we have incurred increased clinical site costs, consulting costs and lab costs. In addition, we are increasing our investment in clinical manufacturing costs to supply DCCR to the patients in the trial and to prepare for the next phase in the regulatory approval process.

General and administrative expense

General and administrative expense of \$2.0 million for the three months ended March 31, 2020 was generally consistent with the expense during the three months ended March 31, 2019.

Change in fair value of contingent consideration

We are obligated to make cash payments of up to a maximum of \$30 million 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 us achieving the commercial sales milestones of \$100 million and \$200 million was estimated to be \$6.5 million as of March 31, 2020, an approximate \$584,000 increase from the estimate as of December 31, 2019. During the three months ended March 31, 2019 the estimate increased approximately \$206,000 from the liability of \$5.6 million estimated at December 31, 2018.

Other income (expense)

We had other income of \$3.4 million in the three months ended March 31, 2020, compared to other expense of \$1.9 million during the three months ended March 31, 2019. The change of \$5.5 million was primarily due to a \$3.4 million decrease in the fair value of our outstanding warrants during the three months ended March 31, 2020 compared to an increase of \$1.9 million during the three months ended March 31, 2019. In addition, during the three months ended March 31, 2019 we recorded an approximate \$190,000 loss from our minority interest investment in Capnia, our former subsidiary. These increases were slightly offset by approximately \$46,000 less of interest income recorded during the three months ended March 31, 2020 compared to March 31, 2019.

Liquidity and Capital Resources

We had a net loss of \$5.9 million during the three months ended March 31, 2020 and an accumulated deficit of \$163.7 million at March 31, 2020 as a result of having incurred losses since our inception. We had \$8.4 million of working capital at March 31, 2020 and used \$5.7 million of cash in operating activities during the three months ended March 31, 2020. We have financed our operations principally through issuances of equity securities.

We expect to continue incurring losses for the foreseeable future and will be required to raise additional capital to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible public or private equity offerings, debt financings, corporate collaborations or other means, but the access to such capital resources is uncertain and is not assured. If we are unable to secure additional capital, we may be required to curtail our clinical trials and development of new products and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our efforts to complete clinical trials and commercialize our products, which is critical to the realization of our business plan and our future operations. These matters raise substantial doubt about our ability to continue as a going concern within one year from the date of filing this quarterly report.

The accompanying condensed consolidated financial statements have been prepared under the assumption we will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

| | Three Months Ended March 31, | |
|---|------------------------------|-------------------|
| | 2020 | 2019 |
| | (in thousands) | |
| Net cash used in operating activities | \$ (5,659) | \$ (3,687) |
| Net cash used in investing activities | — | (10) |
| Net cash used in financing activities | (4) | — |
| Net decrease in cash and cash equivalents | <u>\$ (5,663)</u> | <u>\$ (3,697)</u> |

Cash used in operating activities

During the three months ended March 31, 2020, operating activities used net cash of \$5.7 million, which was primarily due to the net loss of \$5.9 million, adding back the non-cash credit of \$2.8 million for the decrease in the fair value of stock warrants and contingent consideration, less other non-cash expenses of approximately \$489,000 for depreciation and amortization, approximately \$392,000 of expenses paid with equity awards, and approximately \$68,000 for non-cash lease expense. Additionally, the usage of cash during the three months ended March 31, 2020 was reduced by \$2.1 million due to changes in operating assets and liabilities.

During the three months ended March 31, 2019, operating activities used net cash of \$3.7 million, which was primarily due to the loss from continuing operations of \$7.0 million, adjusted for non-cash expenses of approximately \$489,000 for depreciation and amortization, approximately \$248,000 of expenses paid with equity awards, approximately \$110,000 for non-cash lease expense, \$2.1 million for the change in fair value of stock warrants and contingent consideration, and an approximate \$190,000 operating loss on minority interest investment. Additionally, the usage of cash during the three months ended March 31, 2019 was reduced by approximately \$181,000 due to changes in operating assets and liabilities.

Cash used in investing activities

Minimal cash was used for investing activities in the three months ended March 31, 2019 for the costs of acquiring property and equipment.

Cash provided by financing activities

Minimal cash was used for financing activities in the three months ended March 31, 2020 which were related to payments made on our finance lease.

As of March 31, 2020, we had cash and cash equivalents of \$15.1 million.

We believe that we do not have sufficient capital resources to sustain operations through at least the next twelve months from the date of this filing. We expect to continue incurring losses for the foreseeable future and will be required to raise additional capital to pursue our therapeutic product development initiatives. These conditions raise substantial doubt about our ability to continue as a going concern for a period of one year from the date of this report.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have not been any material changes to our exposure to market risk during the three months ended March 31, 2020. For additional information regarding market risk, refer to the *Qualitative and Quantitative Disclosures About Market Risk* section of the Form 10-K.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in U.S. Securities and Exchange Commission, or SEC, rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the first fiscal quarter ended March 31, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, even if determined effective and no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives to prevent or detect misstatements. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 1. Legal Proceedings

We may, from time to time, be party to litigation and subject to claims that arise in the ordinary course of business. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We currently believe that these ordinary course matters will not have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

An investment in our securities has a high degree of risk. Before you invest you should carefully consider the risks and uncertainties. A description of factors that could materially affect our business, financial condition, or operating results is included under “Risk Factors” in Item 1A of Part I of our 2019 Annual Report on Form 10-K and is incorporated herein by reference. Other than as noted below, there have been no material changes to the risk factor disclosure since our 2019 Annual Report on Form 10-K. The risk factors described in our Form 10-K are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial conditions and/or operating results. If any of these risks actually occur, our business, operating results and financial condition could be harmed, and the value of our stock could go down. This means you could lose all or a part of your investment.

Public health epidemics, pandemics or outbreaks, including the recent novel coronavirus pandemic (COVID-19), could adversely affect our business.

In December 2019, the novel coronavirus (“COVID-19”) was identified in Wuhan, China. The virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States. The COVID-19 outbreak is significantly affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The full extent to which the COVID-19 outbreak will impact our business, results of operations, financial condition and cash flows will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions to contain it or treat its impact and the economic impact on local, regional, national and international markets. As the COVID-19 pandemic continues, our results of operations, financial condition and cash flows are likely to be materially adversely affected, particularly if the pandemic persists for a significant amount of time.

COVID-19 or other public health epidemics, pandemics or outbreaks, and the resulting business or economic disruptions resulting therefrom, may adversely impact our business as well as our ability to raise capital. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

While we cannot presently predict the scope and severity of any potential business shutdowns or disruptions, if we or any of our business partners, clinical trial sites, manufacturing sites and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. For example, if our Phase III clinical trial of DCCR for the treatment of PWS were to be delayed, it may have a material adverse effect on our business, results of operations, and financial condition. While there has been no meaningful impact on the timelines for top line data for the Phase III program, there have been certain changes in the conduct of our clinical trials depending on institution-, state- and country-specific restrictions such as stay at home requirements. The changes are consistent with the FDA’s and MHRA’s guidance regarding the conduct of clinical trials during the COVID-19 public health emergency. However, the changes in the way the trial is being conducted may impact the quality of the overall data being collected which may have implications for our future plans.

Several measures are currently being implemented by the United States and other governments to address the current COVID-19 pandemic and its economic impacts. At this time, it is impossible to predict the success of these measures and whether or not they will have unforeseen negative consequences for our business. In addition, our results of operations, financial position and cash flows may be adversely affected by federal or state laws, regulations, orders, or other governmental or regulatory actions addressing the current COVID-19 pandemic or the U.S. healthcare system, which, if adopted, could result in direct or indirect restrictions to our business, results of operations, financial condition and cash flow. For example, the State of California issued Executive Order N-33-20 on March 4, 2020 (the “Executive Order”), which proclaimed a State of Emergency to exist in California as a result of the threat of COVID-19. The Executive Order mandated that all our employees work from home and not come into our corporate offices in Redwood City, California. We currently do not know when and how such regulations may be eased.

The foregoing and other continued disruptions to our business as a result of COVID-19 could result in a material adverse effect on our business, results of operations, financial condition and cash flows. Furthermore, the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

| Exhibit Number | Description of Document | Incorporated by Reference from | | | |
|----------------|---|--------------------------------|-------------------------|----------------|----------------|
| | | Registrant's Form | Date Filed with the SEC | Exhibit Number | Filed Herewith |
| 31.1 | Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934, as amended | | | | X |
| 31.2 | Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934, as amended | | | | X |
| 32.1 | Certification of Principal Executive Officer Required Under Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and 18 U.S.C. §1350 | | | | X |
| 32.2 | Certification of Principal Financial and Accounting Officer Required Under Rule 13a-14(b) of the Securities and Exchange Act of 1934, as amended, and 18 U.S.C. §1350 | | | | X |
| 101.INS | XBRL Instance Document. | | | | X |
| 101.SCH | XBRL Taxonomy Extension Schema Document. | | | | X |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. | | | | X |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. | | | | X |

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, thereunto duly authorized.

Date: May 12, 2020

SOLENO THERAPEUTICS, INC.

By: /s/ James Mackaness

James Mackaness

Chief Financial Officer

**(authorized officer and principal financial and
accounting officer)**

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, Anish Bhatnagar, M.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soleno Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2020

/s/ Anish Bhatnagar

Anish Bhatnagar

President, Chief Executive Officer

(principal executive officer)

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)**

I, James Mackaness, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Soleno Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 12, 2020

/s/ James Mackaness

James Mackaness

Chief Financial Officer

(principal financial and accounting officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Soleno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter March 31, 2020, as filed with the Securities and Exchange Commission (the "Report"), Anish Bhatnagar, President, Chief Executive Officer of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2020

/s/ Anish Bhatnagar

Anish Bhatnagar

President, Chief Executive Officer

(principal executive officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Soleno Therapeutics, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended March 31, 2020, as filed with the Securities and Exchange Commission (the "Report"), James Mackaness, Chief Financial Officer of the Company does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 12, 2020

/s/ James Mackaness

James Mackaness

Chief Financial Officer

(principal financial and accounting officer)