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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 September 30, 2018

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	**77-0523891**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1235 Radio Road, Suite 110,
Redwood City, California
(Address of principal executive offices)

94065
(Zip Code)

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

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	☐	Accelerated filer	☐
Non-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 November 7, 2018, there were 21,435,241 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

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SOLENO THERAPEUTICS, INC.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

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

Assets	September 30, 2018 (Unaudited)	December 31, 2017
Current assets		
Cash and cash equivalents	$ 10,239	$ 17,100
Restricted cash	—	35
Prepaid expenses and other current assets	327	343
Current assets held for sale	847	516
Total current assets	11,413	17,994
Long-term assets		
Property and equipment, net	14	23
Other assets	—	126
Intangible assets, net	18,955	20,413
Long-term assets held for sale	453	466
Total assets	$ 30,835	$ 39,022
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,245	$ 633
Accrued compensation and other current liabilities	1,153	973
Current liabilities held for sale	110	127
Total current liabilities	2,508	1,733
Long-term liabilities		
Series A warrant liability	58	70
Series C warrant liability	2	6
2017 PIPE warrant liability	6,641	5,076
Contingent liability for Essentialis purchase price	5,671	5,082
Other liabilities	—	13
Long-term liabilities held for sale	1,750	225
Total liabilities	16,630	12,205
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 September 30, 2018 and December 31, 2017; nil and 4,571 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 21,435,241 and 19,238,972 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively.	21	19
Additional paid-in-capital	141,479	140,495
Accumulated deficit	(127,295)	(113,697)
Total stockholders' equity	14,205	26,817
Total liabilities and stockholders' equity	$ 30,835	$ 39,022

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses				
Research and development	$ 2,092	$ 946	$ 4,986	$ 2,046
Sales and marketing	—	—	—	26
General and administrative	1,558	1,685	5,191	4,900
Change in fair value of contingent consideration	228	—	589	—
Total operating expenses	3,878	2,631	10,766	6,972
Operating loss	(3,878)	(2,631)	(10,766)	(6,972)
Other income (expense)				
Cease-use income	—	5	6	3
Change in fair value of warrants liabilities	1,543	131	(1,549)	(29)
Interest and other income (expense)	26	3	75	(595)
Total other income (expense)	1,569	139	(1,468)	(621)
Loss from continuing operations	(2,309)	(2,492)	(12,234)	(7,593)
Loss from discontinued operations				
Operating loss	(427)	(1,086)	(1,364)	(2,841)
Loss on sale of assets	—	(208)	—	(208)
Total	(427)	(1,294)	(1,364)	(3,049)
Net loss	$ (2,736)	$ (3,786)	$ (13,598)	$ (10,642)
Loss per common share from continuing operations, basic and diluted	$ (0.11)	$ (0.26)	$ (0.60)	$ (0.94)
Loss per common share from discontinued operations, basic and diluted	(0.02)	(0.13)	(0.07)	(0.37)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.39)	$ (0.67)	$ (1.31)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	21,432,482	9,670,543	20,443,044	8,109,187

See accompanying notes to condensed consolidated financial statements

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

	Nine Months Ended September 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(13,598)	$(10,642)
Loss from discontinued operations	(1,364)	(3,049)
Loss from continuing operations	(12,234)	(7,593)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	1,473	1,029
Stock-based compensation expense	731	749
Board fees paid with common stock	197	195
Change in fair value of stock warrants	1,549	29
Change in fair value of contingent consideration	589	—
Non-cash expense of issuing shares to Aspire Capital	—	602
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	142	101
Accounts payable	612	232
Accrued compensation and other current liabilities	167	(74)
Other long-term liabilities	—	(20)
Net cash used in continuing operating activities	(6,774)	(4,750)
Net cash used in discontinued operating activities	(1,173)	(2,468)
Net cash used in operating activities	(7,947)	(7,218)
Cash flows from investing activities:		
Costs of Essentialis acquisition paid	—	(573)
Purchases of property and equipment	(6)	(4)
Net cash used in continuing investing activities	(6)	(577)
Net cash provided by discontinued investing activities	—	716
Net cash provided by (used) in investing activities	(6)	139
Cash flows from financing activities:		
Proceeds from issuance of common stock	—	10,000
Net cash provided by continuing financing activities	—	10,000
Net cash provided by discontinued financing activities	1,525	—
Net cash provided by financing activities	1,525	10,000
Net increase (decrease) in cash, cash equivalents and restricted cash from continuing operations	(6,780)	4,673
Net increase (decrease) in cash, cash equivalents and restricted cash from discontinued operations	352	(1,752)
Net increase (decrease) in cash, cash equivalents and restricted cash	(6,428)	2,921
Net increase in cash and cash equivalents included in current assets held for sale	(468)	—
Cash, cash equivalents and restricted cash, beginning of period	17,135	2,761
Cash, cash equivalents and restricted cash, end of period	$ 10,239	$ 5,682
Supplemental disclosures of non-cash investing and financing information		
Issuance of common stock in Essentialis acquisition	$ —	$ 18,764
Contingent consideration of Essentialis acquisition	$ —	$ 1,090

See accompanying notes to condensed consolidated financial statements.

Soleno Therapeutics, Inc.
September 30, 2018
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. On May 8, 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." The Company was initially established as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz ® Allergy Relief, or Serenz; CoSense ® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

The Company's previously wholly-owned subsidiary, NeoForce, Inc. or NFI, through which the Company acquired substantially all of the assets of an unrelated privately-held company, NeoForce Group, Inc., or NeoForce, also marketed innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets.

The Company acquired Essentialis, Inc., or Essentialis, through a merger, or the Merger, on March 7, 2017, pursuant to Merger Agreement and Plan of Merger dated December 22, 2016. Essentialis's efforts prior to the Merger were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and CNS diseases. Essentialis has tested Diazoxide Choline Controlled Release Tablet, or DCCR, as a treatment for Prader-Willi Syndrome, or PWS, a complex metabolic/neurobehavioral disorder. 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. Consummation of the Merger was subject to various closing conditions, including the Company's consummation of a financing of at least $8 million at, or substantially contemporaneous with, the closing of the Merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the Merger at a special meeting of its stockholders, which was held on March 6, 2017.

Soleno subsequently explored opportunities to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses. Accordingly, and pursuant to ASC 205-20-45-10, the assets and liabilities related to the discontinued activities of CoSense, NFI and Serenz are presented separately in the balance sheet as held for sale items, and the related operations reported herein for the CoSense, NFI and Serenz activities are reported as discontinued operations in the Statement of Operations.

The Company determined to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses in order to focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. The Company's current research and development efforts are primarily focused on advancing its lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development.

The Company sold its entire interest in NFI in a stock transaction that was completed on July 18, 2017, pursuant to a Stock Purchase Agreement dated July 18, 2017, or the NFI Purchase Agreement, entered into with Neoforce Holdings, Inc., a wholly-owned subsidiary of Flexicare Medical Limited, a privately-held United Kingdom company, for $720,000 and adjustments for inventory and the current cash balances held at NFI.

On December 4, 2017, Soleno, and its wholly-owned subsidiary, Capnia, Inc., a Delaware corporation, or Capnia, entered into a joint venture with OptAsia Healthcare Limited, or OAHL. The purpose of the joint venture is to develop and commercialize medical monitors, including CoSense, that measure end-tidal carbon monoxide in breath to assist in the detection of excessive hemolysis in neonates, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes.

The Company continues to separately evaluate alternatives for its Serenz portfolio.

Restatement of prior periods

During the preparation of the condensed consolidated financial statements as of September 30, 2018 and for the related three- and nine-months then ended, the Company determined that an error had been made in certain previously reported consolidated balance sheets and statements of operations for the valuation and resultant reporting of fair value for the Company's Series A Warrants, resulting in the value of the warrant liability being overstated. The Company has adjusted the prior period information reported in the current period. The Company determined that the error was not material to any of the previously reported periods in which the error occurred and has not amended any previously issued consolidated financial statements.

The following table (in thousands, except share and per share amounts) sets forth the effects of the restatement on affected items within the Company's previously reported Consolidated Balance Sheets and Statements of Operations for the periods ended December 31, 2017, March 31, 2018, and June 30, 2018, had the adjustments been made in the corresponding quarters.

	As of December 31, 2017			As of March 31, 2018			As of June 30, 2018			As of June 30, 2018		
	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated
Series A Warrant liability	$ 352	$ (282)	$ 70	$ 291	$ (233)	$ 58	$ 1,015	$ (812)	$ 203	$ 1,015	$ (812)	$ 203
Total liabilities	12,487	(282)	12,205	13,312	(233)	13,079	17,507	(812)	16,695	17,507	(812)	16,695
Accumulated deficit	(113,979)	282	(113,697)	(117,734)	233	(117,501)	(125,371)	812	(124,559)	(125,371)	812	(124,559)

	Year Ended December 31, 2017			Quarter Ended March 31, 2018			Quarter Ended June 30, 2018			Six Months Ended June 30, 2018		
	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated	As Previously Reported	Correction of error	As Restated
Change in fair value of warrant liabilities	(967)	282	(685)	212	(49)	163	(3,834)	579	(3,255)	(3,622)	530	(3,092)
Total other income (expense)	(1,553)	282	(1,271)	234	(49)	185	(3,801)	579	(3,222)	(3,567)	530	(3,037)
Pro Forma net loss per common share	$ (1.75)	$ (0.04)	$ (1.71)	$ (0.19)	$ -	$ (0.19)	$ (0.38)	$ 0.03	$ (0.35)	$ (0.57)	$ 0.03	$ (0.54)

Note 2. Going Concern and Management's Plans

The Company had a net loss of $13.6 million for the nine months ended September 30, 2018 and has an accumulated deficit of $127.3 million at September 30, 2018 resulting from having incurred losses since its inception. The Company has $8.9 million of working capital at September 30, 2018 and used $7.9 million of cash in its operating activities during the nine months ended September 30, 2018. The Company has financed its operations principally through issuances of equity securities.

The Company has continued to focus on expense control, including reducing its workforce, reducing outside consultants, reducing legal fees and implementing a policy providing for Board members to receive common stock in lieu of cash payments for Board service compensation.

On December 11, 2017, the Company entered into the Unit Purchase Agreement with certain stockholders, pursuant to which the Company sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of $15.0 million. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.74 shares of the Company's common stock at an exercise price of $2.00 a share, for an aggregate of 8,141,116 shares of common stock and corresponding warrants to purchase an aggregate of 6,024,425 warrant shares of common stock and underlying warrants, together referred to as the Resale Shares. The Company also granted certain registration rights to these stockholders, pursuant to which, among other things, the Company prepared and filed a registration statement with the Securities and Exchange Commission, or SEC, to register for resale the Resale Shares. The registration statement was declared effective on February 6, 2018.

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 may 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 nine months ended September 30, 2018 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, 2017. Below are those policies with current period updates.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and the applicable rules and regulations of the SEC for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The condensed consolidated balance sheet at December 31, 2017, has been derived from the audited consolidated financial statements at that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to present fairly the Company's financial position as of September 30, 2018, and results of its operations for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017. The interim results are not necessarily indicative of the results for any future interim period or for the entire year. Certain prior period amounts have been reclassified to conform to current period presentation. These classifications have no effect on the previously reported net loss or loss per share.

The accompanying condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2017, included in the Company's Annual Report on Form 10-K.

Recent Accounting Standards

Recently Adopted Accounting Standards

In November 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or the ASU 2016-18, "*Statement of Cash Flows: Restricted Cash*", which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. These standards are effective for financial statements issued for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted these standards in the first quarter of 2018 utilizing the retrospective transition method. There was no material impact on the Company's condensed consolidated financial statements resulting from the adoption of this guidance.

In May 2017, the FASB issued ASU 2017-09, "*Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*", which clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The standard is effective beginning after December 15, 2017 and early adoption is permitted. The Company adopted the standard in the first quarter of 2018. The adoption did not have a material impact on the Company's consolidated financial position and results of operations.

In March 2018, the FASB issued ASU 2018-05, "*Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*", to add various SEC paragraphs pursuant to the issuance of SEC Staff Accounting Bulletin No. 118, or SAB 118, to ASC 740 "Income Taxes". SAB 118 was issued by the SEC in December 2017 to provide immediate guidance for accounting implications of U.S. tax reform under the "*Tax Cuts and Jobs Act*", or the Tax Act, which became effective for the Company on January 1, 2018. The Company has adopted ASU 2018-09, and adoption of this ASU has no significant impact on its condensed consolidated financial statements.

Recently Issued Accounting Standards

In May 2014, the FASB issued ASU 2014-09, "*Revenue from Contracts with Customers (Topic 606)*", or ASU 2014-09. ASU 2014-09 supersedes the revenue recognition requirements in ASC Topic 605, "Revenue Recognition" and some cost guidance included in ASC Subtopic 605-35, "*Revenue Recognition - Construction-Type and Production-Type Contracts*." The core principle of ASU 2014-09 is that revenue is recognized when the transfer of control of goods or services to customers occurs in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. ASU 2014-09 requires the disclosure of sufficient information to enable readers of the Company's financial statements to understand the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. ASU 2014-09 also requires disclosure of information regarding significant judgments and changes in judgments, and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 provides two methods of retrospective application. The first method would require the Company to apply ASU 2014-09 to each prior reporting period presented. The second method would require the Company to retrospectively apply ASU 2014-09 with the cumulative effect recognized at the date of initial application. Since the Company is an emerging growth company and elected 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, this ASU 2014-09 will be effective for the Company beginning in fiscal 2019 as a result of ASU 2015-14, "*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*," which was issued by the FASB in August 2015 and extended the original effective date by one year. For other public entities the ASU is effective for annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact of adopting the available methodologies of ASU 2014-09 and 2015-14 upon its consolidated financial statements in future reporting periods. The Company is also in the process of evaluating the new standard against its existing revenue recognition accounting policies to determine the effect the guidance will have on its condensed consolidated financial statements and what changes to systems and controls may be warranted.

In February 2016, the FASB issued ASU 2016-02: "*Leases (Topic 842)*". ASU 2016-02 provides new comprehensive lease accounting guidance that supersedes existing lease guidance. Upon adoption of ASU 2016-02, the Company will be required to recognize most leases on its balance sheet at the beginning of the earliest comparative period presented with a corresponding adjustment to stockholders' equity. ASU 2016-02 requires the Company to capitalize most current operating lease obligations as right-of-use assets with a corresponding liability based on the present value of future operating lease obligations. Criteria for distinguishing leases between finance and operating are substantially similar to criteria for distinguishing between capital leases and operating leases in existing lease guidance. Lease agreements that are 12 months or less are permitted to be excluded from the balance sheet. Topic 842 includes a number of optional practical expedients that the Company may elect to apply. Expanded disclosures with additional qualitative and quantitative information will also be required. The adoption will include updates as provided under ASU 2018-01, Leases (Topic 842): Land Easement Practical Expedient for Transition to Topic 842 and ASU 2018-10, Codification Improvements to Topic 842, Leases. Topic 842 is effective for public entities with fiscal years beginning after December 15, 2018 and for all other entities for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company and elected 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, Topic 842 will be effective for the Company beginning in fiscal 2020, although early adoption is permitted. The Company is currently evaluating the potential impact of adoption of this standard on its condensed consolidated financial statements and the additional transition method under ASU 2018-11, which allows the Company to recognize Topic 842's cumulative effect within retained earnings in the period of adoption.

In July 2017, the FASB issued ASU 2017-11, "*Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features; (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*", (ASU 2017-11). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of

future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments (such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Part II of this update addresses the difficulty of navigating Topic 480, Distinguishing Liabilities from Equity, because of the existence of extensive pending content in the FASB Accounting Standards Codification. This pending content is the result of the indefinite deferral of accounting requirements about mandatorily redeemable financial instruments of certain nonpublic entities and certain mandatorily redeemable noncontrolling interests. The amendments in Part II of this update do not have an accounting effect. The amendments in Part I of ASU 2017-11 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. For all other entities, the amendments in Part I are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company and elected 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, this ASU 2016-02 will be effective for the Company beginning in fiscal 2020, although early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2017-11 on its condensed consolidated financial statements and related disclosures.

In February 2018, the FASB issued ASU 2018-02, *"Income Statement—Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income"*, or ASU 2018-02, which allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Act and requires certain disclosures about stranded tax effects. ASU 2018-02 is effective for the Company beginning in 2019, with early adoption permitted, and shall be applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the corporate income tax rate in the Tax Act is recognized. The Company is currently evaluating the potential impact of adopting this guidance on its condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "*Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting"*, to simplify the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Under the guidance, the measurement of equity-classified nonemployee awards will be fixed at the grant date, which may lower their cost and reduce volatility in the income statement. This ASU is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. As the Company is an emerging growth company and elected 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, this ASU 2018-07 will be effective for the Company beginning in fiscal 2020. Early adoption is permitted, including in an interim period. The adoption of this ASU is not expected to have a material impact on the Company's condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-08, "*Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*". The ASU clarifies and enhances current guidance about whether a transfer of assets (or the reduction, settlement, or cancellation of liabilities) is a contribution or an exchange transaction. In addition, the amendments clarify how an entity determines whether a resource provider is participating in an exchange transaction and improves the framework for determining whether a contribution is conditional or unconditional, and for distinguishing a donor-imposed condition from a donor-imposed restriction. ASU 2018-08 is effective for contributions received by public entities in annual periods beginning after June 15, 2018 and interim periods within those fiscal years. However, as the Company is an emerging growth company and elected 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, this ASU 2018-08 will be effective for contributions received beginning in fiscal 2019. The adoption of this ASU is not expected to have a material impact on the Company's condensed consolidated financial statements.

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. This ASU is effective for the Company beginning in 2020. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU No. 2018-13 and delay adoption of the additional disclosures until their effective date. The Company has not yet evaluated the impact of adoption of this ASU on its condensed consolidated financial statements disclosures.

In August 2018, SEC adopted the final rule under SEC Release No. 33-10532, "*Disclosure Update and Simplification*", amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company plans to apply the new guidance to its condensed consolidated financial statements during the first quarter of 2019.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash, restricted cash 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 September 30, 2018			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$10,109	$10,109	$ —	$ —
Liabilities				
Series A warrant liability	$ 58	$ 58	$ —	$ —
Series C warrant liability	2	—	—	2
2017 PIPE warrant liability	6,641	—	—	6,641
Essentialis purchase price contingency liability	5,671	—	—	5,671
Total common stock warrant and contingent consideration liability	$12,372	$ 58	$ —	$ 12,314

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$16,790	$16,790	$ —	$ —
Liabilities				
Series A warrant liability	$ 70	$ 70	$ —	$ —
Series C warrant liability	6	—	—	6
2017 PIPE warrant liability	5,076	—	—	5,076
Essentialis purchase price contingency liability	5,082	—	—	5,082
Total common stock warrant and contingent consideration liability	$10,234	$ 70	$ —	$ 10,164

The Series A Warrant is a registered security that trades on the open market and the fair value of the Series A Warrant liability is based on the publicly quoted trading price of the warrants which is listed on and obtained from NASDAQ. Accordingly, the fair value of Series A Warrants is a Level 1 measurement. The fair value measurement of the Series C Warrants is based on significant inputs that are unobservable and thus represent Level 3 measurements. The Company's estimated fair value of the Series C Warrant liability is calculated using the Black-Scholes valuation model, which is equivalent to fair value computed using the Binomial Lattice Option Model. Key assumptions include the volatility of the Company's stock, the expected warrant term, expected dividend yield and risk-free interest rates. The Company's estimated fair value of the 2017 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 (see Note 10). 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. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers 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 1 and Level 3 warrants, which are treated as liabilities (dollars in thousands).

	Series A Warrant		Series C Warrant		2017 PIPE Warrants		
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability	Purchase Price Contingent Liability
Balance at December 31, 2017	485,121	$ 70	118,083	$ 6	6,024,425	$ 5,076	$ 5,082
Change in value of Series A Warrants	—	(12)	—	—	—	—	—
Change in value of Series C Warrants	—	—	—	(4)	—	—	—
Change in value of 2017 PIPE Warrants	—	—	—	—	—	1,565	—
Change in value of contingent liability	—	—	—	—	—	—	589
Balance at September 30, 2018	485,121	$ 58	118,083	$ 2	6,024,425	$ 6,641	$ 5,671

Note 5. Discontinued Operations and Assets Held for Sale

(i) Assets held for sale and discontinued operations

Subsequent to the Merger with Essentialis described in Note 1, the Company explored opportunities to divest, sell or dispose of the CoSense, NFI, and Serenz businesses.

Under ASC 205-20-45-10, during the period in which a component meets the assets held for sale and discontinued operations criteria, an entity must present the assets and liabilities of the discontinued operation separately in the asset and liability sections of the balance sheet for the comparative reporting periods. The prior period balance sheet should be reclassified for the held for sale items. For income statements, the current and prior periods should report the results of operations of the component in discontinued operations when comparative income statements are presented.

The components of the Balance Sheet accounts presented as assets and liabilities held for sale follow (in thousands).

	September 30, 2018	December 31, 2017
Current assets		
Cash and cash equivalents	$ 468	$ —
Accounts receivable	4	50
Inventory	365	420
Prepaid expenses and other current assets	10	46
Total current assets held for sale	$ 847	$ 516
Long-term assets		
Property and equipment, net	$ 18	$ 20
Other intangible assets	435	446
Total long-term assets held for sale	$ 453	$ 466
Current liabilities		
Accounts payable	$ 61	$ 51
Accrued compensation and other current liabilities	49	76
Total current liabilities for sale	$ 110	$ 127
Long-term liabilities		
Other long-term liabilities	$ 1,750	$ 225
Total long-term liabilities held for sale	$ 1,750	$ 225

The components of the Statements of Operations presented as Discontinued Operations follow (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product revenue	$ 6	$ 61	$ 60	$ 702
Cost of product revenue	2	237	30	769
Gross profit (loss)	4	(176)	30	(67)
Expenses				
Research and development	306	632	1,009	1,946
Sales and marketing	1	37	25	220
General and administrative	124	204	360	600
Total expenses	431	873	1,394	2,766
Operating loss	(427)	(1,049)	(1,364)	(2,833)
Other income (expense)	—	(37)	—	(8)
Loss on sale of assets	—	(208)	—	(208)
Net loss from discontinued operations	$ (427)	$ (1,294)	$ (1,364)	$ (3,049)

Stock-based compensation expense classified in discontinued operations was $20,000 and $23,000 for the three months ended September 30, 2018 and 2017, respectively, and was $58,000 and $106,000 for the nine months ended September 30, 2018 and 2017, respectively.

(ii) NFI Sale

On September 2, 2015, the Company established NFI, a previously wholly owned subsidiary of the Company and through NFI, acquired substantially all of the assets of an unrelated privately held company, NeoForce.

On July 18, 2017, the Company completed the sale of stock of its 100% wholly-owned subsidiary, NFI, primarily related to the Company's portfolio of neonatology resuscitation business pursuant to the NFI Purchase Agreement, with NFI Holdings, a 100% owned subsidiary of Flexicare Medical Limited, a privately held United Kingdom company, for $720,000 and adjustments for inventory and the current cash balances held at NFI. The Company will also receive the total outstanding accounts receivable and inventory held by NFI at the date of sale, as it is collected or sold, respectively. The transactions contemplated by the NFI Purchase

Agreement are a continuation of a process previously disclosed by the Company of evaluating strategic alternatives and focusing on the Company's rare disease therapeutic business. The NFI Purchase Agreement includes customary terms and conditions, including an adjustment to the purchase price based on inventory and accounts receivables, and provisions that require the Company to indemnify NFI Holdings for certain losses that it incurs as a result of a breach by the Company of its representations and warranties in the NFI Purchase Agreement and certain other matters. Proceeds from the sale are payable to the Company as follows: (1) a $720,000 payment to the Company in cash on July 18, 2017, (2) the value of outstanding accounts receivable as it is collected by NFI following July 18, 2017, payable on a monthly basis, and (3) the value of inventory as it is sold following July 18, 2017, payable on a monthly basis. The NFI Purchase Agreement contains customary representations and warranties of each of the parties.

(iii) CoSense Joint Venture Agreement

In December 2017, the Company entered into a joint venture with OAHL with respect to its CoSense product by agreeing to sell common shares of Capnia, its wholly-owned subsidiary, to OAHL. CoSense was Soleno's first Sensalyze Technology Platform product to receive 510(k) clearances from the U.S. Food and Drug Administration, or FDA, and CE Mark certification. CoSense measures CO, which can be elevated due to endogenous causes such as excessive breakdown of red blood cells, or hemolysis, or exogenous causes such as CO poisoning and smoke inhalation. The first target market for CoSense is for the use of ETCO measurements to aid in detection of hemolysis in neonates, a disorder in which CO and bilirubin are produced in excess as byproducts of the breakdown of red blood cells. The Company's entry into the joint venture results 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 provide that OAHL will invest up to a total of $2.2 million for Capnia's common shares on an incremental quarterly basis commencing in December 2017. Going forward, OAHL will be responsible for funding a portion of the Capnia operations. The Joint Venture Agreement provides that Capnia will issue common shares to OAHL when the cumulative investment made by OAHL equals or exceeds $1.2 million. 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, when OAHL's investment was determined to exceed $1.2 million and as of such date reached the total value of $1,690,000. As of September 30, 2018, Capnia had issued no shares of common stock to OAHL. However, refer to Note 12 for information regarding the issuance of Capnia shares subsequent to September 30, 2018.

Note 6. Warrant Liabilities

Warrants terms

The Company has issued multiple warrant series, of which the Series A Warrants, Series C Warrants and 2017 PIPE Warrants (the "Warrants") are considered liabilities pursuant to the guidance established by *ASC 815 Derivatives and Hedging*.

The Company's Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. The Series A and Series C Warrants 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 Series A Warrants and shares underlying the Series A Warrants, or the shares underlying the Series C Warrants, respectively. 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 the shares underlying the Warrants and for the offer and sale of the Series C Warrants. The Series A and Series C Warrants contracts further provide for the payment of liquidated damages at an amount per month equal to 1% of the aggregate volume weighted average price, or VWAP, of the shares into which each Warrant is convertible into 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 these securities 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 related to the warrant financings to the registration payment arrangement. The Warrants also contain a fundamental transactions provision that permits their settlement in cash at fair value at the option of the holder upon the occurrence of a change in control. Such change in control events include tender offers or hostile takeovers, which are not within the sole control of the Company as the issuer of these warrants. Accordingly, the Warrants are considered to have a cash settlement feature that precludes their classification as equity instruments. Settlement at fair value upon the occurrence of a fundamental transaction would be computed using the Black Scholes Option Pricing Model, which approximates the binomial lattice model.

Accounting Treatment

The Company accounts for the Warrants in accordance with the guidance in *ASC 815*. As indicated above, the Company may be obligated to settle Warrants in cash in the case of a Fundamental Transaction.

The Company classified the Warrants, with a term greater than one year, 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 A Warrants

The Company has issued 489,921 Series A Warrants to purchase shares of its Common Stock at an exercise price of $32.50 per share in connection with the unit offering offered in the Company's initial public offering, or the IPO, in November 2014. The Series A Warrants are exercisable at any time prior to the expiration of the five-year term on November 12, 2019.

Upon the completion of the IPO, the Series A Warrants started trading on the NASDAQ under the symbol SLNOW. As the Series A Warrants are publicly traded, the Company uses the closing price on the measurement date to determine the fair value of the Series A Warrants.

Since their issuance, a total of 4,800 Series A Warrants have been exercised. As of September 30, 2018, the fair value of the 485,121 outstanding Series A Warrants was $58,000, which represents a decrease of $145,000 and $12,000 in fair value during the three and nine months ended September 30, 2018, respectively, both of which were recorded as other income in the condensed consolidated statements of operations.

Series C Warrants

On March 5, 2015, the Company entered into separate agreements with certain Series B Warrant holders, who agreed to exercise their Series B Warrants to purchase an aggregate of 117,902 shares of the Company's Common Stock at an exercise price of $32.50 per share, resulting in the de-recognition of $6.7 million of the previously issued Series B Warrant liability and gross proceeds to the Company of approximately $3.8 million based on the exercise price of the Series B Warrants. In connection with this exercise of the Series B Warrants, the Company issued to each investor who exercised Series B Warrants, new Series C Warrants for the number of shares of the Company's Common Stock underlying the Series B Warrants that were exercised. Each Series C Warrant is exercisable at $31.25 per share and will expire on March 5, 2020.

In April 2015, the Company issued a tender offer to the remaining holders of Series B Warrants to induce the holders to cash exercise the outstanding Series B Warrants in exchange for new Series C Warrants with an exercise price of $31.25 per share that expire on March 5, 2020. The tender offer was extended to Series B Warrant holders under a registration statement filed with the SEC on Form S-4, which was declared effective on June 25, 2015 and expired on July 24, 2015. During July 2015, certain Series B Warrant holder(s) tendered their Series B Warrants under the tender offer, which resulted in the issuance of 181 shares of the Company's Common Stock, the issuance of 181 Series C Warrants and proceeds to the Company of $5,882.

The Series C Warrants are exercisable into 118,083 shares of the Company's Common Stock. As of September 30, 2018, the fair value of the Series C Warrants was determined to be $2,000, which represents a decrease of $3,000 and $4,000 in fair value during the three and nine months ended September 30, 2018, respectively, both of which were recorded as other income in the condensed consolidated statements of operations.

The Company has calculated the fair value of the Series C Warrants 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.

	September 30, 2018	December 31, 2017
Volatility	90%	90%
Expected term (years)	1.42	2.17
Expected dividend yield	— %	— %
Risk-free rate	2.68%	1.57%

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 to purchase one share 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 in 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 September 30, 2018, the fair value of the PIPE Warrants was determined to be approximately $6.6 million, which represents a decrease of $1.4 million and an increase of $1.6 million in fair value during the three and nine months ended September 30, 2018, respectively, both of which were 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.

	September 30, 2018	December 31, 2017
Volatility	70%	67%
Expected term (years)	0.8	0.8
Expected dividend yield	— %	— %
Risk-free rate	2.59%	1.76%

Note 7. Commitments and Contingencies

Facility Leases

On July 1, 2015 the Company executed a new four-year non-cancelable operating lease agreement for 8,171 square feet of office space for its headquarters facility. The lease agreement provides for monthly lease payments of $23,300 beginning in September of 2015, with increases in the following three years. An additional 5,265 square feet of office space became part of the new lease agreement on March 1, 2016, and in December 2017 the Company subleased this additional space to a third party through the end of the lease term.

The Company also leased office space under a non-cancelable operating lease agreement that was set to expire in May 2015, and in February 2015 the Company signed an amendment to its lease agreement, extending the lease through June 2018. The amendment provided for monthly lease payments of $22,000 beginning in June 2015, with increases in the following two years. The Company subleased this facility in January 2016.

Rent expense was $78,000 and $62,000 for the three months ended September 30, 2018 and 2017, respectively, and was $246,000 and $405,000 for the nine months ended September 30, 2018 and 2017, respectively.

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 8. Stockholders’ Equity

Convertible Preferred Stock

The Company is authorized to issue 10,000,000 shares of Preferred Stock.

The Company has issued a total of 13,780 shares of Series B Convertible Preferred Stock under the Securities Purchase Agreement entered into on June 29, 2016 with Sabby Healthcare Master Fund Ltd and Sabby Volatility Warrant Fund Ltd, which are funds managed by Sabby Management, LLC, and which the Company collectively refers to as Sabby, as amended by Amendment No. 1 dated September 2016, referred to as the 2016 Sabby Purchase Agreement, with a par value of $0.001 and a stated value of $1,000 per share. The Series B Convertible Preferred Stock is convertible to Common Stock of the Company at the rate of 200 shares of Common Stock for each converted share of Series B Convertible Preferred Stock. Under the terms of the Series B Convertible Preferred Stock, in no event shall shares of Common Stock be issued to Sabby upon conversion of the Series B Convertible Preferred Stock to the extent such issuance of shares of Common Stock would result in Sabby having ownership in excess of 4.99%. The Series B Convertible Preferred Stock do not have an expiration date and are not redeemable at the option of the holders. In connection with each close of the Series B Convertible Preferred Stock, the Company was obligated to repurchase the remaining outstanding Series A Convertible Preferred Stock at the original issuance price. In addition, the exercise price of the existing Series D Warrants originally issued in conjunction with the 2015 Sabby Purchase Agreement was reduced from $12.30 to $8.75 per share on the effective date of the 2016 Sabby Purchase Agreement. Sabby converted 1,000 shares of Series B Convertible Preferred Stock into 200,000 shares of Common Stock during 2016.

During the nine months ended September 30, 2018 and 2017 Sabby converted 4,571 and 2,731 shares of Series B Convertible Preferred stock into 914,200 and 546,200 shares of Common Stock, respectively. As of September 30, 2018, there were no shares of Series B Convertible Preferred Stock outstanding.

Common Stock

On December 22, 2016, the Company entered into the Merger Agreement with Essentialis. Consummation of the Merger was subject to various closing conditions, including the Company's consummation of a financing of at least $8 million at, or substantially contemporaneous with, the closing of the Merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the Merger at a special meeting of stockholders, which the Company received on March 6, 2017.

On March 7, 2017, the Company completed the Merger with Essentialis and issued 3,783,388 shares of common stock to shareholders of Essentialis. Pursuant to the terms of the Merger Agreement, the Company held back shares of common stock as partial recourse to satisfy indemnification claims. Effective March 7, 2018, on the 1-year anniversary of the closing of the merger, the Company issued 180,667 shares for the previously held back amount. In the second quarter of 2018 there were 903,367 additional shares of common stock issued upon the achievement of a development milestone. In total, 4,867,422 shares of common stock were issued to Essentialis stockholders. Additionally, upon the achievement of certain commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Merger Agreement, the Company is obligated to make cash earnout payments of up to a maximum of $30 million to Essentialis stockholders. The merger consideration described above will be reduced by any such shares of common stock issuable, or cash earnout payments payable, to Essentialis' management carve-out plan participants and other service providers of Essentialis, in each case, in accordance with the terms of the Merger Agreement.

On January 27, 2017, the Company entered into the 2017 Aspire Purchase Agreement with Aspire Capital, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $17.0 million in value of shares of the Company's common stock over the 30-month term of the purchase agreement. Additionally, on the date of the closing of the financing, as defined in the Merger Agreement, the Company issued to Aspire Capital, and Aspire Capital purchased from the Company an aggregate of $2.0 million of the Company's common stock.

In December 2017, the Company entered into a Securities Purchase Agreement, or the Unit Purchase Agreement, with purchasers of the Company's securities pursuant to which the Company sold and issued 8,141,116 immediately separable units at a price per unit of $1.84 for aggregate gross proceeds of approximately $15.0 million. Each unit consisted of one share of the Company's common stock and a warrant to purchase 0.74 of a share of the Company's common stock at an exercise price of $2.00 per share, for an aggregate of 8,141,116 shares of common stock, and corresponding warrants, or the 2017 PIPE Warrants, to purchase 6,024,425 shares of common stock. Soleno refers to the Shares and the Warrant Shares collectively as the Resale Shares. The Company also granted certain registration rights to the investors pursuant to the Unit Purchase Agreement pursuant to which, among other things, the Company prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

Stock Incentive Plan

The Company has adopted the 1999 Incentive Stock Plan, the 2010 Equity Incentive Plan, and the 2014 Equity Incentive Plan, or the 2014 Plan, and together, the Plans. The 1999 Incentive Stock Plan expired in 2009, and the 2010 Equity Incentive Plan has been closed to new issuances. Under the 2014 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 2014 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. There have been no grants of stock appreciation rights, performance units or performance shares as of September 30, 2018. As of September 30, 2018, a total of 1,150,218 shares are available for future grant under the 2014 Plan.

The Company recognized stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants for the three months ended September 30, 2018 and 2017 of $231,000 and $226,000, respectively of which $20,000 and $23,000 was recorded in discontinued operations during the three months ended September 30, 2018 and 2017, respectively. Stock-based compensation expense related to options and restricted stock units granted to employees, directors and consultants for the nine months ended September 30, 2018 and 2017 was $789,000 and $855,000, respectively of which $58,000 and $106,000 was recorded in discontinued operations during the nine months ended September 30, 2018 and 2017, respectively. The compensation expense is allocated on a departmental basis, based on the classification of the option holder.

Stock compensation expense was allocated between departments in continuing operations as follows (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	$ 34	$ 23	$ 174	$ 70
General and administrative	177	181	557	679
Total	$ 211	$ 204	$ 731	$ 749

Stock Options

No options were granted by the Company during the three months ended September 30, 2018 and 2017. The Company granted options to purchase 736,086 and 622,755 shares of the Company's common stock during the nine months ended September 30, 2018 and 2017, respectively. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions.

	Nine Months Ended September 30,	
	2018	2017
Expected life (years)	5.5-6.02	5.5-6.08
Risk-free interest rate	2.7%-2.8%	1.9%-2.2%
Volatility	70%	61%-69%
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:

- *Expected volatility:* The estimated volatility rate based on a peer index of common stock of comparable companies in the Company's industry.
- *Expected term:* 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 has elected to use the simplified method, as the Company does not have enough historical exercise experience to provide a reasonable basis upon which to estimate the expected term and the stock option grants are considered "plain vanilla" options.
- *Risk-free 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.
- *Expected dividend yield:* 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 nine months ended September 30, 2018 as issued under the Plans:

	Number of Options Outstanding	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)
Balance at December 31, 2017	1,026,987	$ 9.99	7.94
Options granted	736,086	1.68	
Options exercised	—		
Options canceled/forfeited	(95,177)	14.63	
Balance at September 30, 2018	1,667,896	$ 6.06	8.50
Options vested at September 30, 2018	739,851	$ 10.44	7.77
Options vested and expected to vest at September 30, 2018	1,667,896	$ 6.06	8.50

The weighted-average grant date fair value of employee options granted was $1.09 and $3.05 per share for the nine months ended September 30, 2018 and 2017, respectively. At September 30, 2018, total unrecognized employee stock-based compensation was $1.4 million, which is expected to be recognized over the weighted-average remaining vesting period of 2.7 years. As of September 30, 2018, the outstanding stock options had an intrinsic value of $0.4 million.

The fair value of an equity award granted to a non-employee generally is determined in the same manner as an equity award granted to an employee. In most cases, the fair value of the equity securities granted is more reliably determinable than the fair value of the goods or services received. Stock-based compensation related to its grant of options to non-employees has not been material to date.

Restricted Stock Units

There were 99,217 restricted stock units granted by the Company during the nine months ended September 30, 2018 to employees and nonemployees. The shares were 100% vested on the grant date and were valued based on the Company's common stock price on the grant date, with $159,000 of the related stock-based compensation expense recognized at that time.

2014 Employee Stock Purchase Plan

Soleno'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 September 30, 2018, there were no purchases by employees under the ESPP.

Series D Warrants

The Company issued 256,064 Series D Warrants in October 2015, which are exercisable into 586,182 shares of the company's Common Stock, with an exercise price of $12.30 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 into 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 September 30, 2018, 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 outstanding 1,851 Common Stock warrants issued in 2009, with an exercise price of $108.00 and a term of 10 years, expiring in January 2019 and 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 and nine months ended September 30, 2018 and 2017, 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).

	As of September 30	
	2018	2017
Convertible preferred stock	—	2,009,800
Warrants issued to 2010/2012 convertible note holders to purchase common stock	102,070	102,070
Options to purchase common stock	1,667,896	1,072,004
Warrants issued in 2009 to purchase common stock	1,851	1,851
Warrants issued to underwriter to purchase common stock	16,500	16,500
Series A warrants to purchase common stock	485,121	485,121
Series C warrants to purchase common stock	118,083	118,083
Series D warrants to purchase common stock	586,162	586,162
2017 PIPE warrants	6,024,425	—
Total	9,002,108	4,391,591

Note 10. Fair Value of Contingent Consideration

On March 7, 2017, the Company acquired Essentialis through the Merger of the Company's wholly-owned subsidiary, Company E Merger Sub, Inc., a Delaware corporation, or the Merger Sub, whereby Merger Sub merged into Essentialis, with Essentialis surviving the Merger as a wholly owned subsidiary of the Company.

The transaction has been accounted for as an asset acquisition under the acquisition method of accounting. The amendments in ASU 2017-01 provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set of assets and activities is not a business.

Upon the achievement of certain commercial milestones associated with the sale of Essentialis' product in accordance with the terms of the Merger Agreement, the Company is obligated to make cash earnout payments of up to a maximum of $30 million to Essentialis stockholders. The agreement to pay cash upon the achievement of the commercial milestones results in the recognition of a contingent consideration. The fair value of the contingent cash consideration is based on the Company's analysis of the likelihood of the drug indication moving from phase II through approval in the Federal Drug Administration approval process and then reaching the cumulative revenue milestones.

Management engaged independent professional assistance and advice in order to assess the fair value of the contingent stock and cash consideration as of March 7, 2017 and December 31, 2017. During the process of determining the fair value of the contingent consideration at December 31, 2017, the Company became aware that certain of the subjective assumptions made at the time of the initial valuation should be modified based upon management's increased understanding of the commercial capabilities of the DCCR drug. Accordingly, the Company determined that it was appropriate to adjust the provisional valuation amounts recorded for the contingent stock and cash consideration made at the inception in March 2017. As a result, the value of the contingent cash consideration to be paid upon completing successive sales milestones increased and the value of the contingent stock consideration

payable upon timing milestones was reduced; the resulting combined change to the total contingent consideration was not material. The initial valuation of the contingent consideration determined the fair value of the contingent stock consideration to be $4.2 million and the fair value of the contingent cash consideration to be $1.1 million, for the combined value of $5.3 million. The revision of the initial valuation of the contingent consideration, made within the measurement period, determined the fair value of the contingent stock consideration to be $2.7 million and the fair value of the contingent cash consideration to be $2.6 million, for the combined value of $5.3 million.

Also subsequent to March 7, 2017 and prior to December 31, 2017, the Company completed its assessment of the tax effect on the net assets acquired by obtaining the independent study and report regarding the change in control in the previously outstanding stock of Essentialis. As a result of completing the study, the Company determined that, pursuant to Section 382 of the Internal Revenue Code, the utilization of Essentialis's federal and state operating loss carryforwards were limited, which required the Company to record a net deferred tax liability in the amount of $1.7 million, deferred to future periods, as an element of the assets acquired. As a consequence of recording the net deferred tax liability, the Company's valuation allowance was reduced by $1.7 million, which resulted in the provision for income tax benefit and an increase in the value of the intangible asset acquired.

The probability weighted milestone payments were discounted to determine the present value of future cash payments. The analysis utilized the weighted average cost of capital, or WACC, discount rate which was estimated to be 20%.

The fair value of the liability for the contingent consideration payable by the Company achieving the commercial sales milestones of $100 million and $200 million was initially established as approximately $2.6 million at the time of the merger and approximately $5.7 million at September 30, 2018, based on the Company's assessment that it could reach the commercial sales milestones in 2024 and 2026, respectively.

Note 11. Compensation Plan for Board Members

In 2017, the Compensation Committee of the Board of Directors recommended, and the Board approved a revised compensation plan pursuant to which all board fees are paid in Common Stock of the Company. Payment to the Board of Directors in shares of the Company's Common Stock is made after the close of the quarter in which the compensation is earned. During the nine months ended September 30, 2018 and 2017, the Company issued 98,818 and 58,589 shares, respectively, of Common Stock to its Board members for fees earned.

Note 12. Subsequent Event

The Joint Venture Agreement between the Company and OAHL provides that the Company's previously wholly-owned subsidiary, Capnia, will issue common shares to OAHL when the cumulative investment made by OAHL equals or exceeds $1.2 million (see Note 5). In 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, once each entity had concluded its quarterly and year-to-date record-keeping. As of September 30, 2018, Capnia had issued no shares of common stock to OAHL as the Company and OAHL had not concluded their review prior to the end of the quarter. Immediately after the close of the quarter ended September 30, 2018, the Company and OAHL reconciled and determined that the cumulative investment made by OAHL was $1,690,000 as of the end of the September 2018 quarter and Capnia issued 1,690,322 shares of its common stock to OAHL. Accordingly, the total shares of Capnia's issued and outstanding common stock as of October 16, 2018, is 3,170,322, of which OAHL owns 1,690,322 shares, or 53.3% of the total outstanding shares, and the Company owns 1,480,000 shares, or 46.7% of the shares outstanding. After the sale by Capnia of the 53.3% of its common stock shares, Soleno will no longer have a controlling interest in Capnia and the financial statements of the previously wholly-owned subsidiary will no longer be consolidated with those of the Company. The Company's remaining 46.7% ownership in Capnia will be recorded as an investment and initially measured at fair value. Any gain or loss on the deconsolidation will be included in Other income (expense) in the Company's Consolidated Statement of Operations during the fourth quarter of 2018.

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, 2017, 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, 2017. 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. On May 8, 2017, we received stockholder approval to amend our Amended and Restated Certificate of Incorporation to change our name from "Capnia, Inc." to "Soleno Therapeutics, Inc." We were initially established as a diversified healthcare company that developed and commercialized innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz ® Allergy Relief, or Serenz; CoSense ® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly and which can lead to adverse neurological outcomes; and, products that included temperature probes, scales, surgical tables, and patient surfaces.

Our previously wholly-owned subsidiary NFI also marketed innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets.

On December 22, 2016, we entered into the Merger Agreement with Essentialis. Essentialis's efforts prior to the Merger were focused primarily on developing and testing product candidates that target the ATP-sensitive potassium channel, a metabolically regulated membrane protein whose modulation has the potential to impact a wide range of rare metabolic, cardiovascular, and CNS diseases. Essentialis has tested DCCR as a treatment for PWS, a complex metabolic/neurobehavioral disorder. DCCR has orphan designation for the treatment of PWS in the U.S. as well as in the E.U. Consummation of the Merger was subject to various closing conditions, including our consummation of a financing of at least $8 million at, or substantially contemporaneous with, the closing of the Merger, which occurred on March 7, 2017 and the receipt of stockholder approval of the Merger at a special meeting of our stockholders, which was held on March 6, 2017.

We subsequently explored opportunities, and made a decision to divest, sell or otherwise dispose of the CoSense, NFI and Serenz businesses. Accordingly, and pursuant to ASC 205-20-45-10, the assets and liabilities related to the discontinued activities of CoSense, NFI and Serenz businesses are presented separately in the balance sheet as held for sale items, and the related operations reported herein for the CoSense, NFI and Serenz activities are reported as discontinued operations in the Statement of Operations.

We now primarily focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. Our current research and development efforts are primarily focused on advancing our lead candidate, DCCR tablets for the treatment of PWS, into late-stage clinical development.

We sold NFI in a stock transaction that was completed on July 18, 2017, pursuant to the NFI Purchase Agreement with Neoforce Holdings, a wholly-owned subsidiary of Flexicare Medical Limited, a privately-held United Kingdom company, for $720,000 and adjustments for inventory and the current cash balances held at NFI (see Note 5).

On December 4, 2017, we, and our wholly-owned subsidiary, Capnia, entered into a joint venture with OAHL with the purpose of developing and commercializing CoSense.

We continue to separately evaluate alternatives for our Serenz portfolio.

On July 27, 2018 the FDA has granted Fast Track designation to DCCR for the treatment of PWS. Soleno is currently conducting a Phase III clinical trial of DCCR for the treatment of PWS.

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 Continuing Operations

Comparison of the three months ended September 30, 2018 and 2017, from continuing operations

	Three Months Ended September 30,		Increase (decrease)	
	2018	2017	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 2,092	$ 946	$ 1,146	121%
General and administrative	1,558	1,685	(127)	8%
Change in fair value of contingent consideration	228	—	228	—
Total operating expenses	3,878	2,631	1,247	47%
Operating loss	(3,878)	(2,631)	(1,247)	47%
Other income				
Cease-use income	—	5	(5)	100%
Change in fair value of warrants liabilities	1,543	131	1,412	1,078%
Interest and other income	26	3	23	767%
Total other income	1,569	139	1,430	1,029%
Loss from continuing operations	(2,309)	(2,492)	183	7%
Loss from discontinued operations	(427)	(1,294)	867	67%
Net loss	$(2,736)	$(3,786)	$ 1,050	28%

Revenue

We have yet not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through September 30, 2018, have generated no revenue from continuing operations.

Research and development expense

Research and development expense of $2.1 million for the three months ended September 30, 2018 increased by $1.1 million over the three months ended September 30, 2017, resulting primarily from efforts directed toward development and commencement, during the quarter ended June 30, 2018, of the Phase III trial of DCCR which we acquired with the Essentialis acquisition on March 7, 2017.

General and administrative expense

General and administrative expense of $1.6 million for the three months ended September 30, 2018 decreased $127,000 from the three months ended September 30, 2017. The decrease was primarily a result of a decrease in personnel related expenses of $92,000 due to planned headcount reductions as well as a $30,000 decrease in rent expense as the lease on one of the Company's facilities expired on June 30, 2018.

Change in fair value of contingent consideration

The $228,000 for the three months ended September 30, 2018 represents the change in the fair value of the additional consideration that we expect to pay Essentialis stockholders based on our assessment of the expected likelihood of achieving commercial sales milestones of $100 million and $200 million in future years.

Other income

Other income of $1.6 million in the three months ended September 30, 2018, increased by $1.4 million from the three months ended September 30, 2017. This increase was primarily due to a $1.4 million larger decrease in the fair value for the Company's outstanding warrants during the three months ended September 30, 2018, of which $1.4 million relates to the decrease in the valuation of the 2017 PIPE warrants.

Comparison of the nine months ended September 30, 2018 and 2017, from continuing operations

	Nine Months Ended September 30,		Increase (decrease)	
	2018	2017	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$ 4,986	$ 2,046	$ 2,940	144%
Sales and marketing	—	26	(26)	100%
General and administrative	5,191	4,900	291	6%
Change in fair value of contingent consideration	589	—	589	—
Total operating expenses	10,766	6,972	3,794	54%
Operating loss	(10,766)	(6,972)	(3,794)	54%
Other income (expense)				
Cease-use income	6	3	3	100%
Change in fair value of warrants	(1,549)	(29)	(1,520)	5,241%
Interest and other income (expense)	75	(595)	670	113%
Other expense	(1,468)	(621)	(847)	136%
Loss from continuing operations	(12,234)	(7,593)	(4,641)	61%
Loss from discontinued operations	(1,364)	(3,049)	1,685	55%
Net loss	$(13,598)	$(10,642)	$(2,956)	28%

Revenue

We have yet not commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through September 30, 2018, have generated no revenue from continuing operations.

Research and development expense

Research and development expense of $5.0 million for the nine months ended September 30, 2018 increased by $2.9 million over the nine months ended September 30, 2017, resulting primarily from efforts directed toward development and commencement, during the quarter ended June 30, 2018, of the Phase III trial of DCCR which we acquired with the Essentialis acquisition on March 7, 2017.

Sales and marketing expense

Sales and marketing expense of $26,000 for the nine months ended September 30, 2017 consisted of expense incurred to revise our website. We have not yet commenced commercialization of DCCR, our current sole novel therapeutic product, and accordingly, through September 30, 2018, have incurred no sales and marketing activities in continuing operations.

General and administrative expense

General and administrative expense of $5.2 million for the nine months ended September 30, 2018 increased $291,000 over the nine months ended September 30, 2017. The increase was primarily from a $415,000 increase in the amortization expense of the patent intangible acquired in the March 7, 2017 acquisition of Essentialis, as 2017 only had amortization for a portion of the nine months compared to the entire period in 2018. In addition, during the three months ended March 31, 2017, $267,000 of legal fees that had been previously recorded as expense in an earlier quarter were reclassified as transaction costs, which increased the cost of the intangible asset acquired with the Merger with Essentialis. Professional fees and investor communication expenses also increased by $353,000 between the two periods, primarily related to financing activities and regulatory filings required in 2018. These increases were offset by a decrease in employee and consultant-related expenses of $492,000 due to planned reductions, and $217,000 of general planned cost reductions including the sublease of excess facility space during 2018.

Change in fair value of contingent consideration

The change in fair value of contingent consideration in the amount of $589,000 for the nine months ended September 30, 2018 represents the change in the fair value of the additional consideration that we expect to pay Essentialis stockholders based on our assessment of the expected likelihood of achieving commercial sales milestones of $100 million and $200 million in future years.

Other income (expense)

Net other expense of $1.5 million in the nine months ended September 30, 2018, increased by $847,000 from net other expense of $621,000 in the nine months ended September 30, 2017. This increase was primarily due to a $1.5 million increase in the fair value for the Company's outstanding warrants during the nine months ended September 30, 2018, primarily for the 2017 PIPE warrants. This amount was partially offset by a $670,000 decrease in expense due primarily to the fact that during the nine months ended September 30, 2017 there were commitment shares issued to Aspire Capital with a value of approximately $600,000.

Results of Discontinued Operations

Discontinued operations consist of our activities previously dedicated to the development and commercialization of innovative diagnostics, devices and therapeutics addressing unmet medical needs, which consisted of: precision metering of gas flow technology marketed as Serenz ® Allergy Relief, or Serenz; CoSense ® End-Tidal Carbon Monoxide (ETCO) Monitor, or CoSense, which measures ETCO and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly; and, products that included temperature probes, scales, surgical tables and patient surfaces. In March 2017, we determined to divest, sell or otherwise dispose of the CoSense, NFI, and Serenz businesses in order to focus on the development and commercialization of novel therapeutics for the treatment of rare diseases. The discontinued operations for the development and commercialization of innovative diagnostic devices and therapeutics are summarized below.

Comparison of the three months ended September 30, 2018 and 2017, from discontinued operations

	Three Months Ended September 30,		Increase (decrease)	
	2018	2017	Amount	Percentage
	(in thousands)			
Product revenue	$ 6	$ 61	$ (55)	90%
Cost of product revenue	2	237	(235)	99%
Gross profit	4	(176)	180	102%
Operating expenses:				
Research and development	306	632	(326)	52%
Sales and marketing	1	37	(36)	97%
General and administrative	124	204	(80)	39%
Total operating expenses	431	873	(442)	51%
Operating loss	(427)	(1,049)	622	59%
Other expense	—	(37)	37	100%
Loss on sale of assets	—	(208)	208	100%
Net loss from discontinued operations	$ (427)	$ (1,294)	$ 867	67%

Product revenue

Revenue related to our discontinued operations was $6,000 during the three months ended September 30, 2018, a $55,000 decrease from the three months ended September 30, 2017, resulting primarily from the sale of the NFI business in July 2017.

Cost of product revenue

Cost of product revenue related to our discontinued operations has declined in relation to the decrease in sales activity, resulting from the sale of the NFI business in July 2017. The negative gross profit of $(176,000) during the three months ended September 30, 2017 was the result of the write-off of Serenz product inventory.

Research and development expense

Research and development expense related to our discontinued operations decreased by $326,000 from the three months ended September 30, 2017 compared to the same period of 2018. The decrease resulted primarily from the sale of NFI in July 2017, and the curtailment of spending towards the development of the Serenz product commencing in 2017.

Sales and marketing expense

Sales and marketing expense during the three months ended September 30, 2018 was $1,000, representing a $36,000 decrease from the three months ended September 30, 2017. The decrease is largely attributed to our stopping the promotion and sales of the Serenz product in the second quarter of 2017. The sales and marketing expenses relating to our discontinued operations during the three months ended September 30, 2018 relate only to Capnia's marketing of its CoSense products.

General and administrative expense

General and administrative expense associated with our discontinued operations was $124,000 during the three months ended September 30, 2018, a decrease of $80,000 from the three months ended September 30, 2017, which decrease was primarily due to the sale of the NFI business in July 2017.

Other expense

Other expense associated with discontinued operations during the three months ended September 31, 2017 relates to NFI, which was sold in July 2017.

Loss on sale of assets

In July 2017 we completed the sale of stock of our wholly-owned subsidiary, NFI. A loss was recorded on the sale in the amount of $208,000 as the net book value of assets sold in the amount of $1.2 million exceeded the total proceeds of $977,000.

Comparison of the nine months ended September 30, 2018 and 2017, from discontinued operations

	Nine Months Ended September 30,		Increase (decrease)	
	2018	2017	Amount	Percentage
	(in thousands)			
Product revenue	$ 60	$ 702	$ (642)	91%
Cost of product revenue	30	769	(739)	96%
Gross profit	30	(67)	97	145%
Operating expenses:				
Research and development	1,009	1,946	(937)	48%
Sales and marketing	25	220	(195)	89%
General and administrative	360	600	(240)	40%
Total operating expenses	1,394	2,766	(1,372)	50%
Operating loss	(1,364)	(2,833)	1,469	52%
Other expense	—	(8)	8	100%
Loss on sale of assets	—	(208)	208	100%
Net loss from discontinued operations	$(1,364)	$(3,049)	$ 1,685	55%

Product revenue

Revenue related to our discontinued operations was $60,000 during the nine months ended September 30, 2018, a $642,000 decrease from the nine months ended September 30, 2017, resulting primarily from the sale of the NFI business in July 2017.

Cost of product revenue

Cost of product revenue related to our discontinued operations has declined in relation to the decrease in sales activity, resulting from the sale of the NFI business in July 2017.

Research and development expense

Research and development expense related to our discontinued operations decreased by $937,000 from the nine months ended September 30, 2017 to the same period of 2018. The decrease primarily resulted from the sale of NFI in July 2017, and the curtailment of spending towards the development of the Serenz product during 2017.

Sales and marketing expense

Sales and marketing expense during the nine months ended September 30, 2018 was $25,000, representing a $195,000 decrease from the nine months ended September 30, 2017. The decrease is largely attributed to our stopping the promotion and sales of the Serenz product in the second quarter of 2017. The sales and marketing expenses relating to our discontinued operations during the nine months ended September 30, 2018 relate only to Capnia's marketing of its CoSense products.

General and administrative expense

General and administrative expense associated with our discontinued operations was $360,000 during the nine months ended September 30, 2018, a decrease of $240,000 from the nine months ended September 30, 2017. The decrease was primarily due to the sale of NFI in July 2017.

Other expense

Other expense associated with discontinued operations has been nominal in the periods reported.

Loss on sale of assets

In July 2017 we completed the sale of stock of our wholly-owned subsidiary, NFI. A loss was recorded on the sale in the amount of $208,000 as the net book value of assets sold in the amount of $1.2 million exceeded the total proceeds of $977,000.

Liquidity and Capital Resources

We had a net loss of $13.6 million for the nine months ended September 30, 2018 and an accumulated deficit of $127.3 million at September 30, 2018 from having incurred losses since our inception. We had $8.9 million of working capital at September 30, 2018 and used $7.9 million of cash in operating activities during the nine months ended September 30, 2018. We have financed our operations principally through issuances of equity securities.

We have continued to focus on expense control, including reducing our workforce, eliminating outside consultants, reducing legal fees and implementing a plan to allow Board members to receive common stock, in lieu of cash payments.

On December 11, 2017, we entered into the Unit Purchase Agreement with certain stockholders, pursuant to which we sold and issued 8,141,116 immediately separable units at a price per unit of $1.84, for aggregate gross proceeds of $15.0 million. Each unit consisted of one share of our common stock and a warrant to purchase 0.74 shares of our common stock at an exercise price of $2.00 a share, for an aggregate of 8,141,116 shares of common stock and corresponding warrants to purchase an aggregate of 6,024,425 shares of common stock underlying the warrants. We also granted certain registration rights to these stockholders, pursuant to which, among other things, we prepared and filed a registration statement with the SEC to register for resale the Resale Shares. The registration statement was declared effective in February 2018.

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.

We expect to continue incurring losses for the foreseeable future and may 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 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 we be unable 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:

	Nine Months Ended September 30,	
	2018	2017
	(in thousands)	
Net cash used in continuing operating activities	$ (6,774)	$ (4,750)
Net cash used in discontinued operating activities	(1,173)	(2,468)
Net cash used in operating activities	(7,947)	(7,218)
Net cash used in continuing investing activities	(6)	(577)
Net cash provided by discontinued investing activities	—	716
Net cash provided by (used in) investing activities	(6)	139
Net cash provided by continuing financing activities	—	10,000
Net cash provided by discontinued financing activities	1,525	—
Net cash provided by financing activities	1,525	10,000
Net increase (decrease) in cash, cash equivalents and restricted cash		
Continuing operations	(6,780)	4,673
Discontinued operations	352	(1,752)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (6,428)	$ 2,921

Continuing Operations

Cash used in operating activities

During the nine months ended September 30, 2018, operating activities used net cash of $6.8 million, which was primarily due to the loss from continuing operations of $12.2 million, which loss is adjusted for non-cash expenses of $1.5 million for depreciation and amortization, $928,000 of expenses paid with common stock or equity awards, and $2.1 million for the change in fair value of stock warrants and contingent consideration. Additionally, the usage of cash during the nine-months ended September 30, 2018 was reduced by $920,000 by an increase in accounts payable, accrued compensation and other current liabilities and a decrease in prepaid expenses.

During the nine months ended September 30, 2017, operating activities used net cash of $4.8 million, which was primarily due to the loss from continuing operations of $7.6 million, adjusted for non-cash expenses of $1.0 million for depreciation and amortization, $1.0 million of non-cash expenses paid with common stock or equity awards, $29,000 for the change in fair value of stock warrants and contingent consideration, and $602,000 for issuing shares to Aspire Capital. There were also decreases in accounts receivable, prepaid expenses and other current assets, accrued compensation and other current liabilities and other long-term liabilities and an increase in accounts payable that offset the cash usage by $242,000.

Cash used in investing activities

Minimal cash was used for investing activities in the nine months ended September 30, 2018 and September 30, 2017 for the costs of acquiring property and equipment. During the nine months ended September 30, 2017 cash used in investing activities also includes the payment of costs associated with the acquisition of Essentialis.

Cash provided by financing activities

There were no financing activities related to continued operations during the nine months ended September 30, 2018. During the nine months ended September 30, 2017, we received $10.0 million as a result of the completion of the concurrent financing associated with the Essentialis Merger.

As of September 30, 2018, we had cash, cash equivalents and restricted cash of approximately $10.2 million.

We do not believe that we 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 may be required to raise additional capital to pursue its 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.

Discontinued Operations

Cash used in operating activities

During the nine months ended September 30, 2018 we used net cash of $1.2 million for discontinued operating activities, compared to $2.5 million during the nine months ended September 30, 2017. The decrease was primarily due to the lower comparative level of operating activities for the discontinued operations, reflecting primarily the sale of NFI in July 2017.

Cash provided by investing activities

There were no investing activities related to discontinued operations during the nine months ended September 30, 2018. During the nine months ended September 30, 2017, net cash provided by investing activities was $716,000, resulting primarily from the sale of the NFI operations in July 2017.

Cash provided by financing activities

Net cash provided by financing activities related to discontinued operations was $1.5 million during the nine months ended September 30, 2018, representing the cash received during the period from our joint venture partner. There were no financing activities related to discontinued operations during the nine months ended September 30, 2017.

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 nine months ended September 30, 2018. 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 third fiscal quarter ended September 30, 2018, 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.

PART II – OTHER INFORMATION

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 2017 Annual Report on Form 10-K and is incorporated herein by reference. We have marked below with an asterisk (*) those risk factors that reflect substantive changes to the text of the risk factors in our 2017 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.

*** Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and trials may not be predictive of future trial results, and our clinical trials may fail to adequately demonstrate the safety and efficacy of DCCR or other potential product candidates.**

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We may experience delays in our clinical trials. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients in a timely manner or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including failure to:

- generate sufficient nonclinical, toxicology, or other in vivo or in vitro data, or clinical safety data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on trial design, to commence a trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- obtain and maintain institutional review board, or IRB, approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a trial;
- have a sufficient number of patients complete a trial and/or return for post-treatment follow-up;
- ensure clinical investigators observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;

- address any conflicts or compliance with new or existing laws, rule, regulations or guidelines;
- have a sufficient number of clinical trial sites to conduct the trials;
- timely manufacture sufficient quantities of product candidate suitable for use at the stage of clinical development; or
- raise sufficient capital to fund a trial.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating or any investigational new drugs or treatment under development for the indications we are investigating.

There has recently been increased activity in the development of drugs to treat PWS. As of November 2018, we are aware of eight other current or proposed clinical trials evaluating PWS therapies. If all of these clinical trials are ongoing concurrently, given the limited number of patients, it may hamper recruitment and enrollment of qualified patients for our current trial of DCCR in PWS.

We could also encounter delays if a clinical trial is suspended or terminated by us, by a data safety monitoring board for such trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates for any reason, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We may need additional funds to support our operations, and such funding may not be available to us on acceptable terms, or at all, which would force us to delay, reduce or suspend our research and development programs and other operations or commercialization efforts. Raising additional capital may subject us to unfavorable terms, cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our planned products and technologies.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As of September 30, 2018, we have incurred significant operating losses since inception and continue to generate losses from operations and have an accumulated deficit of $127.3 million. These matters raise substantial doubt about our ability to continue as a going concern. The 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 we be unable to continue as a going concern.

Commercial results have been limited and we have not generated significant revenues. We cannot assure our stockholders that our revenues will be sufficient to fund our operations, including expenses related to our current ongoing clinical trial of DCCR. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds through dilutive financings or entering into arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish.

At September 30, 2018, our cash balance was $10.2 million. We intend to raise additional capital, either through debt or equity financings to achieve our business plan objectives, including increased expenses for additional resources deployed to manage enrollment of patients and other activities related to our current ongoing clinical trial of DCCR. We believe that we can be successful in obtaining additional capital; however, no assurance can be provided that we will be able to do so. There is no assurance that any funds raised will be sufficient to enable us to attain profitable operations or continue as a going concern. To the extent that we are unsuccessful, we may need to curtail or cease our operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

We do not have any material committed external source of funds or other support for our commercialization and development efforts. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never achieve, we expect to finance future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. Additional financing may not be available to us when we need it, or it may not be available on favorable terms. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our current and planned products, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of, or suspend one or more of our clinical studies or research and development programs or our commercialization efforts.

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			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
2.1	Stock Purchase Agreement, dated as of July 18, 2017, and between Soleno Therapeutics, Inc., a Delaware corporation, and NeoForce Holdings, Inc. a Delaware corporation	8-K	July 24, 2017	2.1	
2.2	Joint Venture Agreement, dated as of December 4, 2017, by and among Soleno Therapeutics, Inc., Capnia, Inc., and OptAsia Healthcare Limited	8-K	December 8, 2017	2.1	
2.3	PRC IP Purchase Agreement, dated as of December 4, 2017, by and between OptAsia Healthcare Limited and Capnia, Inc.	8-K	December 8, 2017	2.2	
2.4	Transition Services Agreement, dated as of December 4, 2017, by and among Soleno Therapeutics, Inc., a Delaware corporation, Capnia, Inc. and OptAsia Healthcare, Ltd., a Hong Kong company	8-K	December 8, 2017	2.3	
3.1	Amended and Restated Certificate of Incorporation of Soleno Therapeutics, Inc.	S-1/A	August 7, 2014	3.2	
3.2	Amended and Restated Bylaws of Soleno Therapeutics, Inc.	S-1/A	July 1, 2014	3.4	
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	8-K	October 15, 2015	3.1	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock	8-K	July 6, 2016	3.1	
3.5	Certificate of Amendment	8-K	May 11, 2017	3.1	
3.6	Certificate of Amendment to the Certificate of Incorporation	8-K	October 6, 2017	3.1	
4.1	Form of the common stock certificate.	S-1/A	August 5, 2014	4.1	
4.2	Amended And Restated Investors' Rights Agreement, dated March 20, 2008, by and among Soleno Therapeutics, Inc. and certain holders of the Soleno Therapeutics, Inc.'s capital stock named therein.	S-1/A	July 1, 2014	4.2	
4.3	Form of Series A Warrant Agreement.	S-1/A	August 5, 2014	4.3	
4.4	Form of the Series A Warrant certificate.	S-1/A	August 5, 2014	4.4	
4.5	Form of Underwriters' Compensation Warrant.	S-1/A	August 5, 2014	4.5	
4.6	Form of Convertible Promissory Note issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.6	
4.7	Form of Warrant to Purchase Shares issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.7	
4.8	Form of Convertible Promissory Note issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.8	
4.9	Form of Warrant to Purchase Shares issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.9	
4.10	Form of Convertible Promissory Note issued in January 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.10	
4.11	Form of Warrant to Purchase Shares issued in January 2012 in connection with Soleno Therapeutics, Inc.'s 2012 convertible note financing.	S-1	June 10, 2014	4.11	
4.12	Form of Convertible Promissory Note issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.12	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
4.13	Form of Warrant to Purchase Shares issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.13	
4.14	Form of Convertible Promissory Note issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.14	
4.15	Form of Warrant to Purchase Shares issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.15	
4.16	Form of unit certificate.	S-1/A	August 5, 2014	4.16	
4.17	Form of Series B Warrant Agreement.	S-1/A	November 4, 2014	4.17	
4.18	Form of the Series B Warrant certificate.	S-1/A	November 4, 2014	4.18	
4.19	Form of the Series C Warrant Agreement.	S-4	April 1, 2015	4.19	
4.20	Form of the Series C Warrant certificate.	S-4	April 1, 2015	4.20	
4.21	Form of Series D Common Stock Purchase Warrant.	8-K	October 15, 2015	4.1	
4.22	Form of Placement Agent Warrant.	8-K	October 15, 2015	4.2	
4.23	Form of Series D common stock Warrant Certificate.	8-K	October 15, 2015	4.3	
4.24	Form of Series A Convertible Preferred Stock Certificate.	8-K	October 15, 2015	4.4	
4.25	Form of Placement Agent Warrant.	8-K	July 6, 2016	4.1	
4.26	Form of Series B Convertible Preferred Stock Certificate.	8-K	July 6, 2016	4.2	
4.27	Form of Common Stock Purchase Warrant	8-K	December 13, 2017	4.1	
9.10	Form of Voting Agreement.	8-K	October 15, 2015	9.1	
9.20	Form of Voting Agreement.	8-K	July 6, 2016	9.1	
9.30	Form of Voting Agreement.	8-K	December 27, 2016	10.1	
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	June 10, 2014	10.1	
10.2	1999 Incentive Stock Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.2	
10.3	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.3	
10.4	2014 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.4	
10.5	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.5	
10.6	Offer Letter, dated June 22, 2007, by and between Soleno Therapeutics, Inc. and Ernest Mario, Ph.D.	S-1	June 10, 2014	10.6	
10.7	Employment Agreement, dated April 6, 2010, by and between Soleno Therapeutics, Inc. and Anish Bhatnagar.	S-1	June 10, 2014	10.7	
10.8	Offer Letter, dated May 29, 2013, between Soleno Therapeutics, Inc. and Anthony Wondka.	S-1	June 10, 2014	10.8	
10.9	Offer Letter, dated April 17, 2014, by and between Soleno Therapeutics, Inc. and Antoun Nabhan.	S-1	June 10, 2014	10.9	
10.10	Asset Purchase Agreement dated May 11, 2010, by and between Soleno Therapeutics, Inc. and BioMedical Drug Development Inc.	S-1	June 10, 2014	10.10	
10.11	Convertible Note and Warrant Purchase Agreement, dated February 10, 2010, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.11	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.12	Amendment No. 1 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated November 10, 2010, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.12	
10.13	Amendment No. 2 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated January 17, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.13	
10.14	Convertible Note and Warrant Purchase Agreement, dated January 16, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.14	
10.15	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated July 31, 2012, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.15	
10.16	Omnibus Amendment to Convertible Promissory Notes and Warrants to Purchase Shares, dated April 28, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.16	
10.17	Convertible Note and Warrant Purchase Agreement, dated April 28, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.17	
10.18	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated May 5, 2014, by and among Soleno Therapeutics, Inc. and the investors named therein.	S-1	June 10, 2014	10.18	
10.19	Sublease, dated May 20, 2014, by and among Soleno Therapeutics, Inc. and Silicon Valley Finance Group.	S-1/A	July 1, 2014	10.19	
10.20	Offer Letter, dated June 24, 2014, by and between Soleno Therapeutics, Inc. and David D. O'Toole.	S-1/A	July 22, 2014	10.20	
10.21	Loan Agreement by and between Soleno Therapeutics, Inc. and the investors named therein, dated September 29, 2014.	S-1/A	September 29, 2014	10.21	
10.22	Revised Second Tranche Closing Notice and Letter Amendment dated August 18, 2014 relating to the August 2014 Notes.	S-1/A	November 4, 2014	10.22	
10.23	Second Tranche Subsequent Closing Notice and Letter Amendment dated October 22, 2014 relating to the October 2014 Notes.	S-1/A	November 4, 2014	10.23	
10.24	Form of Warrant Exercise Agreement.	8-K	March 5, 2015	10.1	
10.25	Advisory Agreement by and between Soleno Therapeutics, Inc. and Maxim Group LLC, dated March 4, 2015.	S-4	April 1, 2015	10.25	
10.26	Agreement and First Amendment to Asset Purchase Agreement between the Company, BDDI and affiliate of BDDI, dated June 30, 2015.	8-K	July 7, 2015	10.1	
10.27	Common Stock Purchase Agreement between the Company and an affiliate of BDDI, dated June 30, 2015.	8-K	July 7, 2015	10.2	
10.28	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	4.1	
10.29	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	10.1	
10.30	Engagement Letter dated September 17, 2015, between Soleno Therapeutics, Inc. and Maxim Group, LLC.	8-K	October 15, 2015	1.1	

Exhibit Number	Description of Document	Incorporated by Reference from			Filed Herewith
		Registrant's Form	Date Filed with the SEC	Exhibit Number	
10.31	Securities Purchase Agreement dated October 12, 2015.	8-K	October 15, 2015	10.1	
10.32	Form of Registration Rights Agreement.	8-K	October 15, 2015	10.2	
10.33	Form of Lock-Up Agreement.	8-K	October 15, 2015	10.3	
10.34	Amendment No. 1 to Securities Purchase Agreement dated October 29, 2015.	S-1/A	December 22, 2015	10.33	
10.35	Transfer and Distribution Agreement: United States: by and between Soleno Therapeutics, Inc. and Bemes, Inc. signed January 26, 2016.	8-K	January 28, 2016	10.1	
10.36	Engagement Letter dated June 26, 2016, between Soleno Therapeutics, Inc. and Maxim Group, LLC.	8-K	July 6, 2016	1.1	
10.37	Securities Purchase Agreement dated June 29, 2016.	8-K	July 6, 2016	10.1	
10.38	Form of Registration Rights Agreement dated June 29, 2016.	8-K	July 6, 2016	10.2	
10.39	Amendment No. 1 to Securities Purchase Agreement dated September 20, 2016.	S-1/A	September 20, 2016	10.39	
10.40	Agreement and Plan of Merger and Reorganization, dated as of December 22, 2016, by and among Soleno Therapeutics, Inc., a Delaware corporation, Essentialis, Inc., a Delaware corporation, Company E Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Soleno Therapeutics, and Neil Cowen as the stockholders' representative.	8-K	December 27, 2016	2.1	
10.41	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.51	
10.42	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.52	
10.43	Stock Purchase Agreement made by and between the Company and NeoForce Holdings, Inc. a Delaware corporation dated July 18, 2017	8-K	July 24, 2017	2.1	
10.44	Joint Venture Agreement dated as of December 4, 2017 by and among Soleno Therapeutics, Inc., Capnia, Inc., and OptAsia Healthcare Limited	8-K	December 8, 2017	2.1	
10.45	Securities Purchase Agreement, dated as of December 11, 2017	8-K	December 13, 2017	10.1	
31.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended				X
32.1	Certification of Principal Executive Officer and Principal Financial and Accounting Officer Required Under Rule 13a-14(b) of the Securities 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: November 14, 2018

SOLENO THERAPEUTICS, INC.

By: /s/ Jonathan Wolter
Jonathan Wolter
Chief Financial Officer
(authorized officer and principal financial and accounting officer)

Exhibit 31.1

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: November 14, 2018

/s/ Anish Bhatnagar
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)

Exhibit 32.1

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 September 30, 2018, 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: November 14, 2018

/s/ Anish Bhatnagar
Anish Bhatnagar
President, Chief Executive Officer
(principal executive officer)