SOLENO THERAPEUTICS INC
Form 10-Q
November 14, 2017

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2017
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.
(formerly known as Capnia, 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 x No ¨
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes x No ¨
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

Emerging growth company x

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 x

As of November 9, 2017, there were 10,002,256 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

SOLENO THERAPEUTICS, INC.
(formerly known as Capnia, Inc.)
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PART I—FINANCIAL INFORMATION

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

	September 30, 2017	December 31, 2016
Assets	(Unaudited)	
Current assets		
Cash and cash equivalents	$ 5,647	$ 2,726
Accounts receivable	—	3
Restricted cash	35	35
Prepaid expenses and other current assets	145	247
Current assets held for sale	563	790
Total current assets	6,390	3,801
Long-term assets		
Property and equipment, net	55	54
Other intangible assets, net	19,353	—
Other assets	126	126
Long-term assets held for sale	458	1,584
Total assets	$ 26,382	$ 5,565
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	642	411
Accrued compensation and other current liabilities	976	1,050
Current liabilities held for sale	113	246
Total current liabilities	1,731	1,707
Long-term liabilities		
Series A warrant liability	289	194
Series C warrant liability	20	86
Other long-term liabilities	1,132	62
Long-term liabilities held for sale	—	81
Total liabilities	3,172	2,130
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series B convertible preferred stock, 13,780 are designated at September 30, 2017 and December 31, 2016; 10,049 and 12,780 shares issued and outstanding at September 30, 2017 and at December 31, 2016, respectively. Liquidation value of zero.	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 9,970,538 and 3,357,390 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively. (Note 14)	10	4
Additional paid-in-capital	132,154	101,743
Accumulated deficit	(108,954)	(98,312)
Total stockholders' equity	23,210	3,435

Total liabilities and stockholders' equity	$ 26,382	$ 5,565

See accompanying notes to condensed consolidated financial statements

Soleno Therapuetics, Inc.
(formerly known as Capnia, 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,	
	2017	2016	2017	2016
Operating expenses				
Research and development	$982	$708	$2,046	$1,959
Sales and marketing	—	—	26	—
General and administrative	1,707	1,260	4,900	4,532
Total expenses	2,689	1,968	6,972	6,491
Operating loss	(2,689)	(1,968)	(6,972)	(6,491)
Interest and other income (expense)				
Interest Income	4	—	7	—
Change in fair value of warrants liabilities income (expense)	130	200	(29)	1,295
Cease-use expense	4	—	3	(94)
Other expense	—	(9)	(602)	(26)
Interest and other income (expense), net	138	191	(621)	1,175
Loss from continuing operations	(2,551)	(1,777)	(7,593)	(5,316)
Loss from discontinued operations:				
Operating loss	(1,027)	(973)	(2,841)	(4,136)
Loss on sale of assets	(208)	—	(208)	—
Total	(1,235)	(973)	(3,049)	(4,136)
Net loss	$(3,786)	$(2,750)	$(10,642)	$(9,452)
Loss per common share from continuing operations, basic and diluted (Note 14)	$(0.24)	$(0.56)	$(0.85)	$(1.73)
Loss per common share from discontinued operations, basic and diluted (Note 14):				
Operating	$(0.09)	$(0.31)	$(0.32)	$(1.35)
Loss on sale of assets	$(0.02)	$—	$(0.02)	$—
Total	$(0.11)	$(0.31)	$(0.34)	$(1.35)
Net loss per common share, basic and diluted (Note 14)	$(0.35)	$(0.87)	$(1.19)	$(3.08)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share (Note 14)	10,766,608	3,152,306	8,936,255	3,072,729

See accompanying notes to condensed consolidated financial statements

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

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$(10,642)	$(9,452)
Loss from discontinued operations	(3,049)	(4,136)
Loss from continuing operations	(7,593)	(5,316)
Adjustments to reconcile net loss from continuing operations to net cash used in operating activities:		
Depreciation and amortization	1,029	1
Stock-based compensation expense	855	560
Loss on disposition of property & equipment	—	1
Board fees paid with common stock	195	—
Change in fair value of common stock warrants	29	(1,323)
Non-cash expense of issuing shares to Aspire Capital	602	—
Change in operating assets and liabilities:		
Accounts receivable	3	—
Prepaid expenses and other assets	101	(52)
Other long-term assets	—	(49)
Accounts payable	232	336
Accrued compensation and other current liabilities	(74)	(166)
Other long-term liabilities	(20)	52
Net cash used in continuing operating activities	(4,641)	(5,956)
Net cash used in discontinued operating activities	(2,577)	(4,853)
Net cash used in operating activities	(7,218)	(10,809)
Cash flows from investing activities:		
Costs of Essentialis acquisition paid	(573)	—
Purchase of property and equipment	(4)	(22)
Net cash used in continuing investing activities	(577)	(22)
Net cash provided by (used for) discontinued investing activities	716	(17)
Net cash used in investing activities	139	(39)
Cash flows from financing activities:		
Proceeds from sale of Series A preferred convertible stock	—	5,070
Series A preferred convertible stock transaction costs paid	—	(71)
Proceeds from sale of Series B preferred stock	—	13,479
Redemption of Series A preferred stock in conjunction with issuance of Series B preferred stock	—	(7,780)
Proceeds from issuance of common stock	10,000	70
Net cash provided by continuing financing activities	10,000	10,768
Net cash provided by discontinued financing activities	—	—
Net cash provided by financing activities	10,000	10,768

Net increase (decrease) in cash and cash equivalents		
Continuing operations	4,783	4,790
Discontinued operations	(1,862)	(4,870)
Net increase (decrease) in cash and cash equivalents	2,921	(80)
Cash and cash equivalents, beginning of period	2,726	5,495
Cash and cash equivalents, end of period	$5,647	$5,415
Supplemental disclosures of non-cash investing and financing information		
Conversion of Series A preferred to common stock	$—	$2,220
Issuance of common stock in Essentialis acquisition	$18,764	$—
Contingent consideration of Essentialis acquisition	$1,090	$—
De-recognition of Series B warrant liability (cashless exercise)	$—	$593
Series B preferred transactions costs in accounts payable	$—	$52
Fixed asset purchases in accounts payable	$—	$11

See accompanying notes to condensed consolidated financial statements.

Soleno Therapeutics, Inc.
(formerly known as Capnia, Inc.)
September 30, 2017
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 1. Description of Business

Soleno Therapeutics, Inc. (formerly known as Capnia, Inc.) (the “Company”) was incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. On May 8, 2017, the Company received stockholder approval to amend the Amended and Restate Certificate of Incorporation of the Company, to change the name of the Company to Soleno Therapeutics, Inc.

On September 2, 2015, the Company established NeoForce, Inc. ("NFI"), a wholly owned subsidiary of the Company and through NFI, acquired substantially all of the assets of an unrelated privately held company NeoForce Group, Inc.("NeoForce"). NFI markets innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets. The Company sold NFI in a stock transaction that was completed on July 18, 2017, pursuant to a Stock Purchase Agreement with Neoforce Holdings, Inc. a wholly-owned subsidiary of Flexicare Medical Limited, a privately-held United Kingdom company (see Note 5).

On April 27, 2015, the Company established Capnia UK Limited, a wholly owned foreign subsidiary in the United Kingdom.

On March 7, 2017, the Company completed the merger with Essentialis, Inc., a Delaware corporation, or Essentialis. After the merger, the Company's primary focus is transitioning to the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately held, clinical stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Prior to the merger, Essentialis’s efforts 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 central nervous system diseases. Essentialis has tested Diazoxide Choline Controlled Release, or DCCR, tablets as a treatment for Prader-Willi syndrome, or PWS, a complex metabolic/neurobehavioral disorder.

In May of 2017 the Company had a scientific advice meeting with the U. S. Food and Drug Administration, or FDA . The FDA supported change in hyperphagia score (without a change in weight) compared to placebo as the primary endpoint for the planned Phase III study. The dosing paradigm proposed for the Phase III study was acceptable. The FDA proposed and the Company agreed that the duration of the randomized double-blind placebo controlled study should be shorter (3-4 months). Safety information about DCCR could be obtained in a long-term, safety extension study. There was agreement on several other aspects of the study and the overall development program, and additional regulatory input is being sought on others.

On June 1, 2017, the Company established Capnia, Inc. ("Capnia"), a wholly owned subsidiary of the Company. The Company, through its wholly owned subsidiary Capnia, continues to sell the 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. When present in neonates with jaundice, excessive hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U.

Following the merger with Essentialis, the Company initiated a comprehensive review of strategic alternatives for the legacy products and product candidates, CoSense® ETCO Monitor, and its portfolio of innovative pulmonary resuscitation solutions for the neonatal market. The Company may also license elements of its Sensalyze Technology Platform to other companies that have complementary development or commercial capabilities (see Note 5).

On October 6, 2017, the Company effected a one-for-five (1:5) reverse stock split of its then outstanding Common Stock and, accordingly, all common share and per share data are retrospectively restated to give effect of the split for all periods presented herein (see Note 14).

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.

Note 2. Liquidity, Going Concern and Management’s Plans

The Company had a net loss of approximately $10.6 million for the nine months ended September 30, 2017, and has an accumulated deficit of approximately $109.0 at September 30, 2017, from having incurred losses since its inception. The Company has approximately $4.7 million of working capital at September 30, 2017, and used approximately $7.2 million of cash in its operating activities during the nine months ended September 30, 2017. The Company has financed its operations principally through issuances of debt and equity securities.

On January 27, 2017, the Company entered into a Common Stock Purchase Agreement (the "2017 Aspire Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $17.0 million in value of shares of our Common Stock over the 30-month term of the 2017 Aspire Purchase Agreement. The Company issued Aspire Capital 141,666 shares of Common Stock as commitment shares under the 2017 Aspire Purchase Agreement.

On March 7, 2017, the Company completed the merger with Essentialis. Concurrently, the Company issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the concurrent financing and issued 416,666 shares of common stock for an investment of $2 million from Aspire Capital.

On July 18, 2017, the Company sold NFI, its wholly owned subsidiary, for $977,000 (see Note 5).

The Company expects 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 the Company's ability to continue as a going concern for a period of twelve months from the date of this report.

The Company has been successful over the last 12 months in raising additional capital including the completed closings pursuant to the 2016 Sabby Purchase Agreement, the 2017 Aspire Purchase Agreement and the concurrent financing associated with the merger of Essentialis. 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; however, other than the 2017 Aspire Purchase Agreement, the Company has not secured any commitment for future financing at this time, nor can it provide any assurance that new financing will be available on commercially acceptable terms, if at all. If the Company is unable to secure additional capital, it may be required to curtail its development of its therapeutic product development initiative and take additional measures to reduce costs 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 complete its therapeutic development program, which is critical to the realization of its business plan and the future operations of the Company.

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, 2017, 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, 2016. 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 ("GAAP") and the applicable rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial information. Accordingly, they do not include all of the information and notes required by accounting principles generally accepted in the United States, or GAAP, for complete financial statements. The condensed consolidated balance sheet at December 31, 2016, 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, 2017, and results of its operations for the three and nine months ended September 30, 2017, and 2016, and cash flows for the nine months ended September 30, 2017, and 2016. 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 of 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, 2016, included in the Company's Annual Report on Form 10-K.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of expenses in the financial statements and accompanying notes. Actual results could differ from those estimates. Key estimates included in the financial statements include the valuation of: deferred income tax assets, liability and equity instruments, stock-based compensation, acquired intangibles, contingent earn-out consideration, and allowances for accounts receivable and inventory.

Inventory

As of September 30, 2017, and December 31, 2016, the Company had no inventory in continuing operations.

Business Combinations

For business combinations the Company utilizes the acquisition method of accounting in accordance with ASC Topic 805, Business Combinations. This standard requires that the total cost of an acquisition be allocated to the tangible and intangible assets acquired and liabilities assumed based on their respective fair values at the date of acquisition. The allocation of the purchase price is dependent upon certain valuations and other studies. Acquisition costs are expensed as incurred.

The Company recognizes separately from goodwill the fair value of assets acquired and the liabilities assumed. Goodwill as of the acquisition date is measured as the excess of consideration transferred and the acquisition date fair values of the assets acquired and liabilities assumed. While the Company uses its best estimates and assumptions as a part of the purchase price allocation process to accurately value assets acquired and liabilities assumed at the acquisition date, the Company’s estimates are subject to refinement. As a result, during the measurement period, which may be up to one year from the acquisition date, the Company may retroactively record adjustments to the fair value of the assets acquired and liabilities assumed, with the corresponding adjustment to goodwill. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the Company’s consolidated statements of operations.

Intangible Assets

Intangible assets with finite lives are amortized on a straight-line basis over their estimated useful lives, which range in term from 5 to 12 years. The useful life of the intangible asset is evaluated each reporting period to determine whether events and circumstances warrant a revision to the remaining useful life.

Common Stock Purchase Warrants and Other Derivative Financial Instruments

The Company classifies Common Stock purchase warrants and other free standing derivative financial instruments as equity if the contracts (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions, as either an asset or a liability. The Company assesses classification of its freestanding derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required. The Company determined that certain freestanding derivatives, which consist of Series A and Series C Warrants to purchase Common Stock, do not satisfy the criteria for classification as equity instruments due to the existence of certain cash settlement features that are not within the sole control of the Company or variable settlement provision that cause them to not be indexed to the Company’s own stock; accordingly, they are recorded as liabilities on the balance sheet.

Recent Accounting Pronouncements

In July 2017, FASB issued ASU No. 2017-11, Earnings per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815). ASU 2017-11 consists of two parts. The amendments in Part I of this Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments

require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. Convertible instruments with embedded conversion options that have down round features are now subject to the specialized guidance for contingent beneficial conversion features (in Subtopic 470-20, Debt-Debt with Conversion and Other Options), including related EPS guidance (in Topic 260). The amendments in Part II of this Update re-characterize the indefinite deferral of certain provisions of Topic 480 that now are presented as pending content in the Codification, to a scope exception. Those amendments do not have an accounting effect. For public business entities, the amendments in Part I of this Update 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 of this Update are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The amendments in Part II of this Update do not require any transition guidance because those amendments do not have an accounting effect. The Company is in the process of evaluating this ASU and adoption of this ASU is not expected to have a material impact on the Company's condensed consolidated financial position and results of operations.

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; early adoption is permitted. The Company is currently evaluating the effect that ASU 2017-09 will have on the Company's condensed consolidated financial position and results of operations.

In January 2017, the FASB issued ASU 2017-04: "Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment" ("ASU 2017-04"), which removes Step 2 from the goodwill impairment test. It is effective for annual and interim periods beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment test performed with a measurement date after January 1, 2017. The Company is currently evaluating the effect that ASU 2017-04 will have on the Company's condensed consolidated financial position and results of operations.

In January 2017, the FASB issued ASU 2017-01 "Business Combinations (Topic 805): Clarifying the Definition of a Business", which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. Early application of the amendments in ASU 2017-01 are allowed for transactions for which the acquisition date is before the effective date of the amendments, but only when the transactions have not been reported in the financial statements that have been issued. The Company early adopted ASU 2017-01 for the acquisition of Essentialis, Inc. (see Note 11).

Besides the accounting pronouncement above, there have been no other new accounting pronouncements or changes to accounting pronouncements during the nine months ended Septmber 30, 2017, as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, that are of significance or potential significance to the Company.

Note 4. Fair Value of Financial Instruments

The carrying value of the Company's cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities, 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 recurring basis by level within the fair value hierarchy (in thousands).

	Fair Value Measurements at September 30, 2017			
	Total	Level 1	Level 2	Level 3
Liabilities				
Series A warrant liability	$289	$289	$—	$—
Series C warrant liability	20	—	—	20
Total liabilities	$309	$289	$—	$20

	Fair Value Measurements at December 31, 2016			
	Total	Level 1	Level 2	Level 3
Liabilities				
Series A warrant liability	$194	$194	$—	$—
Series C warrant liability	86	—	—	86
Total common stock warrant liability	$280	$194	$—	$86

The Series A Warrant is a registered security that trades on the open market. 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 measurements of the Series C Warrants are 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. Key assumptions include the volatility of the Company's stock, the expected warrant term, expected dividend yield and risk-free interest rates (see Note 6). The Level 3 estimates are based, in part, on subjective assumptions.
The agreement to pay the annual royalty in the NeoForce acquisition (Note 8) resulted in the recognition of a contingent consideration, which was recognized on the acquisition date. Subsequent changes to estimates of the amount of contingent consideration to be paid were recognized as charges or credits in the statement of operations. The fair value of the contingent consideration was based on preliminary cash flow projections, growth in expected product sales and other assumptions. Based on the assumptions, the fair value of the royalty obligation was determined to be $153,000 at September 30, 2016. The fair value of the royalty obligation was determined by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate of 20% commensurate with the Company's cost of capital and expectation of the revenue growth for products at their life cycle stage. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance. The Neo Force royalty obligation was assumed by Flexicare Medical Limited to whom the company sold NFI on July 18, 2017 (see Note 5).

The agreement to pay the commercial milestones in the Essentials acquisition resulted in the recognition of a contingent consideration, which is recognized at the inception of the transaction, and subsequent changes to estimate of the amounts of contingent consideration to be paid will be recognized as charges or credits in the statement of operations. The fair value of the contingent consideration is based on the Company's analysis of the likelihood of the drug indication moving from phase II through approval in the FDA approval process and then reaching the cumulative

revenue milestones. Based on the assumptions, the fair value of the milestone obligation was determined to be $1.1 million at March 7, 2017. There was no change to the fair value of the contingent consideration as of September 30, 2017. The fair value of the contingent consideration was determined by applying a 15.3% probability of achieving each milestone. Additionally, the Company made an assessment that the commercial milestones of $100 million and $200 million in applicable revenue could be reached in 2023 and 2025, respectively. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance.

On January 13, 2016, the Company entered into an agreement to sublease its excess space located in Redwood City. By the end of February 2016 the Company removed all equipment, furniture and fixtures being stored in this excess space and ceased use of this space. The fair value of the cease-use liability was calculated using the remaining lease payments, offset by future sub-lease payments, offset by deferred rent amortization, and discounted to present value using our current cost of capital of 20%. These inputs are considered Level 3 inputs under the fair value measurements and disclosure guidance.

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.
As of September 30, 2017, and December 31, 2016, the Company had $5.3 million and $2.6 million in money market funds, respectively.
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, as follows (dollars in thousands).

	Series A Warrant		Series C Warrant	
	Number of Warrants	Liability	Number of Warrants	Liability
Balance at December 31, 2016	485,121	$ 194	118,083	$ 86
Change in value of Series A Warrants	—	95	—	—
Change in value of Series C Warrants	—	—	—	(66)
Balance at September 30, 2017	485,121	$ 289	118,083	$ 20

Note 5. Discontinued Operations, Assets Held for Sale and Asset Sale Transaction

Subsequent to the merger with Essentialis (see Note 11), the Company explored opportunities divest, sell or dispose of the CoSense, Neo Force, Inc. 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 were as follows:

	September 30, 2017	December 31, 2016
Current assets		
Accounts receivable	$ 126	$ 130
Inventory	437	660
Current assets held for sale	563	790
Long-term assets		
Property & equipment, net	—	39
Goodwill	—	718
Other intangible assets	458	818
Long-term assets held for sale	458	1,575
Current liabilities		
Accounts payable	23	127
Accrued compensation and other current liabilities	90	119
Total current liabilities for sale	113	246
Long-term liabilities		
Other long-term liabilities	$ —	81
Long-term liabilities held for sale	$ —	$ 81

The components of the income statement accounts presented as Discontinued Operations were as follows.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Product revenue	$61	$329	$702	$1,166
Cost of product revenue	237	399	769	1,288
Gross loss	(176)	(70)	(67)	(122)
Expenses				
Research and development	573	423	1,946	2,273
Sales and marketing	37	342	220	1,454
General and administrative	204	138	600	314
Total expenses	814	903	2,766	4,041
Operating loss	(990)	(973)	(2,833)	(4,163)
Other income (expense)	(37)	—	(8)	27
Operating loss	(1,027)	(973)	(2,841)	(4,136)
Loss on sale of assets	(208)	—	(208)	—
Net loss from discontinued operations	$(1,235)	$(973)	$(3,049)	$(4,136)

On July 18, 2017, the Company completed the sale of stock of its wholly-owned subsidiary, NFI, which operations related primarily to the Company's portfolio of neonatology resuscitation business pursuant to a Stock Purchase Agreement (the "Purchase Agreement") with NeoForce Holdings, Inc. ("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. The Company will also receive payment for the total outstanding accounts receivable and inventory balances held by NFI at the time of the closing of the sale transaction as the receivable balances are collected and the inventory is sold. The Purchase Agreement includes customary terms and conditions, including an adjustment to the purchase price based on inventory and accounts receivable, and provisions that require the Company to indemnify Holdings for certain losses that Holdings might incur resulting from a breach by the Company of its representations and warranties stated in the Purchase Agreement and other matters. Total sales proceeds recorded by the Company were $977,000 consisting of $720,000 received in cash upon completing the sales transaction and a receivable recorded by the Company in the total amount of $257,000 as the fair value of accounts receivable and inventory collections expected to be realized. Upon completing the sale transaction, the Company recorded a loss on the sale in the amount of $208,000 as the net book value of assets sold in the amount of $1.185 million exceeded the total proceeds of $977,000. The Company collected $142,000 of the receivable for inventory and accounts receivable by September 30, 2017, and the remaining balance of $115,000 for the receivable for inventory and accounts receivable is recorded in Current Assets Held for Sale in the Condensed Consolidated Balance Sheet as of September 30, 2017.

The NFI sale transaction is a continuation of the process previously disclosed by the Company of evaluating strategic alternatives and focusing on the Company's rare disease therapeutic business.

Note 6. Warrant Liabilities

Warrants terms

The Company has issued and outstanding Series A Warrants and Series C Warrants (the “Warrants”).

The Company’s 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 requirement to cause or maintain the effectiveness of a registration statement for the offer and sale of these securities. The Warrant contracts further provide for the payment of liquidated damages at an amount per month equal to 1% of the aggregate 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 Company's cash or cash equivalents 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.

Accounting Treatment

The Company accounts for the Warrants in accordance with the guidance in ASC 815 Derivatives and Hedging. 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 as 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 statement of operations.

Under ASC 815-40-35, the Company adopted a sequencing policy that reclassifies contracts, with the exception of stock options, from equity to assets or liabilities for those with the latest inception date first. Future issuance of

securities will be evaluated as to reclassification as a liability under our sequencing policy of latest inception date first until either all of the Series B Warrants are settled or expire. The Series B Warrants expired on February 12, 2016.

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 ("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 CAPNW, and now under the symbol SLNOW as the result of the The Company name change to Soleno Therapeutics, Inc. in May 2017. As the Series A Warrants are publicly traded, the Company uses the closing price on the measurement date to determine the fair value of these the Series A Warrants.

Since their issuance, a total of 4,800 Series A Warrants have been exercised. As of September 30, 2017, the fair value of the 485,121 outstanding Series A Warrants was approximately $289,000, and the decrease of $126,000 and the increase of $95,000, respectively, in fair value during the three and nine months ended September 30, 2017, was recorded as other income and other expense, respectively, in the statement of operations. As of September 30, 2016, the fair value of the outstanding Series A warrants was approximately $509,000, and the decrease of $121,000 and $703,000 in fair value during the three and nine months ended September 30, 2016, was recorded as other income in the statement of operations.

Series B Warrants

The Company issued 489,921 Series B Warrants to purchase shares of its Common Stock at an exercise price of $32.50 per share in connection with the IPO. Certain Series B Warrant holders elected to exercise Series B Warrants for an aggregate of 117,902 shares of Common Stock and a new Series C Warrant for each share of Common Stock for which the Series B Warrants were exercised. Between January 1, 2016, and the expiration of the Series B Warrants on February 12, 2016, certain holders of the Series B Warrants exercised in cashless transactions a total of 20,460 Series B Warrants resulting in the issuance of 97,100 shares of Common Stock. The remaining Series B Warrants expired on February 12, 2016 and no Series B Warrants remain outstanding thereafter.

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 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 905 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, 2017, the fair value of the Series C Warrants was determined to be $20,000. The decline in the fair value of the Series C Warrants of $4,000 during the three months ended September 30, 2017 and $66,000 in the nine months ended September 30, 2017, was recorded as other income in the consolidated statement of operations. As of September 30, 2016, the fair value of the Series C Warrants was determined to be $115,000. The decline in the fair value of the warrants of $79,000 during the three months ended September 30, 2016, and $348,000 in the nine months ended

September 30, 2016 was recorded as other income in the consolidated statement of operations.

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

	June 30, 2017	December 31, 2016
Volatility	90 %	90 %
Expected Term (years)	2.42	3.17
Expected dividend yield	— %	— %
Risk-free rate	1.53%	1.51 %

Note 7. Common Stock Purchase Agreement

On January 27, 2017, the Company entered into the 2017 Aspire Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is 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 2017 Aspire Purchase Agreement. The Company issued Aspire Capital 141,666 shares of Common Stock as commitment shares under the 2017 Aspire Purchase Agreement and the resulting expense for issuing these commitment shares, in the amount of $602 thousand, is recorded as Other Expense in the Statement of Operations. Further, on March 7, 2017, the closing of the financing, as described in the Agreement and Plan of Merger dated December 22, 2016 (the "Merger Agreement"), the Company sold to Aspire Capital, 416,666 of the Company's common stock at $4.80 per share for an aggregate of $2.0 million.

Note 8. 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.

The Company leases office space under a non-cancelable operating lease agreement which was set to expire in May 2015. On February 2, 2015, the Company signed an amendment to its lease agreement, extending the lease through June 2018. The amendment provides 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 and ceased use of the facility in March 2016 (See Note 4).

The Company also leased approximately 2,100 square feet of office space for its operations in Ivyland, Pennsylvania under a month-to-month lease, which lease was assumed by Holdings pursuant to the Purchase completed on July 18, 2017 (see Note 5).

Rent expense was $405,000 and $462,000 during the nine months ended September 30, 2017, and 2016, 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.

In connection with the acquisition of the assets of NeoForce, the Company agreed to pay the former NeoForce shareholder an annual royalty payment for a period of 36 months. The agreement to pay the annual royalty resulted in the recognition of a contingent consideration, which was recognized at the closing of the transaction, and subsequent changes to estimate of the amounts of contingent consideration to be paid will be recognized as charges or credits in the statement of operations. The fair value of the contingent consideration is based on preliminary cash flow projections, growth in expected product sales and other assumptions. Based on the assumptions, the fair value of the

royalty obligation was determined to be $153,000 at June 30, 2016. The fair value of the royalty obligation was determined by applying the income approach, using several significant unobservable inputs for projected cash flows and a discount rate of 20% commensurate with the Company's cost of capital and expectation of the revenue growth for products at their life cycle stage. These inputs are considered Level 3

inputs under the fair value measurements and disclosure guidance. The contingent consideration was classified as liabilities held for sale as of June 30, 2017. The Neo Force royalty obligation was assumed by Flexicare Medical Limited to whom the company sold NFI on July 18, 2017 (see Note 5).

In connection with the merger with Essentialis, the Company agreed to pay Essentialis stockholders earnout payments up to a maximum of $30 million upon the achievement of certain commercial milestones associated with the sale of Essentialis' product. The agreement to pay the commercial milestones resulted in the recognition of a contingent consideration, which was recognized at the inception of the transaction, and subsequent changes to estimate of the amounts of contingent consideration to be paid will be recognized as charges or credits in the statement of operations. The fair value of the contingent 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. Based on the assumptions, the fair value of the milestone obligation was determined to be $1.1 million at March 7, 2017. There was no change to the fair value of the contingent consideration as of September 30, 2017. The entire $1.1 million was classified as a long-term liability.

Note 9. 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 Series B Convertible Preferred Stock under 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, 2017, Sabby converted 2,731 Series B Convertible Preferred stock into 546,200 shares of Common Stock. As of September 30, 2017, there were 10,049 Series B Convertible Preferred Stock outstanding.

Common Stock

The Company issued 3,783,388 shares of common stock to stockholders of Essentialis. The Company held back 182,675 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the merger. The Company is also obligated to issue an additional 913,389 shares of common stock to Essentialis stockholders upon the achievement of a development milestone.

The Company also issued 1,666,666 shares of common stock at $4.80 per share for an investment of $8 million from the completion of the concurrent financing and issued 416,666 shares of common stock at $4.80 per share for an investment of $2 million from Aspire Capital.

Stock Option Plan

The Company has adopted the 1999 Incentive Stock Plan, the 2010 Equity Incentive Plan, and the 2014 Equity Incentive Plan (together, the "Plans"). The 1999 Incentive Stock Plan expired in 2009, and the 2010 Equity Incentive Plan has been closed to new issuances. Therefore, the Company may issue options to purchase shares of common stock to employees, directors, and consultants only under the 2014 Equity Incentive Plan. 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 and directors. NSOs may be granted to employees, directors, advisors, and consultants. The Board of Directors has the authority to determine to whom 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 an ISO or 85% of fair value for an NSO. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be for 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 5 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.

Compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements as of September 30, 2017, and September 30, 2016.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Research & Development	$43	$41	$140	$116
Sales & Marketing	—	11	7	22
General & Administrative	183	154	708	422
Total	$226	$206	$855	$560

No options were granted during the three months ended September 30, 2017 and 2016, and the fair value of each award granted for the nine months ended September 30, 2017 and 2016, was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Expected life (years)	-	-	5.5-6.08	5.5-6.08
Risk-free interest rate	-	-	1.9%-2.2%	1.3%-1.7%
Volatility	-	-	61%-69%	65% - 73%
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 do 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, 2017 as issued under the Plans:

	Shares Available for Grant	Number of Options Outstanding	Weighted-Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in years)
Balance at January 1, 2017	191,771	581,686	$ 17.10	8.48
Additional shares authorized	134,295	—		
Amendment to plan to authorize additional shares	1,785,837	—		
Options granted	(622,755)	622,755	3.05	
Options exercised	—	—		
Options canceled/forfeited	132,437	(132,437)	9.30	
Balance at September 30, 2017	1,621,585	1,072,004	9.9	8.11
Options vested at September 30, 2017		533,202	$ 14.05	6.96
Options vested and expected to vest at September 30, 2017		1,072,004	$ 9.90	8.11

The weighted-average grant date fair value of employee options granted was $3.05 and $4.05 per share for the nine months ended September 30, 2017 and year ended December 31, 2016, respectively. At September 30, 2017, 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, 2017, the outstanding stock options had an intrinsic value of zero.

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.

2014 Employee Stock Purchase Plan

Our Board of Directors and stockholders have adopted the 2014 Employee Stock Purchase Plan, or the ESPP. The ESPP has become effective, and our Board of Directors will implement commencement of offers thereunder in its discretion. A total of 27,967 shares of our Common Stock has been made available for sale under the ESPP. In addition, our 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 our Board of Directors authorizes commencement, equal to the least of:

- 1.0% of the outstanding shares of our Common Stock on the first day of such year; 55,936 shares; or
- such amount as determined by our Board of Directors.

As of September 30, 2017 there were no purchases by employees under this plan.

Series D Warrants

As part of the 2015 Sabby Purchase Agreement, the Company previously issued 562,162 Series D Warrants, with an exercise price of $12.30. The exercise price of 540,540 Series D Warrants issued to Sabby were subsequently amended to $8.75 per share and a term of five years expiring on October 15, 2020 pursuant to the 2016 Sabby Purchase Agreement. The exercise price of the remaining 21,621 Series D Warrants issued to Maxim LLC, as placement agent, was $12.30, and are exercisable beginning on April 15, 2016, and through and including October 15, 2020. The Company’s Series D Warrants

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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 requirement 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 therein. The Company evaluated the registration payment arrangement stipulated in the terms of the 2015 Sabby Purchase 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.

As part of the 2016 Sabby Purchase Agreement, the Company issued to Maxim LLC, as its placement agent, 24,000 Series D Warrants, with an exercise price of $8.75 and a term of five years expiring in July and September of 2021.

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, 2017, the Company had 102,070 Common Stock warrants outstanding originally issued in conjunction with 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 has 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 our IPO, with an exercise price of 35.70 and a term of 10 years, expiring in November 2024.

Note 10. 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 including contingent shares to be issued to Essentialis stockholders of 182,675 shares of common stock to be issued on the 1 year anniversary of the closing of the merger and 913,389 shares of common stock to be issued upon the achievement of a development milestone. 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, 2017 and 2016 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	
	2017	2016
Series A Convertible preferred stock	—	—
Series B Convertible preferred stock	2,009,800	2,756,000
Warrants issued to 2010/2012 convertible note holders to purchase common stock	102,070	102,070
Options to purchase common stock	1,072,004	587,630
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
Total	4,391,591	4,653,417

Note 11. Essentialis, Inc. Acquisition

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 ("Merger Sub"), whereby Merger Sub merged into Essentialis,with Essentialis surviving the merger as a wholly owned subsidiary of the Company.

In consideration, the Company issued 3,783,388 shares of common stock to stockholders of Essentialis. The Company held back 182,675 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the merger. The Company is also obligated to issue an additional 913,389 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. 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 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.

Since the acquisition was determined to be an asset acquisition, the total value of the purchase consideration will be allocated to the asset acquired. The value of the shares issued on the completion of the merger and the shares to be issued was based on the stock price of the Company on the date of completion of the merger. In addition, the trading history of the Company was reviewed to assess the reliability of the implied consideration value. The Company trades on the NASDAQ, a major U.S. stock exchange, and has significant average daily trading volume with tight intraday bid-ask spreads. These characteristics indicate Capnia's shares are actively traded and provide a reliable indication of value. On March 7, 2017, the date of the transaction close, the Company's stock was trading at $3.85 per common share. Additionally, the average closing price of the stock in the 30 calendar days leading up to the close was also approximately $3.85. Accordingly, the identifiable intangible assets acquired are recorded at fair value based on this stock price.

The agreement to pay the commercial milestones resulted in the recognition of a contingent consideration, which is recognized at the inception of the transaction, and subsequent changes to estimate of the amounts of contingent consideration to be paid will be recognized as charges or credits in the statement of operations. The fair value of the contingent 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. In determining the likelihood of this occurring, the analysis relied on 2016 research published by BIO, Biomedtraker, & Amplion titles "Clinical Development Success Rates 2006-2015." Based on management's assessment, a 15.3% probability of achieving each milestone was determined to be reasonable. Additionally, the Company anticipates that it could reach the commercial milestones of $100 million and $200 million in applicable revenue in 2023 and 2025, respectively.

The probability weighted milestone payments were discounted to determine the present value of future payments. The analysis utilized the weighted average cost of capital (WACC) discount rate. The WACC used for the first and second milestones were 30% and 21%, respectively.

The aggregate purchase price consideration was as follows:

Fair value of stock consideration	$18,785,926
Fair value of contingent consideration	1,090,125
Total purchase price consideration	$19,876,051

The fair value of the asset acquired is as follows:

Patents	19,876,051
Net Assets Acquired	$19,876,051

As an asset acquisition, the Company also capitalized $573,000 of total costs of acquiring the assets. These included legal fees of $469,000, printing fees of $75,000 and accounting and other fees of $29,000. The total intangible asset of $20.4 million was recorded on the balance sheet and amortized over the life of the patents through June 30, 2028.

The following table presents the unaudited pro forma results of Soleno Therapeutics, Inc. (including the operations of Essentialis) for the three and nine months ended September 30, 2017, and 2016 (in thousands, except per share amounts). The unaudited pro forma financial information combines the results of operations of Soleno and Essentialis as though the companies had been combined as of the beginning of each of the fiscal periods presented. The unaudited pro forma financial information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at the beginning of fiscal 2016 or 2017.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Pro forma total revenue	$—	$329	$641	$1,167
Pro forma net loss	$(3,786)	$(7,075)	$(11,988)	$(15,039)
Pro forma net loss per share - basic and diluted	$(0.56)	$(1.20)	$(0.81)	$(1.68)
Proforma weighted-average shares - basic and diluted	6,797,067	5,906,396	14,802,976	8,939,450

Note 12. Compensation Plan for Board Members

The Compensation Committee of the Board of Directors of the Company recommended and the Board approved a new compensation plan for the payment of quarterly Board fees. Starting in the first quarter of 2017, all board fees have been 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, 2017, the Company issued 58,589 shares of Common Stock to its Board members (see Note 14).

Note 13. Shareholder Lawsuit

On February 16, 2017, a purported stockholder class action lawsuit captioned Garfield v. Capnia, Inc., et al., Case No. C17-00284, or the Lawsuit, was filed in Superior Court of the State of California, County of Contra Costa against us and certain of our officers and directors. The Lawsuit alleged, generally, that our directors breached their fiduciary duties to our stockholders by seeking to sell control of the company through an allegedly defective process, and on unfair terms. The Lawsuit also alleged that defendants failed to disclose all material facts concerning the merger with Essentialis to stockholders. The Lawsuit sought, among other things, equitable relief that would have enjoined the consummation of the merger, compensatory and/or rescissory damages, and attorneys' fees and costs.

On February 28, 2017, the Company settled the Lawsuit by making certain supplemental disclosures in a Current Report on Form 8-K filed with the SEC on February 28, 2017 in connection with the plaintiff's agreement to voluntarily dismiss plaintiff's claims in the Lawsuit. The Company also agreed to pay $175,000 in attorney's fees. This amount was accrued as a current liability on the balance sheet as of December 31, 2016 and recorded as a general and administrative expense on the statement of operations for the year ended December 31, 2016. The stipulation of dismissal was approved by the court on April 14, 2017.

Note 14. Subsequent Events

On October 2, 2017, the Company issued 31,718 shares of Common Stock to members of its Board of Directors as compensation for Board of Directors fees earned during the quarter ended September 30, 2017 (see Note 12).

On October 6, 2017, the Company effected a one-for-five reverse stock split of its then outstanding Common Stock. Consequently, all earnings per share and other per share amounts and disclosures have been retroactively adjusted for all periods presented herein.

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, 2016, 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, 2016. 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

On March 7, 2017, we completed our merger, or the Merger, with Essentialis, Inc., a Delaware corporation, or Essentialis. After the Merger with Essentialis, our primary focus is on the development and commercialization of novel therapeutics for the treatment of rare diseases. Essentialis was a privately-held, clinical stage biotechnology company focused on the development of breakthrough medicines for the treatment of rare metabolic diseases where there is increased mortality and risk of cardiovascular and endocrine complications. Essentialis has been developing Diazoxide Choline Controlled Release, or DCCR, tablets as a treatment for Prader-Willi syndrome, or PWS, a complex neurobehavioral/metabolic disorder.

We sell CoSense, which measures end-tidal carbon monoxide, or ETCO, and aids in the detection of excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, excessive hemolysis is a dangerous condition which can lead to adverse neurological outcomes. CoSense is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the E.U. (see Note 5).

We are actively pursuing monetization opportunities for CoSense. 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.

DCCR tablets consist of the active ingredient diazoxide choline, a choline salt of diazoxide, which is a benzothiadiazine. Once solubilized from the formulation, diazoxide choline is rapidly hydrolyzed to diazoxide prior to absorption. Diazoxide acts by stimulating ion flux through ATP sensitive K (K_{ATP}) channels. The K_{ATP} channel links the cellular energy status to the membrane potential. Diazoxide appears to act on signs and symptoms of PWS in a variety of ways. Agonizing the K_{ATP} channels in the hypothalamus has the potential to address hyperphagia, which is an abnormally increased appetite for food. Agonizing the channel in GABAergic neurons improves GABA signaling and may reduce aggressive behaviors.

In the U.S., diazoxide was first approved in 1973 as an intravenous formulation for the emergency treatment of malignant hypertension. In 1976, immediate-release oral formulations, including Proglycem® Oral Suspension and Capsules, or Proglycem, were approved and there has been nearly 40 years of use of the 2-3 times a day orally-administered drug in the approved indications. In addition to the approved indications for Proglycem, there is also a long history of its chronic use in neonates, infants and children with congenital hyperinsulinism, or CHI, persistent hyperinsulinemic hypoglycemia of infancy, and in adults with insulinoma, which is a tumor of the pancreas that produces excessive amounts of insulin. Insulinoma patients tend to be older, with 50% of them over 70 years old. The average duration of use of Proglycem in CHI and insulinoma patients is 5 years and 7 years, respectively.

DCCR tablets were formulated with the goals of improving the safety and bioavailability of orally-administered diazoxide and reducing the frequency of daily dosing required by current diazoxide formulations. Diazoxide choline is formulated into a controlled-release tablet that lowers peak plasma concentration compared to diazoxide oral suspension and slows release of diazoxide from DCCR, making it suitable for once-a-day dosing.

PWS is a rare, complex neurobehavioral/metabolic disorder which is due to the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 70 75% of the cases due to a de novo deletion in the paternally inherited chromosome 15 11-q13 region, 20-30% from maternal uniparental disomy 15, or UPD, and the remaining 2-5% from either microdeletions or epimutations of the imprinting center (i.e.,

imprinting defects; IDs). The committee on genetics of the American Academy of Pediatrics states PWS affects both genders equally and occurs in people from all geographic regions; its estimated incidence is 1 in 15,000 to 1 in 25,000 live births. The

mortality rate among PWS patients is 3% a year across all ages 3 years and older and 7% in those over 30 years of age. The mean age of death reported from a 40-year mortality study in the U.S. was 29.5 ± 15 years (range: 2 months - 67 years).

In addition to hyperphagia, which is an abnormally increased appetite for food, typical behavioral disturbances associated with PWS include skin picking, difficulty with change in routine, obsessive and compulsive behaviors and mood fluctuations. The majority of older adolescent and adult PWS patients display some degree of aggressive or threatening behaviors including being verbally aggressive, seeking to intimidate others, being physically aggressive including attacking others and destroying property, throwing temper tantrums and directing rage or anger at others. Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, distress, mood lability, food stealing, withdrawal, sulking, nail-biting, hoarding and overeating, and more pronounced attention-deficit hyperactivity disorder symptoms, and their association with maladaptive conduct problems. The reported rates of psychotic symptoms, between 6% and 28%, are higher than those for individuals with other intellectual disabilities. Individuals with PWS show age-related increases in internalizing problems such as anxiety, sadness and a feeling of low self-esteem. Males are at greater risk for aggressive behavior, depression and dependent personality disorder and overall severity of psychopathology than females. Cognitively, most individuals with PWS function in the mild mental retardation range with a mean IQ in the 60s to low 70s. The combination of food-related preoccupations and numerous maladaptive behaviors makes it difficult for individuals with PWS to perform to their IQ potential.

In May of 2017 we had a scientific advice meeting with the FDA . The FDA supported change in hyperphagia score (without a change in weight) compared to placebo as the primary endpoint for the planned Phase III study. The dosing paradigm proposed for the Phase III study was acceptable. The FDA proposed and we agreed that the duration of the randomized double-blind placebo controlled study should be shorter (3-4 months). Safety information about DCCR could be obtained in a long-term, safety extension study. There was agreement on several other aspects of the study and the overall development program, and additional regulatory input is being sought on others.

The Phase III Proposed Study Design consists of:

- C601: Multi-center, randomized, double-blind, placebo-controlled, parallel arm study in patients with PWS (Phase III).
  - The study will consist of approximately 100 patients at 10-12 sites in the US, with a duration of 3-4 months.
  - Patients will be randomized in a 2:1 ratio to DCCR or placebo.
  - Study start expected in the first quarter of 2018.
  - Primary endpoint is expected to be change in hyperphagia compared to placebo.
- C602: Open label safety extension study. All patients completing C601 are eligible to enroll in C602.

In September 2017, we received scientific advice from the European Medicines Agency (EMA). The EMA, like the FDA, supported the use of change in hyperphagia compared to placebo as the primary endpoint for the study as well as the proposed dosing paradigm. In addition, the EMA noted that children with hyperphagia could be treated in the pivotal trial without further toxicology studies.

On December 22, 2016, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Essentialis.

On March 6, 2017, we held a special stockholder meeting and received approval for the issuance of the merger shares under the Merger Agreement with Essentialis, the issuance of the shares of common stock for the $8 million of concurrent financing and the issuance of the shares of Common Stock for the $2 million investment by Aspire Capital, LLC, or Aspire Capital.

On March 7, 2017, we completed the Merger with Essentialis and issued 3,783,388 shares of Common Stock to stockholders of Essentialis. We held back 182,675 shares of Common Stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger. We are also obligated to issue an additional 913,389 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issue all of the shares of our Common Stock held back and the development milestone is achieved, we would issue a total of 4,879,453 shares of Common Stock 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, we are 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.

In addition, we issued 1,666,666 shares of CommonStock for an investment of $8 million from the completion of the concurrent financing and issued 416,666 shares of Common Stock for an investment of $2 million from Aspire Capital.

During the year ended December 31, 2016 and the nine months ended September 30, 2017, we received $0.1 million and zero, respectively, from the exercise of stock options.

As of September 30, 2017, we had an accumulated deficit of $109.0 million, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, potentially including sales of our therapeutic products, license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships, we have, to date, generated revenue only from the 2013 license agreement pertaining to Serenz, $2.2 million in revenue from our neonatology products and $0.2 million in government grants. We may never be successful in commercializing our neonatology products, therapeutic products or in developing additional products. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

On July 18, 2017, the Company sold NFI, its wholly owned subsidiary, for $977,000 (see Note 5).

Management does not believe that we have sufficient capital resources to sustain operations through at least the next twelve months.

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 the accompanying unaudited consolidated condensed financial statements.

Results of Operations

Comparison of the nine months ended September 30, 2017, and 2016, from continuing operations

	Nine Months Ended September 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$2,046	$1,959	$87	4 %
Sales and marketing	26	—	26	-
General and administrative	4,900	4,532	368	8 %
Total	6,972	6,491	481	7 %
Loss from operations	(6,972)	(6,491)	(481)	7 %
Interest Income	7	—	7	— %
Change in fair value of warrants	(29)	1,295	(1,324)	(102)%
Cease-use expense	3	(94)	97	(103)%
Other income (expense)	(602)	(26)	(576)	2,215 %
Interest and other income (expense), net	(621)	1,175	(1,803)	(153)%
Loss from continuing operations	(7,593)	(5,316)	(2,284)	43 %
Loss from discontinued operations:				
Operating	(2,841)	(4,136)	1,295	(31)%
Non-operating	(208)	—	(208)	— %
Total	(3,049)	(4,136)	1,087	(26)%
Net loss	$(10,642)	$(9,452)	$(1,190)	13 %

Revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the nine months ended September 30, 2017, and 2016.

Cost of product revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the nine months ended September 30, 2017, and 2016.

Research and development expense

Research and development expense in the nine months ended September 30, 2017, increased $87,000 as compared to the nine months ended September 30, 2016. The decrease was primarily due to reduction in headcount.

Sales and marketing expense

Sales and marketing expense, which consisted primarily of costs incurred in the United Kingdom, in the nine months ended September 30, 2017, increased $26,000 over the nine months ended September 30, 2016, primarily due to the cessation of sales of Serenz in the United Kingdom.

General and administrative expense

General and administrative expense in the nine months ended September 30, 2017, increased $368,000 compared to the nine months ended September 30, 2016, due primarily to expense for amortizing intangible assets acquired in the Essentialis acquisition.

Interest and other income (expense), net

Interest and other income/(expense) in the nine months ended September 30, 2017, decreased $1.8 million to net interest and other expense of $602,000 in the nine months ended September 30, 2017, compared to net interest and other income of approximately $1.2 million in the nine months ended September 30, 2016, due primarily to the $1.324 million decline in the fair value of warrants between the two comparative periods and from the expense of $600 resulting from the value assigned to the commitment shares issued to Aspire Capital in January 2017 (see Note 7).

Comparison of the three months ended September 30, 2017, and 2016 from continuing operations

	Three Months Ended September 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	(in thousands)			
Operating expenses:				
Research and development	$982	$708	$274	39 %
General and administrative	1,707	1,260	447	35 %
Total	2,689	1,968	721	37 %
Loss from operations	(2,689)	(1,968)	(721)	37 %
Interest Income	3	—	3	— %
Change in fair value of warrants	130	200	(70)	(35)%
Other income (expense)	4	(9)	13	(144)%
Interest and other income (expense), net	138	191	(53)	(28)%
Loss from continuing operations	(2,551)	(1,777)	(774)	44 %
Loss from discontinued operations:			—	
Operating	(1,027)	(973)	(54)	6 %
Non-operating	(208)	—	(208)	— %
Total	(1,235)	(973)	(262)	27 %
Net loss	$(3,786)	$(2,750)	$(1,036)	38 %

Revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the three months ended September 30, 2017, and 2016.

Cost of product revenue

During the quarter, the business component associated with sales of Serenz was determined to meet the criteria as a discontinued operations and, accordingly, operating activities for the Serenz product component is reported in Discontinued Operations for the three months ended September 30, 2017, and 2016.

Research and development expense

Research and development expense in the three months ended September 30, 2017 increased $274,000 compared to the three months ended September 30, 2016. The increase was due primarily to expenditures for clinical services to advance DCCR development and legal fees associated with intellectual property related to DCCR.

Sales and marketing expense

No sales and marketing expenses were reported in continuing operations during the three months ended September 30, 2017, and 2016 as the Company's remaining sales operations are related to the Serenz product, which is included in discontinued operations.

General and administrative expense
General and administrative expense in the three months ended September 30, 2017 increased $447,000 compared to the three months ended September 30, 2016, due primarily to the expense of amortizing intangible assets acquired in the Essentialis merger completed in March 2017.

Interest and other income (expense), net
Interest and other expense, net in the three months ended September 30, 2017 decreased $53,000 compared to the three months ended September 30, 2016, due primarily to the change in the fair value of the Series A warrants.

Comparison of the three and nine months ended September 30, 2017, and 2016, from discontinued operations
Revenue
During the nine months ended September 30, 2017, and 2016, the Company's revenues were generated by product sales for the CoSense, Precision Sampling Sets, Serenz, and NFI, whose product portfolio consists of neonatology resuscitation devices. These medical device products are associated with operations discontinued by the Company and sales have declined as the Company has focused its efforts sell or otherwise monetize these operations. Sales by the Company of the NFI products ceased in July 2017 when the Company sold NFI to Holdings (see Note 5).
Cost of product revenue
Cost of product revenue has declined in relation to the decrease in sales activity, and resulting decrease in revenue, for the CoSense, Precision Sampling Sets, Serenz, and NFI products for which sales have declined as the Company has focused effort sell or otherwise monetize these discontinued operations.
Research and development expense
Research and development expense related to the CoSense, Precision Sampling Sets and NFI products, whose products are has declined as development efforts have been redirected by the Company to its therapeutic product, DCCR, into late-stage clinical development.
Sales and marketing expense
Sales and marketing expense, which consisted primarily of expenses incurred in the United Kingdom with efforts associated with the Company's sales effort for its discontinued Serenz products rimarily due to the cessation of sales of Serenz in the United Kingdom and the reduction of sales of all medical device products in the United States.
General and administrative expense
General and administrative expense associated with discontinued development and sale of medical device products reflects additional legal and professional expenses associated with efforts to reduce operations of medical device products and actively focus on efforts to sell or otherwise monetize thse operations..
Other income and (expense)
Other income and expense associated with discontinued operations has been nominal in the periods reported.
Loss on sale of assets
In July 2017 the Company completed the sale of stock of its wholly-owned subsidiary, NFI. The Company recorded a loss on the sale in the amount of $208,000 as the net book value of assets sold in the amount of $1.185 million exceeded the total proceeds of $977,000 (see Note 5).

Liquidity and Capital Resources

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,	
	2017	2016
	(in thousands)	
Cash Flows		
Net cash used in continuing operating activities	$(4,641)	$(5,956)
Net cash used in discontinued operating activities	(2,577)	(4,853)
Net cash used in operating activities	(7,218)	(10,809)
Net cash used in continuing investing activities	(577)	(22)
Net cash used in discontinued investing activities	716	(17)
Net cash used in investing activities	139	(39)
Net cash provided by continuing financing activities	10,000	10,768
Net cash provided by discontinued financing activities	—	—
Net cash provided by financing activities	10,000	10,768
Net increase (decrease) in cash and cash equivalents		
Continuing operations	4,783	4,790
Discontinued operations	(1,862)	(4,870)
Net increase (decrease) in cash and cash equivalents	$2,921	$(80)

Continuing Operations

Cash used in operating activities

During the nine months ended September 30, 2017, operating activities used net cash of approximately $4.6 million, which was primarily due to the use of funds resulting in the operating loss of $7.6 million, partially offset by non-cash expenses which were primarily $1.0 million of non-cash amortization and depreciation, approximately $855,000 of non-cash stock compensation expense, approximately $600,000 of non-cash expense for issuing shares to Aspire Capital, and approximately $200 thousand non-cash expense for board member fees paid with shares of the Company's stock.

During the nine months ended September 30, 2016, net cash used in operating activities was $6.0 million, which was due primarily to the use of funds resulting in the operating loss of approximately $5.3 million, including costs incurred to launch Serenz in the E.U. and excluding the non-cash income of $1.3 million from change in fair value of warrants, all of which were partially offset by approximately $560,000 of non-cash expense for stock-based compensation expense.

Cash used in investing activities

During the nine months ended September 30, 2017, we used $577,000 for investing activities resulting from $573,000 expenses incurred resulting from our merger with Essentialis and for the purchase of property and equipment in the amount of $4,000.

Cash provided by financing activities

During the Nine months ended September 30, 2017, cash provided by financing activities was $10 million resulting from the completion of the concurrent financing associated with the Essentialis merger.

During the nine months ended September 30, 2016, cash provided by financing activities was $10.8 million resulting from the second close under the 2015 Sabby Purchase Agreement and from the first and second close under the 2016 Sabby Purchase Agreement.

On March 7, 2017, the Company completed the merger with Essentialis. Concurrently, the Company issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the concurrent financing and issued 416,666 shares of common stock for an investment of $2 million from Aspire Capital.
As of September 30, 2017, The Company had cash and cash equivalents of approximately $5.6 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.The Company expects 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 the Company's ability to continue as a going concern for a period of twelve months from the date of this report.
Discontinued Operations

Cash used in operating activities

Net cash used in operating activities for the nine months ended September 30, 2017 totaled $2.6 million compared to $4.9 million for the nine months ended September 30, 2016 representing a decrease of $2.3 million. The decrease was primarily due to the lower comparative level of operating activities for the discontinued operations which resulted in lower cash requirements during the first half of 2017.

Cash used in investing activities

Net cash provided by investing activities for the nine months ended September 30, 2017 totaled $716,000 compared to net cash used of $17,000 for investing activities in the nine months ended September 30, 2016, resulting primarily from the sale of the NFI operations in July 2017 which eliminated operating expenditures from that activity and for cash proceeds of $862,000 from the sale collected prior to September 30, 2017.

Cash provided by financing activities

There were no financing activities related to discontinued operations during either period.

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 month period ended September 30, 2017. 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, under the supervision and with the participation of our Chief Executive Officer, who also currently serves as our principal financial and accounting 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 has 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, 2017, 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

On February 16, 2017, a purported stockholder class action lawsuit captioned Garfield v. Capnia, Inc., et al., Case No. C17-00284, or the Lawsuit, was filed in Superior Court of the State of California, County of Contra Costa against us and certain of our officers and directors. The Lawsuit alleged, generally, that our directors breached their fiduciary duties to our stockholders by seeking to sell control of the company through an allegedly defective process, and on unfair terms. The Lawsuit also alleged that defendants failed to disclose all material facts concerning the merger with Essentialis to stockholders. The Lawsuit sought, among other things, equitable relief that would have enjoined the consummation of the merger, compensatory and/or rescissory damages, and attorneys' fees and costs.

On February 28, 2017, we settled the Lawsuit by making certain supplemental disclosures in a Current Report on Form 8-K filed with the SEC on February 28, 2017 in connection with the plaintiff's agreement to voluntarily dismiss plaintiff's claims in the Lawsuit. We also agreed to pay $175,000 in attorney's fees. This amount was accrued as a current liability on the balance sheet as of December 31, 2016, and recorded as a general and administrative expense on the statement of operations for the year ended December 31, 2016. The stipulation of dismissal was approved by the court on April 14, 2017.

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. However, litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

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 described below together with all the of the other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. If any of the following 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.

Risks related to our financial condition and capital requirements

We have a limited commercialization history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the foreseeable future. We have generated limited commercial sales to date, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a developer of therapeutics with a limited commercialization history. Evaluating our performance, viability or future success will be more difficult than if we had a longer operating history or approved products for sale on the market. We continue to incur significant research and development and general and administrative expenses related to our operations. Investment in medical product development is highly speculative, because it entails substantial upfront capital expenditures and significant risk that any planned product will fail to demonstrate adequate accuracy or clinical utility. We have incurred significant operating losses in each year since our inception, and expect that we will not be profitable for an indefinite period of time. As of September 30, 2017, we had an accumulated deficit of $108.9 million.

We expect that our future financial results will depend primarily on our success in launching, selling and supporting our therapeutic products. This will require us to be successful in a range of activities, including manufacturing, marketing and selling our products. We are only in the preliminary stages of some of these activities. We may not succeed in these activities and may never generate revenue that is sufficient to be profitable in the future. Even if we are profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our planned products, market our current and planned products, or continue our operations.

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We currently have generated limited product revenue and may never become profitable.

To date, we have not generated significant revenues to achieve profitability. Our ability to generate significant revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize products that we may develop, in-license or acquire in the future. Our ability to generate revenue from product sales from planned products also depends on a number of additional factors, including our ability to:

- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- achieve market acceptance of our current and future products, if any;
- set a commercially viable price for our current and future products, if any;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing to maintain that supply;
- obtain coverage and adequate reimbursement from third-party payors, including government and private payors;
- find suitable global and U.S. distribution partners to help us market, sell and distribute our commercial products in other markets;
- complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
- complete development activities successfully and on a timely basis;
- establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with product development and commercialization, including that our planned products may not advance through development, achieve the endpoints of applicable clinical trials or obtain approval, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or clinical trials in addition to those that we currently anticipate.

Even if we are able to generate significant revenue from the sale of any of our products that may be approved or commercialized, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or shut down our operations.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or below our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into collaboration agreements with other companies that include development funding and significant upfront and milestone payments or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under any potential future collaboration and license agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period, and any such variance could cause a significant fluctuation in our operating results from one period to the next. In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our Board of Directors, and recognize the cost as an expense over the employee’s requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the cost and risk of initiating sales and marketing activities;
- the timing and cost of, and level of investment in, research and development activities relating to our planned products, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;

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- the cost of manufacturing our products may vary depending on FDA and other regulatory requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional planned products and technologies;
- the design, timing and outcomes of clinical studies;
- changes in the competitive landscape of our industry, including consolidation among our competitors or potential partners;
- any delays in regulatory review or approval in the U.S., or, if applicable, globally, of any of our planned products;
- the level of demand for our products may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our future products, if approved, and existing and potential future drugs that compete with our planned products;
- competition from existing and potential future offerings that compete with our products;
- our ability to commercialize our products inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

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 condensed 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, 2017, we have incurred significant operating losses since inception and continue to generate losses from operations and has an accumulated deficit of $108.9 million. These matters raise substantial doubt about our ability to continue as a going concern. 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.

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 its operations. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds through 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, 2017, our cash balance was $5.6 million. We intend to raise additional capital, either through debt or equity financings to achieve its business plan objectives. 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.

The extent to which we utilize the 2017 Aspire Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the 2017 Aspire Purchase Agreement on any given day and during the term of the agreement is limited. Additionally, we and Aspire Capital may not effect any sales of shares of our common stock under the 2017 Aspire Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than $1.25 per share. Even if we are able to access the full $17.0 million under the 2017 Aspire Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions, asset purchases and sales, and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures, could not result in perceived benefits that were contemplated upon entering into the transaction, and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations, solvency and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown and contingent liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- the timing and likelihood of payment of milestones or royalties;
- write-downs of assets or goodwill or impairment charges;
- increased operating expenditures, including additional research, development and sales and marketing expenses;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel; and
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above or that we will achieve an economic benefit that justifies such transactions,

any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be able to enter into strategic transactions on a timely basis or on acceptable terms, which may impact our development and commercialization plans.

We have relied, and expect to continue to rely, on strategic transactions, which include in-licensing, out-licensing, purchases and sales of assets, and other ventures. The terms of any additional strategic transaction that we may enter into may not be favorable to us, and the contracts governing such strategic transaction may be subject to differing interpretations exposing us to potential litigation. We may also be restricted under existing collaboration or licensing arrangements from entering into future agreements on certain terms with potential strategic partners. We may not be able to negotiate additional strategic transactions on a timely basis, on acceptable terms, or at all. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our products or bring them to market and generate product revenue. Furthermore, there is no assurance that any such transaction will be successful or that we will derive an economic benefit as a result.

Risks Relating to the Company after the Merger with Essentialis

Completion of the Merger and concurrent financing transactions, which happened on March 7, 2017, resulted in the issuance of a significant amount of additional common stock, which could depress the trading price of our common stock.

The Merger and concurrent financing resulted in the issuance of a significant amount of our common stock. The common stock issued in the Merger and concurrent financing represents an increase in the outstanding our common stock as of the date of the completion of the Merger of up to approximately 172% of the common stock currently outstanding. The issuance of such a significant amount of our common stock could depress the trading price of our common stock and you may lose all or a part of your investment.

Our executive officers, directors and principal stockholders will maintain the ability to control or significantly influence all matters submitted to stockholders for approval and under certain circumstances may have control over key decision making.

Our executive officers, directors and principal stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures, Forward Ventures, Technology Partners and our Chairman, Ernest Mario, as of September 30, 2017, own approximately 61.7% of our common stock. As a result, the forgoing group of stockholders are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Failure to retain key employees could diminish the benefits of the Merger and concurrent financing transactions.

Continued success will depend in part on the retention of key personnel at Essentialis, including senior management. There can be no assurances that we will be able to retain Essentialis’s key personnel. In addition, no assurance can be given that after the transactions, that we will be able to attract or retain key management personnel and other key employees to the same extent that we or Essentialis had been previously able to attract or retain their own employees.

We are now primarily a clinical-stage company with no approved products, which makes assessment of our future viability difficult.

We are now primarily a clinical-stage company, with a relatively limited operating history upon and with no approved therapeutic products or revenues from the sale of therapeutic products. Essentialis’s operations prior to the Merger had been limited to organizing, staffing and financing, applying for patent rights, undertaking clinical trials of its primary product candidate, DCCR, and engaging in research and development. Prior to the Merger, Essentialis had not yet demonstrated an ability to obtain regulatory approval, manufacture commercial-scale products, or conduct the sales and marketing activities necessary for successful product commercialization. As a result, there is limited information about Essentialis for investors to use when assessing our future viability as a combined company and our potential to

successfully develop product candidates, conduct clinical trials, manufacture our products on a commercial scale, obtain regulatory approval and profitably commercialize any approved products.

We will now be significantly dependent upon the success of DCCR, our sole therapeutic product candidate.

Prior to the Merger, Essentialis had invested, and following the Merger, we expect to continue to invest, a significant portion of our efforts and financial resources in the development of DCCR for the treatment of PWS, a rare complex genetic neurobehavioral/metabolic disease. Our ability to generate product revenues, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval, and commercialization of DCCR.

Any delay or impediment in our ability to obtain regulatory approval to commercialize in any region, or, if approved, obtain coverage and adequate reimbursement from third-parties, including government payors, for DCCR, may cause us to be unable to generate the revenues necessary to continue our research and development pipeline activities, thereby adversely affecting our business and our prospects for future growth. Further, the success of DCCR will depend on a number of factors, including the following:

- obtain a sufficiently broad label that would not unduly restrict patient access;
- receipt of marketing approvals for DCCR in the U. S. and E. U.;
- building an infrastructure capable of supporting product sales, marketing, and distribution of DCCR in territories where we pursue commercialization directly;
- establishing commercial manufacturing arrangements with third party manufacturers;
- establishing commercial distribution agreements with third party distributors;
- launching commercial sales of DCCR, if and when approved, whether alone or in collaboration with others;
- acceptance of DCCR, if and when approved, by patients, the medical community, and third party payors;
- the regulatory approval pathway that we pursue for DCCR in the United States;
- effectively competing with other therapies;
- a continued acceptable safety profile of DCCR following approval;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio; and
- obtaining a commercially viable price for our products.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize DCCR, which would materially harm our business.

If we fail to obtain regulatory approval for DCCR in the U.S. and E.U., our business would be harmed.

We are required to obtain regulatory approval for each indication we are seeking before we can market and sell DCCR in a particular jurisdiction, for such indication. Our ability to obtain regulatory approval of DCCR depends on, among other things, successful completion of clinical trials by demonstrating efficacy with statistical significance and clinical meaning, and safety in humans. The results of our current and future clinical trials may not meet the FDA, the European Medicines Agency, or EMA, or other regulatory agencies' requirements to approve DCCR for marketing under any specific indication, and these regulatory agencies may otherwise determine that our third parties' manufacturing processes, validation, and/ or facilities are insufficient to support approval. As such, we may need to conduct more clinical trials than we currently anticipate and upgrade the manufacturing processes and facilities, which may require significant additional time and expense, and may delay or prevent approval. If we fail to obtain regulatory approval in a timely manner, our commercialization of DCCR would be delayed and our business would be harmed.

If we are unable to implement our sales, marketing, distribution, training and support strategies or enter into agreements with third parties to perform these functions in markets outside of the U.S. and E.U., we will not be able to effectively commercialize DCCR and may not reach profitability.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of therapeutic products. To achieve commercial success for DCCR, if and when we obtain marketing approval, we will need to establish a sales and marketing organization.

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In the future, we expect to build a targeted sales, marketing, training and support infrastructure to market DCCR in the U.S. and E.U. and to opportunistically establish collaborations to market, distribute and support DCCR outside of the U.S. and E.U. There are risks involved with establishing our own sales, marketing, distribution, training and support capabilities. For example, recruiting and training sales and marketing personnel is expensive and time consuming and could delay any product launch. If the commercial launch of DCCR is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales, marketing, training and support personnel.

Factors that may inhibit our efforts to commercialize DCCR on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe DCCR or any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- efforts by our competitors to commercialize products at or about the time when our product candidates would be coming to market.

If we are unable to establish our own sales, marketing, distribution, training and support capabilities and instead enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute DCCR ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute DCCR or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to commercialize DCCR effectively. If we do not establish sales, marketing, distribution, training and support capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing DCCR and achieving profitability, and our business would be harmed.

If the market opportunity for DCCR is smaller than we believe it is, then our revenues may be adversely affected and our business may suffer.

PWS is a rare disease, and as such, our projections of both the number of people who have this disease, as well as the subset of people with PWS who have the potential to benefit from treatment with our product candidate, are based on estimates.

Currently, most reported estimates of the prevalence of PWS are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the broader world population. In addition, as new studies are performed the estimated prevalence of these diseases may change. There can be no assurance that the prevalence of PWS in the study populations, particularly in these newer studies, accurately reflects the prevalence of this disease in the broader world population. If our estimates of the prevalence of PWS, or of the number of patients who may benefit from treatment with our product candidates prove to be incorrect, the market opportunities for our product candidate may be smaller than we believe it is, our prospects for generating revenue may be adversely affected and our business may suffer.

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 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.

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 be unable to obtain regulatory approval for DCCR or other potential product candidates following the merger. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, record keeping, marketing, distribution, post-approval monitoring and reporting, and export and import of drug products are subject to extensive regulation by the FDA, and by foreign regulatory authorities in other countries. The

legislation and regulations differ from country to country. To gain approval to market our product candidates, we must provide development, manufacturing and

clinical data that adequately demonstrates the safety and efficacy of the product for the intended indication. We have not yet obtained regulatory approval to market any of our product candidates in the U.S. or any other country. Our business depends upon obtaining these regulatory approvals. The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate that the product candidates are safe and effective for the requested indication;
- the FDA's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial may not be sufficiently broad or representative to assess safety in the full population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that additional preclinical or clinical trials are required;
- the FDA's non-approval of the formulation, labeling or the specifications of our product candidates;
- the FDA's failure to accept the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations and prospects.

Even if DCCR receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.

If DCCR receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community. If DCCR does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third party coverage or reimbursement.

Our ability to negotiate, secure and maintain third party coverage and reimbursement may be affected by political, economic and regulatory developments in the U.S., E.U., and other jurisdictions. Governments continue to impose cost containment measures, and third party payors are increasingly challenging prices charged for medicines and examining their

cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of DCCR or any of our other potential product candidates that receive marketing approval.

Our patent rights may prove to be an inadequate barrier to competition following the completion of the Merger.

We are the sole owner of patents and patent applications in the U.S. with claims covering the compounds underlying our primary product candidate, DCCR. Foreign counterparts of these patents and applications have been issued in the E.U., Japan, China, Canada, Australia, India and Hong Kong. However, the lifespan of any one patent is limited, and each of these patents will ultimately expire and we cannot be sure that pending applications will be granted, or that we will discover new inventions which we can successfully patent. Moreover, any of our granted patents may be held invalid by a court of competent jurisdiction, and any of these patents may also be construed narrowly by a court of competent jurisdiction in such a way that it is held to not directly cover DCCR. Furthermore, even if our patents are held to be valid and broadly interpreted, third parties may find legitimate ways to compete with DCCR by inventing around our patent. Finally, the process of obtaining new patents is lengthy and expensive, as is the process for enforcing patent rights against an alleged infringer. Any such litigation could take years, cost large sums of money and pose a significant distraction to management. Indeed, certain jurisdictions outside of the U.S. and E.U., where we hope to initially commercialize DCCR have a history of inconsistent, relatively lax or ineffective enforcement of patent rights. In such jurisdictions, even a valid patent may have limited value. Our failure to effectively prosecute our patents would have a harmful impact on our ability to commercialize DCCR in these jurisdictions.

Risks related to the development and commercialization of our products

We may not be successful in commercializing our approved products

Commercialization of products is subject to a variety of regulations regarding the manner in which potential customers may be engaged, the manner in which products may be lawfully advertised, and the claims that can be made for the benefits of the product, among other things. Our lack of experience with product launches may expose us to a higher than usual level of risk of non-compliance with these regulations, with consequences that may include fines or the removal of our approved products from the marketplace by regulatory authorities.

If we are unable to execute our sales and marketing strategy for our products, and are unable to gain acceptance in the market, we may be unable to generate sufficient revenue to sustain our business.

Although we believe that DCCR and our other planned products represent promising commercial opportunities, our products may never gain significant acceptance in the marketplace and therefore may never generate substantial revenue or profits for us. We will need to establish a market for DCCR globally and build these markets through physician education, awareness programs, and other marketing efforts. Gaining acceptance in medical communities depends on a variety of factors, including clinical data published or reported in reputable contexts and word-of-mouth between physicians. The process of publication in leading medical journals is subject to a peer review process and peer reviewers may not consider the results of our studies sufficiently novel or worthy of publication. Failure to have our studies published in peer-reviewed journals may limit the adoption of our products. Our ability to successfully market our products will depend on numerous factors, including:

- the outcomes of clinical utility studies of such products in collaboration with key thought leaders to demonstrate our products' value in informing important medical decisions such as treatment selection;
- the success of our distribution partners;
- whether healthcare providers believe such tests provide clinical utility;
- whether the medical community accepts that such tests are sufficiently sensitive and specific to be meaningful in patient care and treatment decisions; and
- whether hospital administrators, health insurers, government health programs and other payors will cover and pay for such tests and, if so, whether they will adequately reimburse us.

We are relying, or will rely, on third parties with whom we are directly engaged with, but who we do not control, to distribute and sell our products. If these distributors are not committed to our products or otherwise run into their own financial or other difficulties, it may result in failure to achieve widespread market acceptance of our products, and would materially harm our business, financial condition and results of operations.

If physicians decide not to order our products in significant numbers, we may be unable to generate sufficient revenue to sustain our business.

To generate demand for our current and planned products, we will need to educate physicians and other health care professionals on the clinical utility, benefits and value of the tests we provide through published papers, presentations at scientific conferences, educational programs and one-on-one education sessions by members of our sales force. In addition, we will need support of hospital administrators that the clinical and economic utility of our products justifies payment for the device and consumables at adequate pricing levels. We need to hire additional commercial, scientific, technical and other personnel to support this process.

If our products do not continue to perform as expected, our operating results, reputation and business will suffer.

Our success depends on the market's confidence that our products can provide reliable, high-quality results or treatments. We believe that our customers are likely to be particularly sensitive to any test defects and errors in our products, and prior products made by other companies for the same diagnostic purpose have failed in the marketplace, in part as a result of poor accuracy. As a result, the failure of our current and planned products to perform as expected would significantly impair our reputation and the clinical usefulness of such tests. Reduced sales might result, and we may also be subject to legal claims arising from any defects or errors.

If clinical studies of any of our planned products fail to demonstrate safety and effectiveness to the satisfaction of the FDA or similar regulatory authorities outside the U.S. or do not otherwise produce positive results, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of our planned products.

Before obtaining regulatory approval for the sale of any planned product we must conduct extensive clinical studies to demonstrate the safety and effectiveness of our planned products in humans. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing.

Numerous unforeseen events during, or as a result of, clinical studies could occur, which would delay or prevent our ability to receive regulatory approval or commercialize any of our planned products, including the following:

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate or patients may drop out of these clinical studies at a higher rate than we anticipate;
- the cost of clinical studies or the manufacturing of our planned products may be greater than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical studies of our planned products for various reasons, including a finding that our planned products have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;
- regulators may not approve our proposed clinical development plans;
- regulators or independent institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and
- the supply or quality of our planned products or other materials necessary to conduct clinical studies of our planned products may be insufficient or inadequate.

If we or any future collaboration partners are required to conduct additional clinical trials or other testing of any planned products beyond those that we contemplate, if those clinical studies or other testing cannot be successfully completed, if the results of these studies or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our planned products;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;

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- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any clinical studies will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our planned products or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our planned products and harm our business and results of operations.

Even if any planned products receive regulatory approval, these products may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.

If any planned products receive regulatory approval from the FDA or other regulatory agencies in jurisdictions in which they are not currently approved, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of our planned products, if approved for commercial sale, will depend on a number of factors, including the following:

- the prevalence and severity of any side effects;
- their effectiveness and potential advantages compared to alternative treatments;
- the price we charge for our planned products;
- the willingness of physicians to change their current treatment practices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength or effectiveness of marketing and distribution support or partners; and
- the availability of third-party coverage or reimbursement.

For example, a number of companies offer therapies for treatment of AR patients based on a daily regimen, and physicians, patients or their families may not be willing to change their current treatment practices in favor of Serenz even if it is able to offer additional efficacy or more attractive product attributes. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis or at all.

We currently have limited sales and distribution personnel, and limited marketing capabilities. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing our products, or other planned products.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming, and could delay any product launch. If the commercial launch of a planned product for which we recruit a sales force and establish marketing capabilities is delayed, or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

To achieve commercial success for any approved product, we must either develop a sales and marketing infrastructure or outsource these functions to third parties. We also may not be successful entering into arrangements with third parties to sell and market our planned products or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and could damage our reputation. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our planned products.

We may attempt to form partnerships with respect to our products, but we may not be able to do so, which may cause us to alter our development and commercialization plans, and may cause us to terminate any such programs.

We may form strategic alliances, create joint ventures or collaborations, or enter into licensing agreements with third parties that we believe will more effectively provide resources to develop and commercialize our programs. For example, we currently intend to identify one or more new partners or distributors for the commercialization of our products.

We face significant competition in seeking appropriate strategic partners, and the negotiation process to secure favorable terms is time-consuming and complex. In addition, the termination of our license agreement for Serenz with our former partner, may negatively impact the perception of Serenz held by other potential partners for the program. We may not be successful in our efforts to establish such a strategic partnership for any future products and programs on terms that are acceptable to us, or at all.

Any delays in identifying suitable collaborators and entering into agreements to develop or commercialize our future products could negatively impact the development or commercialization of our future products, particularly in geographic regions like the E.U., where we do not currently have development and commercialization infrastructure. Absent a partner or collaborator, we would need to undertake development or commercialization activities at our own expense. If we elect to fund and undertake development and commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our future products or bring them to market, and our business may be materially and adversely affected.

Our products may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial desirability of an approved label or result in significant negative consequences following any marketing approval.

The risk of failure of clinical development is high. It is impossible to predict when or if any planned products will prove safe enough to receive regulatory approval. Undesirable side effects caused by any of our products could cause us or regulatory authorities to interrupt, delay or halt clinical trials or could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Additionally, if any of our planned products receives additional marketing approvals, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular planned product, if approved.

We face competition, which may result in others discovering, developing or commercializing products before we do, or more successfully than we do.

Alternatives exist for our products and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, medical device companies, and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell AR therapies to our target patient group. These companies may reduce prices for their competing drugs in an effort to gain or retain market share, and

undermine the value our products might otherwise be able to

offer to payors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified technical and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to maintain our existing partners in commercializing our products, they may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more planned products, even if our planned products obtain regulatory approval.

Our ability to commercialize our products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any planned product that we successfully develop.

In the U.S., eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower cost products that are already reimbursed and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the U.S. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies.

Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. In some foreign countries, including major markets in the E.U. and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take nine to twelve months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. Our business could be materially harmed if reimbursement of our products, if any, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our products. The marketing, sale and use of our products could lead to the filing of product liability claims against us if someone alleges that our tests failed to perform as

designed. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that our products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any planned products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from clinical studies or cancellation of studies;
- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently hold $8.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions, including Dr. Anish Bhatnagar, our Chief Executive Officer, Chief Financial Officer, Neil M. Cowen, our Senior Vice President of Drug Development, and Kristen Yen, our Vice President of Clinical Operations. The collective efforts of each of these persons, and others working with them as a team, are critical to us as we continue to develop our technologies, tests and research and development and sales programs. As a result of the difficulty in locating qualified new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy. Our officers all have employment agreements; however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We have secured a $1,000,000 “key person” life insurance policy on our Chief Executive Officer, Dr. Anish Bhatnagar, but do not otherwise maintain “key person” life insurance on any of our employees.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments under agreements with other entities that may limit their availability to us.

Management turnover creates uncertainties and could harm our business

We have recently experienced changes in our executive leadership. Specifically, on August 29, 2017, David O'Toole, Senior Vice President and Chief Financial Officer, notified us of his decision to resign form employment effective September 11, 2017. Mr. Jonathan Wolter, a partner at FLG Partners, LLC, was retained as our interim Chief Financial Officer; however, no permanent replacement has been appointed. We also expect that we may have other officers leave as we rationalize our legacy business and focus on our DCCR development program. Changes to strategic or operating goals, which can often times occur with the appointment of new executives, can create uncertainty, may negatively impact our ability to execute quickly and effectively, and may ultimately be unsuccessful. In addition, executive leadership transition periods are often difficult as the new executives gain detailed knowledge of our operations, and friction can result from changes in strategy an management style. Management turnover inherently causes some loss of institutional knowledge, which can negatively affect strategy and execution. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business, and our financial condition and profitability may suffer.

Further, to the extent we experience additional management turnover, competition for top management is high and it may take months to find a candidate that meets our requirements. If we are unable to attract and retain qualified management personnel, our business could suffer.

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There is a scarcity of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among biotechnology businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions or licenses of assets or acquisitions of businesses, including the Merger with Essentialis pursuant to the Merger Agreement. We completed the Merger with Essentialis on March 7, 2017, and concurrently with the closing of the Merger, completed financing transaction with total aggregate proceeds of approximately $10 million from current stockholders and new investors. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution resources. Our company has limited experience with acquiring other companies, acquiring or licensing assets or forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations.

We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

International expansion of our business will expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S.

Our business strategy contemplates international expansion, including partnering with distributors, and introducing our current products and other planned products outside the U.S. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- potential failure by us or our distributors to obtain regulatory approvals for the sale or use of our current products and our planned future products in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;
- limits on our ability to penetrate international markets if our distributors do not execute successfully;
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financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;

- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;

- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

Intrusions into our computer systems could result in compromise of confidential information.

The accuracy of CoSense depends, in part, on the function of software run by the microprocessors embedded in the device. This software is proprietary to us. While we have made efforts to test the software extensively, it is potentially subject to malfunction. It may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, or similar problems. Any of these might result in confidential medical, business or other information of other persons or of ourselves being revealed to unauthorized persons.

The CoSense monitor also stores test results, a feature which assists medical professionals in interfacing the device with electronic medical records systems. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's protected healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements for individuals whose health information has been inappropriately accessed or disclosed: notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

Risks related to the operation of our business

Any future distribution or commercialization agreements we may enter into for our products may place the development of these products outside our control, may require us to relinquish important rights, or may otherwise be on terms unfavorable to us.

We may enter into additional distribution or commercialization agreements with third parties with respect to our products. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size companies, regional and national companies, and distribution or group purchasing organizations. We will have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our products. Our ability to generate revenue from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our products are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to any such collaborations;

- collaborators may not pursue development and commercialization of our products, or may elect not to continue or renew efforts based on clinical study results, changes in their strategic focus for a variety of

reasons, potentially including the acquisition of competitive products, availability of funding, and mergers or acquisitions that divert resources or create competing priorities;

- collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a product, repeat or conduct new clinical studies or require a new engineering iterations of a product for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable products; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

Any termination or disruption of collaborations could result in delays in the development of products, increases in our costs to develop the products or the termination of development of a product.

We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2017, we had 14 employees and 16 full-time or part-time consultants. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, quality assurance, engineering, product development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;
- identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- managing additional relationships with various strategic partners, suppliers and other third parties;
- improving our managerial, development, operational and finance reporting systems and procedures; and
- expanding our facilities.

Our failure to accomplish any of these tasks could prevent us from successfully growing. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Because we intend to commercialize our products outside the U.S., we will be subject to additional risks.

A variety of risks associated with international operations could materially adversely affect our business, including:

- different regulatory requirements for drug approvals in foreign countries;

- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires

We rely on third parties to conduct certain components of our clinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies.

We rely on third parties, such as contract research organizations, or CROs, investigational product packaging, labeling and distribution, laboratories, medical institutions and clinical investigators and staff, to perform various functions for our clinical trials. Our reliance on these third parties for clinical development activities reduces our control over these activities but does not relieve us of our responsibilities. We remain responsible for ensuring that each of our clinical studies is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us and third parties involved in the set-up, conduct, analysis and reporting of the clinical studies to comply with regulations and with standards, commonly referred to as good clinical practices, or GCP, to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical studies are protected. Our clinical investigators are also required to comply with GCPs. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our planned products and will not be able to, or may be delayed in our efforts to, successfully commercialize our planned products.

If we use biological and hazardous materials in a manner that causes injury, we could be liable for damages.

Our manufacturing processes currently require the controlled use of potentially harmful chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject to, on an ongoing basis, federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. These are particularly stringent in California, where our Cosense manufacturing facility and several suppliers are located. The cost of compliance with these laws and regulations may become significant and could have a material adverse effect on our financial condition, results of operations and cash flows. In the event of an accident or if we otherwise fail to comply with applicable regulations, we could lose our permits or approvals or be held liable for damages or penalized with fines.

Risks related to intellectual property

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Patent litigation is prevalent in our sectors. Our commercial success depends upon our ability and the ability of our distributors, contract manufacturers, and suppliers to manufacture, market, and sell our planned products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue

developing and marketing our products and technology.

We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees.

We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our planned products or force us to cease some of our business operations, which could materially harm our business. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we fail to comply with our obligations in our intellectual property agreements, we could lose intellectual property rights that are important to our business.

We are a party to intellectual property arrangements and expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, any licensor may have the right to terminate such agreements, in which event we may not be able to develop and market any product that is covered by such agreements.

The risks described elsewhere pertaining to our intellectual property rights also apply to any intellectual property rights that we may license, and any failure by us or any future licensor to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business.

Our ability to successfully commercialize our technology and products may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights for our technologies and planned products, or if the scope of the intellectual property protection is not sufficiently broad.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the U.S. and in other countries with respect to our proprietary technology and products.

The patent position of pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that

we were the first to make the inventions claimed in our patents or pending patent applications, or that we or were the first to file for patent protection of such inventions.

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

We may become involved in legal proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming, or unsuccessful.

Competitors may infringe or otherwise violate the patents we rely on, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, in an infringement proceeding, a court may decide that a patent we are asserting is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents we are asserting do not cover the technology in question. An adverse result in any litigation proceeding could put one or more patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to patents and patent applications. We may become involved in proceedings, including oppositions, interferences, derivation proceedings inter partes reviews, patent nullification proceedings, or re-examinations, challenging our patent rights or the patent rights of others, and the outcome of any such proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, important patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Our business also could be harmed if a prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may also become involved in disputes with others regarding the ownership of intellectual property rights. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical or management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary

information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information, however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or

violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the U.S. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

We may not be able to protect or enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our planned products throughout the world would be prohibitively expensive to us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the U.S. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to our current and planned products, but that are not covered by claims in our patents;
- The original filers of our patents that we developed or purchased might not have been the first to make the inventions covered by the claims contained in such patents;
- We might not have been the first to file patent applications covering an invention;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- Pending patent applications may not lead to issued patents;
- Issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop or in-license additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid by us to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application,

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resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.

In March 2013, under the America Invents Act, or AIA, the U.S. moved to a first-to-file system and made certain other changes to its patent laws. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. Accordingly, it is not yet clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, all of which could have a material adverse effect on our business and financial condition.

If we do not obtain a patent term extension in the U.S. under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for our planned products, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our products, if any, one or more of the U.S. patents covering any such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our planned products. Nevertheless, we may not be granted patent term extension either in the U.S. or in any foreign country because of, for example, our failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than requested, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks related to government regulation

The regulatory approval process is expensive, time consuming and uncertain, and may prevent us from obtaining approvals for our planned products.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of our products are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market our planned products in the U.S. until we received the requisite approval or clearance from the FDA. We have not submitted an application or received marketing approval for any planned products. Obtaining approvals from the FDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;
- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

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Prior to receiving approval to commercialize any of our planned products in the U.S. or abroad, we may be required to demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such planned products are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we believe the preclinical or clinical data for our planned products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our planned products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications. Regulatory approval from the FDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies, or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on the planned product, the disease or condition that the planned product is designed to address and the regulations applicable to any particular planned product. The FDA can delay, limit or deny approval of a planned product for many reasons, including, but not limited to, the following:

- a planned product may not be deemed safe or effective;
- FDA officials may not find the data from preclinical studies and clinical studies sufficient;
- the FDA might not approve our or our third-party manufacturer’s processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If any planned products fail to demonstrate safety and effectiveness in clinical studies or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

The research, development, conduct of clinical trials, manufacturing, labeling, approval, selling, import, export, marketing and distribution of pharmaceutical and biologic products also are subject to extensive regulation by the FDA in the U.S. and other regulatory authorities in other countries, which regulations differ from country to country.

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Nonclinical Testing

Before a drug candidate in can be tested in humans, it must be studied in laboratory experiments and in animals to generate data to support the drug candidate's potential benefits and safety. Additional nonclinical testing may be required during the clinical development process such as reproductive toxicology and juvenile toxicology studies. Carcinogencity studies in 2 species are generally required for products intended for long-term use.

Investigational New Drug exemption Application (IND)

The results of initial nonclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. If FDA does not identify significant issues during the initial 30-day IND review, the drug candidate can then be studied in human clinical trials to determine if the drug candidate is safe and effective. Each clinical trial protocol and/or amendment, new nonclinical data, and/or new or revised manufacturing information must be submitted to the IND, and the FDA has 30 days to complete its review of each submission.

Clinical Trials

These clinical trials involve three separate phases that often overlap, can take many years and are very expensive. These three phases, which are subject to considerable regulation, are as follows:

- Phase 1. The drug candidate is given to a small number of healthy human control subjects or patients suffering from the indicated disease, to test for safety, dose tolerance, pharmacokinetics, metabolism, distribution and excretion.
- Phase 2. The drug candidate is given to a limited patient population to determine the effect of the drug candidate in treating the disease, the best dose of the drug candidate, and the possible side effects and safety risks of the drug

candidate. It is not uncommon for a drug candidate that appears promising in Phase 1 clinical trials to fail in the more rigorous Phase 2 clinical trials.

- Phase 3. If a drug candidate appears to be effective and safe in Phase 2 clinical trials, Phase 3 clinical trials are commenced to confirm those results. Phase 3 clinical trials are conducted over a longer term, involve a significantly larger population, are conducted at numerous sites in different geographic regions and are carefully designed to provide reliable and conclusive data regarding the safety and benefits of a drug candidate. It is not uncommon for a drug candidate that appears promising in Phase 2 clinical trials to fail in the more rigorous and extensive Phase 3 clinical trials.

For each clinical trial, an independent IRB or independent ethics committee, covering each site proposing to conduct a clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials.

At any point in this process, the development of a drug candidate can be stopped for a number of reasons including safety concerns and lack of treatment benefit. We cannot be certain that any clinical trials that we are currently conducting or any that we conduct in the future will be completed successfully or within any specified time period. We may choose, or FDA may require us, to delay or suspend our clinical trials at any time if it appears that the patients are being exposed to an unacceptable health risk or if the drug candidate does not appear to have sufficient treatment benefit

FDA Approval Process

When we believe that the data from our clinical trials show an adequate level of safety and efficacy, we submit the application to market the drug for a particular use, normally a New Drug Application (NDA) with FDA. FDA may hold a public hearing where an independent advisory committee of expert advisors asks additional questions and makes recommendations regarding the drug candidate. This committee makes a recommendation to FDA that is not binding but is generally followed by FDA. If FDA agrees that the compound has met the required level of safety and efficacy for a particular use, it will allow the drug candidate in the United States to be marketed and sold for that use. It is not unusual, however, for FDA to reject an application because it believes that the risks of the drug candidate outweigh the purported benefit or because it does not believe that the data submitted are reliable or conclusive. The FDA may also issue a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

FDA may also require Phase 4 non-registrational studies to explore scientific questions to further characterize safety and efficacy during commercial use of our drug. FDA may also require us to provide additional data or information, improve our manufacturing processes, procedures or facilities or may require extensive surveillance to monitor the safety or benefits of our product candidates if it determines that our filing does not contain adequate evidence of the safety and benefits of the drug. In addition, even if FDA approves a drug, it could limit the uses of the drug. FDA can withdraw approvals if it does not believe that we are complying with regulatory standards or if problems are uncovered or occur after approval.

In addition to obtaining FDA approval for each drug, we obtain FDA approval of the manufacturing facilities for companies who manufacture our drugs for us. All of these facilities are subject to periodic inspections by FDA. FDA must also approve foreign establishments that manufacture products to be sold in the United States and these facilities are subject to periodic regulatory inspection.

Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems are identified after the product reaches the market. In addition, the FDA may require post-approval testing, including

Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require the development of additional data or conduct of additional pre-clinical studies and clinical trials.

Even if we receive marketing approval for a planned product, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once marketing approval has been obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. The current clearance for CoSense, as well as any additional regulatory approval that we receive for any planned products may be subject to limitations on the indicated uses for which the product may be marketed. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and effectiveness of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products.

In addition, we are required to comply with cGMP regulations regarding the manufacture of our drugs, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

Once an pharmaceutical product is approved, a product will be subject to pervasive and continuing regulation by the FDA, EMA, and other health authorities, including, among other things, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and generally require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP or QSR compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market, though the FDA must provide an application holder with notice and an opportunity for a hearing in order to withdraw its approval of an application. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
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product seizure or detention, or refusal to permit the import or export of products; and

- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug and device products that are placed on the market. While physicians may prescribe drugs and devices for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Drugs that treat serious or life threatening diseases and conditions that are not adequately addressed by existing drugs, and for which the development program is designed to address the unmet medical need, may be designated as fast track and/or breakthrough candidates by FDA and may be eligible for accelerated and priority review.

Drugs that are developed for rare diseases (i.e., in the U.S., the disease or condition has an incidence of < 200,000 persons; in the EU, the prevalence of the condition must be not more than 5 in 10,000) can be designated as Orphan Drugs. In the U.S., orphan-designated drugs are granted up to 7-year market exclusivity. In the EU, products granted orphan designation are subject to reduced fees for protocol assistance, marketing authorization applications, inspections before authorization, applications for changes to marketing authorizations, and annual fees, access to the centralized authorization procedure, and 10 years of market exclusivity.

Drugs are also subject to extensive regulation outside of the United States. In the European Union, there is a centralized approval procedure that authorizes marketing of a product in all countries of the European Union (which includes most major countries in Europe). If this centralized approval procedure is not used, approval in one country of the European Union can be used to obtain approval in another country of the European Union under one of two simplified application processes: the mutual recognition procedure or the decentralized procedure, both of which rely on the principle of mutual recognition. After receiving regulatory approval through any of the European registration procedures, separate pricing and reimbursement approvals are also required in most countries. The European Union also has requirements for approval of manufacturing facilities for all products that are approved for sale by the European regulatory authorities.

Failure to obtain marketing approvals in foreign jurisdictions will prevent us from marketing our products internationally.

We intend to seek distribution and marketing partners for our current products outside the U.S. and may market planned products in international markets. We have obtained a CE Mark certification for CoSense and Serenz and they are therefore authorized for sale in the E.U.; however, in order to market these products in Asia, Latin America and other foreign jurisdictions, we must obtain separate regulatory approvals.

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA and CE Mark certification does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

Healthcare reform measures could hinder or prevent our planned products' commercial success.

In the U.S., there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that could affect our future revenue and profitability and the future revenue and profitability of our potential customers. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. For example, one of the most significant healthcare reform measures in decades, the Patient Protection and Affordable Care Act of 2010, or PPACA, was enacted in 2010. The PPACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement changes and fraud and abuse measures, all of which will impact existing government healthcare programs and will

result in the development of new programs. The PPACA, among other things:

- imposes a tax of 2.3% on the retail sales price of medical devices sold after December 31, 2012;
- could result in the imposition of injunctions;

- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. In December of 2015, Congress passed a two-year suspension of the 2.3% medical device tax. If after two years, the suspension is not extended, at this time we believe the 2.3% tax on sales of medical devices will be applicable to sales of CoSense devices and may be applicable to CoSense consumables and Serenz devices. We cannot assure you that after the two-year suspension, the reinstatement of the 2.3% medical device tax would not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals for spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, which triggered the legislation's automatic reduction to several government programs, including aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, former President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by the sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of health care may adversely affect:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, changes in regulatory requirements and guidance may occur and we may need to amend clinical study protocols to reflect these changes. Amendments may require us to resubmit our clinical study protocols IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical study. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Governmental Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the recall and withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products or require safety surveillance or patient education. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical studies and the drug approval process. Data from clinical studies may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate or suspend clinical studies before completion, or require longer or additional clinical studies that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Given the serious public health risks of high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, preapproval of promotional materials and restrictions on

direct-to-consumer advertising.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The regulations that may affect our ability to operate include, without limitation:

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;
- the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the HHS information related to physician payments and other transfers of value and physician ownership and investment interests;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The PPACA, among other things, amends the intent requirement of the Federal Anti-Kickback Statute and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Risks related to ownership of our securities

Our stock price may be volatile, and purchasers of our securities could incur substantial losses.

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. During the period from September 30, 2016, through September 30, 2017, the reported high and low prices of our common stock ranged from $6.60 to $1.50. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the following:

- our ability to successfully commercialize, and realize significant revenues from sales of our products;
- the success of competitive products or technologies; results of clinical studies of our products or those of our competitors;

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- regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;
- introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or planned products;
- developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- developments concerning our ability to bring our manufacturing processes to scale in a costeffective manner;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- the other risks described in this “Risk Factors” section.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management’s attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. All of our shares of common stock are freely tradable, without restriction, in the public market, except for any shares held by our affiliates.

We have issued 13,780 shares of Series B Convertible Preferred Stock, of which 1,000 shares were converted into 200 shares of the Company's Common Stock in 2016 and 2,731 shares were converted into 546,200 shares of Common Stock during the nine months ended September 30, 2017. As of September 30, 2017, there are 10,049 shares of Series B Convertible Preferred Stock outstanding which are convertible into 2,009,800 shares of Common 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%.

In connection with the sale and issuance of Series B Convertible Preferred Stock to Sabby pursuant to the 2016 Sabby Purchase Agreement, we also amended the Series D Common Stock Purchase Warrants that were issued to Sabby under the

2015 Sabby Purchase Agreement. The per share exercise price of the common stock underlying the Series D Common Stock Purchase Warrants was reduced from $12.30 per share to $8.75 per share, which, if exercised, may result in sales of substantial amounts of the underlying common stock in the public market, or the perception that these sales may occur, and which could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

In addition, on March 7, 2017, we issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares may, in the future, be available for resale upon the filing of a registration statement that covers such shares and which has been declared effective by the SEC, and issued 416,666 shares of common stock for an investment of $2 million from Aspire Capital pursuant to the 2017 Aspire Purchase Agreement. Aspire Capital may ultimately purchase all, some or none of the $17.0 million worth of common stock, of which $2 million was sold on March 7, 2017, issuable under the 2017 Aspire Purchase Agreement, including the 141,666 commitment shares. All the shares issued under the 2017 Aspire Purchase Agreement are eligible for future resale under a registration statement on Form S-1 on February 1, 2017 that was declared effective by the SEC on February 15, 2017.

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, or IPO, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period under the JOBS Act.

Our executive officers, directors and principal stockholders may continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval and under certain circumstances Vivo Ventures, Technology Partners, Forward Ventures and its affiliates may have control over key decision making.

Our executive officers, directors and stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures, Forward Ventures, Technology Partners and our Chairman, Ernest Mario, as of September 30, 2017, own approximately 61.7% of our common stock. As a result, the forgoing group of stockholders are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will be required to continue to devote substantial time to new compliance initiatives.

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the SEC, and the rules and regulations of The NASDAQ Capital Market, or NASDAQ. The expenses of being a public company

are material, and compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, these rules and regulations may make it difficult and expensive for us to obtain adequate director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our Board of Directors, our board committees, or as executive officers.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404, beginning with our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, which was filed March 13, 2015. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources. Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

Our ability to use our net operating loss carry forwards and certain other tax attributes will be limited.

Our ability to utilize our federal net operating loss, carryforwards and federal tax credit will be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if an “ownership change,” as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect “five percent shareholders” increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period (typically three years). During the year ended December 31, 2016, we experienced an “ownership change”, which will limit our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income will be subject to limitations, which could potentially result in increased future tax liability to us.

Our common stock is eligible for sale and as a result, any such sales could depress the market price of our common stock.

As of September 30, 2017, we had Series A Warrants outstanding exercisable for an aggregate of 485,121 shares of common stock, Series C Warrants outstanding exercisable for an aggregate of 118,083 shares of common stock, Series D Warrants outstanding exercisable for an aggregate of 586,162 shares of common stock and other warrants

exercisable for an aggregate of 120,421 shares of common stock. As of September 30, 2017, we had 10,049 shares of Series B Convertible Preferred Stock outstanding exercisable for an aggregate of 2,009,800 shares of common stock. As of September 30, 2017, options to purchase 1,072,004 shares of our common stock were issued and outstanding with a weighted average exercise price of $9.90 per share. The sale or even the possibility of sale of the shares of common stock, or the exercise of options or warrants to purchase shares of our common stock and subsequent sale thereof could substantially reduce the market price for our common stock or our ability to obtain future financing.

In connection with the sale and issuance of Series B Convertible Preferred Stock to Sabby pursuant to the 2016 Sabby Purchase Agreement, we also amended the 540,540 Series D Common Stock Purchase Warrants issued to Sabby under the 2015 Sabby Purchase Agreement. The per share exercise price of the common stock underlying the Series D common stock Warrants was reduced from $12.30 per share to $8.75 per share. The sale or even the possibility of sale of the common stock or the underlying shares of common stock issuable upon the conversion of the Series A Convertible Preferred Stock or the Series B Convertible Preferred Stock, or upon exercise of the amended Series D Common Stock Purchase Warrants could substantially reduce the market price for our common stock or our ability to obtain future financing.

In addition, on March 7, 2017, we issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares may, in the future, be available for resale upon the filing of a registration statement that covers such shares and which has been declared effective by the SEC, and issued 416,666 shares of common stock for an investment of $2 million from Aspire Capital pursuant to the 2017 Aspire Purchase Agreement. Aspire Capital may ultimately purchase all, some or none of the $17.0 million worth of common stock, of which $2 million was sold on March 7, 2017, issuable under the 2017 Aspire Purchase Agreement, including the 141,666 commitment shares. All the shares issued under the 2017 Aspire Purchase Agreement are eligible for future resale under a registration statement on Form S-1 on February 1, 2017 that was declared effective by the SEC on February 15, 2017.

As our warrant holders exercise their warrants into shares of our common stock, our stockholders will be diluted.

The exercise of some or all of our warrants results in issuance of common stock that dilute the ownership interests of existing stockholders. Any sales of the common stock issuable upon exercise of the warrants could adversely affect prevailing market prices of our common stock.

If holders of our warrants elect to exercise their warrants and sell material amounts of our common stock in the market, such sales could cause the price of our common stock to decline, and the potential for such downward pressure on the price of our common stock may encourage short selling of our common stock by holders of our warrants or other parties.

If there is significant downward pressure on the price of our common stock, it may encourage holders of our warrants, or other parties, to sell shares by means of short sales or otherwise. Short sales involve the sale, usually with a future delivery date, of common stock the seller does not own. Covered short sales are sales made in an amount not greater than the number of shares subject to the short seller’s right to acquire common stock, such as upon exercise of warrants. A holder of warrants may close out any covered short position by exercising all, or a portion, of its warrants, or by purchasing shares in the open market. In determining the source of shares to close out the covered short position, a holder of warrants will likely consider, among other things, the price of common stock available for purchase in the open market as compared to the exercise price of the warrants. The existence of a significant number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

Under certain circumstances we may be required to settle the value of the Series A Warrants and Series C Warrants in cash.

If, at any time while the Series A Warrants and Series C Warrants are outstanding, we enter into a “Fundamental Transaction” (as defined in the Series A Warrant and Series C Warrant Agreements), which includes, but is not limited to, a purchase offer, tender offer or exchange offer, a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or other scheme of arrangement), then each registered holder of outstanding Series A Warrants and Series C Warrants as at any time prior to the consummation of the Fundamental Transaction, may elect and require us to purchase the Series A and Series C Warrants held by such person immediately prior to the consummation of such Fundamental Transaction by making a cash payment in an amount equal to the Black Scholes Value of the remaining unexercised portion of such registered holder’s Series A Warrants and Series C Warrants.

We might not be able to maintain the listing of our securities on The NASDAQ Capital Market.

We have listed our common stock and Series A Warrants on NASDAQ. We might not be able to maintain the listing standards of that exchange, which includes requirements that we maintain our shareholders’ equity, total value of

shares held by unaffiliated shareholders, market capitalization above certain specified levels and minimum bid requirement of $1.00 per common share. On October 24, 2016, we received a letter from the Listing Qualifications Department of NASDAQ indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we did not meet the minimum bid price of $1.00 per share required for continued listing on NASDAQ pursuant to Nasdaq Listing Rule 5550(a)(2). We were not in compliance with this minimum bid price requirement until we implemented a reverse stock split on October 6, 2017 at which time we effected a one-for-five reverse stock split of our outstanding common stock. In addition, we do not

expect to become profitable for some time and there is a risk that our shareholders' equity could fall below the $2.5 million level required by NASDAQ. If we do not regain compliance with the minimum bid requirement or our shareholders' equity falls below $2.5 million, it will cause us to fail to conform to the NASDAQ listing requirements on an ongoing basis, which in turn could cause our common stock to cease to trade on the NASDAQ exchange, and be required to move to the Over the Counter Bulletin Board or the "pink sheets" exchange maintained by OTC Markets Group, Inc. The OTC Bulletin Board and the "pink sheets" are generally considered to be markets that are less efficient, and to provide less liquidity in the shares, than the NASDAQ market.

Due to the speculative nature of warrants, there is no guarantee that it will ever be profitable for holders of the warrants to exercise the warrants.

The warrants we have issued and outstanding do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, holders of Series A Warrants may exercise their right to acquire the common stock and pay an exercise price of $32.50 per share prior to the expiration of the five-year term on November 12, 2019, after which date any unexercised Series A Warrants will expire and have no further value. Holders of Series C Warrants may exercise their right to acquire common stock and pay an exercise price of $31.25 per share prior to the expiration of the five-year term on March 4, 2020. Following amendment of the Series D Common Stock Purchase Warrants, the holders may exercise their right to acquire common stock and pay an amended exercise price of $8.75 per share prior to the expiration of the five-year term on October 15, 2020. In certain circumstances, the Series A Warrants, Series C Warrants, and Series D Warrants may be exercisable on a cashless basis. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

- our Board of Directors is divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our Board of Directors has the right to elect directors to fill a vacancy created by the expansion of our Board of Directors or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our Board of Directors;
- our stockholders are not able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock cannot take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by our Board of Directors, the chairman of our board, the chief

executive officer or the president;

- our certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- amendments of our certificate of incorporation and bylaws require the approval of 66 2/3% of our outstanding voting securities;
- our stockholders are required to provide advance notice and additional disclosures in order to nominate individuals for election to our Board of Directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our Board of Directors are able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our Board of Directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our employment agreements with our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately $1.4 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $1.1 million, in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be our stockholders' sole source of gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

The sale of our common stock to Aspire Capital and Sabby may cause substantial dilution to our existing stockholders and the sale of common stock by Aspire Capital and Sabby could cause the price of our common stock to decline.

We have registered for sale 1,858,333 shares of common stock that we may sell to Aspire Capital under the 2017 Aspire Purchase Agreement plus 141,666 shares of common stock that were commitment shares that we issued to Aspire Capital. Depending upon market liquidity at the time, sales of shares of our common stock under the 2017 Aspire Purchase Agreement, which we have previously registered for resale, may cause the trading price of our common stock to decline. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the 2017 Aspire Purchase Agreement, including the 141,666 commitment shares issued to it under the 2017 Aspire Purchase Agreement. Sales by Aspire Capital or any of the purchasers of our common stock in the concurrent financing may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the 2017 Aspire Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

We have also registered for sale the shares of common stock underlying the Series B Convertible Preferred Stock sold and issued, or available for sale and issuance, to Sabby pursuant to the 2016 Sabby Purchase Agreement. Sabby may sell all, some or none of our shares that it holds under the 2016 Sabby Purchase Agreement. The issuance of of the shares of common stock underlying the Series B Convertible Preferred Stock and the amended Series D Common Stock Purchase Warrants to Sabby may cause substantial dilution to our existing stockholders, and the sale of the

underlying shares of common stock by Sabby could cause the price of our common stock to decline. The sale of a substantial number of shares of our common stock by Sabby, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at

a time and at a price that we might otherwise wish to effect sales. The 2016 Sabby Purchase Agreement also provides Sabby a right to participate in any future sale of our equity securities.

In addition, on March 7, 2017, as contemplated by the Merger Agreement, we issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the concurrent financing, which shares are being registered in this offering.

Risks Associated with a Reverse Stock Split

On May 8, 2017, we received stockholder approval for a reverse stock split of our common stock at a ratio ranging between one-for-two (1:2) and one-for-ten (1:10), or the Reverse Split, pursuant to the proxy statement filed with the SEC on March 29, 2017. On October 6, 2017, the Company effected a one-for-five (1:5) Reverse Split of its Common Stock. Our board of directors expects that, over time, the Reverse Split of the outstanding common stock will increase the market price of the common stock. However, we cannot be certain whether the Reverse Split would lead to a sustained increase in the trading price or the trading market for our common stock. The Reverse Split could result in a significant devaluation of our market capitalization and trading price of the common stock. The history of similar stock split combinations for companies in like circumstances is varied. There is no assurance that:

- the market price per share of the common stock after the Reverse Split will rise in proportion to the reduction in the number of pre-split shares of common stock outstanding before the Reverse Split;
- the Reverse Split will result in a per share price that will attract brokers and investors, including institutional investors, who do not trade in lower priced stocks;
- the Reverse Split will result in a per share price that will increase our ability to attract and retain employees and other service providers;
- the market price per share post Revise Split will remain in excess of the $1.00 minimum closing bid price as required by the Nasdaq Marketplace Rules or that we would otherwise meet the requirements of Nasdaq for continued inclusion for trading on The Nasdaq Global Select Market or The Nasdaq Capital Market; and
- the Reverse Split will increase the trading market for our common stock, particularly if the stock price does not increase as a result of the reduction in the number of shares of common stock available in the public market.

The market price of the common stock will also be based on our performance and other factors, some of which are unrelated to the number of shares outstanding. As a result of the Reverse Split, the trading price of our common stock may decline, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of the Reverse Split. Furthermore, the liquidity of the common stock could be adversely affected by the reduced number of shares that would be outstanding after the Reverse Split and this could have an adverse effect on the market price of the common stock. If the market price of the common stock declines following the Reverse Split, this will detrimentally impact our market capitalization and the market value of our public float. The Reverse Split may result in some stockholders owning “odd lots” that may be more difficult to sell or require greater transaction costs per share to sell. The Reverse Split may result in some stockholders owning “odd lots” of less than 100 shares of common stock on a post-split basis. These odd lots may be more difficult to sell, or require greater transaction costs per share to sell, than shares in “round lots” of even multiples of 100 shares. As a result of the Reverse Split of all of the outstanding shares of our common stock at a ratio of one-for-five (1:5), certain stockholders might be fully cashed out in the Reverse Split and thus, such stockholders would no longer have any equity interest in us and therefore would not participate in our future earnings or growth, if any. The Reverse Split may not help generate additional investor interest.There can be no assurance that the Reverse Split will result in a per share price that will attract institutional investors or investment funds or that such share price will satisfy the investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock may not necessarily improve.

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

On March 7, 2017, we completed the Merger with Essentialis and issued 3,783,388 shares of common stock to stockholders of Essentialis. We held back 182,675 shares of common stock as partial recourse to satisfy indemnification claims, and such shares will be issued to Essentialis stockholders on the 1 year anniversary of the closing of the Merger. We are also obligated to issue an additional 913,389 shares of common stock to Essentialis stockholders upon the achievement of a development milestone. Assuming that we issue all of the shares of our common stock held back and the development milestone is achieved, we would issue a total of 4,879,452 shares of common stock to Essentialis stockholders. These shares were registered on a Registration Statement on Form S-1 filed with the SEC on April 21, 2017, and declared effective on August 10, 2017.
In addition, we issued 1,666,666 shares of common stock for an investment of $8 million from the completion of the concurrent financing and issued 416,666 shares of common stock for an investment of $2 million from Aspire Capital. These shares were registered on a Registration Statement on Form S-1 filed with the SEC on February 1, 2017, and declared effective on February 14, 2017.

Item 3. Defaults Upon Senior Securities
None.
Item 4. Mine Safety Disclosures
Not applicable.
Item 5. Other Information
None.
Item 6. Exhibits
See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this Quarterly Report on Form 10-Q, which Exhibit Index is incorporated herein by reference.

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Capnia, Inc.	S-1/A	August 7, 2014	3.2	
3.2	Amended and Restated Bylaws of Capnia, 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	
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 Capnia, Inc. and certain holders of the Capnia, Inc.'s capital stock named therein.	S-1	June 10, 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 Capnia, 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	
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		4.17	

4.18	Form of the Series B Warrant certificate.	S-1/A	November 4, 2014 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

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
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	
9.10	Form of Voting Agreement.	8-K	October 15, 2015	9.1	
9.2	Form of Voting Agreement.	8-K	July 6, 2016	9.1	
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 Capnia, Inc. and Ernest Mario, Ph.D.	S-1	June 10, 2014	10.6	
10.7	Employment Agreement, dated April 6, 2010, by and between Capnia, Inc. and Anish Bhatnagar.	S-1	June 10, 2014	10.7	
10.8	Offer Letter, dated May 29, 2013, between Capnia, Inc. and Anthony Wondka.	S-1	June 10, 2014	10.8	
10.9	Offer Letter, dated April 17, 2014, by and between Capnia, Inc. and Antoun Nabhan.	S-1	June 10, 2014	10.9	
10.10	Asset Purchase Agreement dated May 11, 2010, by and between Capnia, 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 Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.11	
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 Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.12	
10.13	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.3	
10.14	2014 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.4	
10.15	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.5	
10.16	Offer Letter, dated June 22, 2007, by and between Capnia, Inc. and Ernest Mario, Ph.D.	S-1	June 10, 2014	10.6	
10.17	Employment Agreement, dated April 6, 2010, by and between Capnia, Inc. and Anish Bhatnagar.	S-1	June 10, 2014	10.7	
10.18		S-1	June 10, 2014	10.8	

Offer Letter, dated May 29, 2013, between Capnia, Inc. and Anthony Wondka.

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
10.19	Offer Letter, dated April 17, 2014, by and between Capnia, Inc. and Antoun Nabhan.	S-1	June 10, 2014	10.9	
10.20	Asset Purchase Agreement dated May 11, 2010, by and between Capnia, Inc. and BioMedical Drug Development Inc.	S-1	June 10, 2014	10.10	
10.21	Convertible Note and Warrant Purchase Agreement, dated February 10, 2010, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.11	
10.22	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 Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.12	
10.23	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 Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.13	
10.24	Convertible Note and Warrant Purchase Agreement, dated January 16, 2012, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.14	
10.25	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated July 31, 2012, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.15	
10.26	Omnibus Amendment to Convertible Promissory Notes and Warrants to Purchase Shares, dated April 28, 2014, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.16	
10.27	Convertible Note and Warrant Purchase Agreement, dated April 28, 2014, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.17	
10.28	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated May 5, 2014, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.18	
10.29	Sublease, dated May 20, 2014, by and among Capnia, Inc. and Silicon Valley Finance Group.	S-1/A	July 1, 2014	10.19	
10.30	Offer Letter, dated June 24, 2014, by and between Capnia, Inc. and David D. O'Toole.	S-1/A	July 22, 2014	10.20	
10.31	Loan Agreement by and between Capnia, Inc. and the investors named therein, dated September 29, 2014.	S-1/A	September 29, 2014	10.21	
10.32	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	
10.33	Second Tranche Subsequent Closing Notice and Letter Amendment dated October 22, 2014 relating to the	S-1/A	November 4, 2014	10.23	

	October 2014 Notes.			
10.34	Form of Warrant Exercise Agreement.	8-K	March 5, 2015	10.1
10.35	Advisory Agreement by and between Capnia, Inc. and Maxim Group LLC, dated March 4, 2015.	S-4	April 1, 2014	10.25
10.36	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
10.37	Common Stock Purchase Agreement between the Company and an affiliate of BDDI, dated June 30, 2015.	8-K	July 7, 2015	10.2
10.38	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	4.1
10.39	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated July 24, 2015.	8-K	July 27, 2015	10.1
10.40	Engagement Letter dated September 17, 2015, between Capnia, Inc. and Maxim Group, LLC.	8-K	October 15, 2015	1.1
10.41	Securities Purchase Agreement dated October 12, 2015.	8-K	October 15, 2015	10.1

Exhibit Number	Description of Document	Incorporated by Reference from Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
10.42	Form of Registration Rights Agreement.	8-K	October 15, 2015	10.2	
10.43	Form of Lock-Up Agreement.	8-K	October 15, 2015	10.3	
10.44	Amendment No. 1 to Securities Purchase Agreement dated October 29, 2015.	S-1/A	December 22, 2015	10.33	
10.45	Transfer and Distribution Agreement: United States: by and between Capnia, Inc. and Bemes, Inc. signed January 26, 2016.	8-K	January 28, 2016	10.1	
10.46	Engagement Letter dated June 26, 2016, between Capnia, Inc. and Maxim Group, LLC.	8-K	July 6, 2016	1.1	
10.47	Securities Purchase Agreement dated June 29, 2016.	8-K	July 6, 2016	10.1	
10.48	Form of Registration Rights Agreement dated June 29, 2016.	8-K	July 6, 2016	10.2	
10.49	Amendment No. 1 to Securities Purchase Agreement dated September 20, 2016.	S-1/A	September 20, 2016	10.39	
10.50	Agreement and Plan of Merger and Reorganization, dated as of December 22, 2016, by and among Capnia, Inc., a Delaware corporation, Essentialis, Inc., a Delaware corporation, Company E Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of Capnia, and Neil Cowen as the stockholders' representative.	8-K	December 27, 2016	2.1	
10.51	Registration Rights Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.51	
10.52	Common Stock Purchase Agreement between the Company and Aspire Capital Fund, LLC, dated January 27, 2017.	S-1	February 1, 2017	10.52	
10.53	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	
31.2	Certification of Principal Financial 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 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

* The certifications attached as Exhibit 32.1 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Capnia, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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, 2017 SOLENO THERAPEUTICS, INC.

By: /s/ Anish Bhatnagar
Anish Bhatnagar
Chief Executive Officer
(chief executive and principal financial and accounting officer)