Capnia, Inc.
Form 10-Q
November 14, 2016
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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, 2016
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

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

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 October 31, 2016 there were 15,761,530 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements
Capnia, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands except share and per share data)

	September 30, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 5,415	$ 5,495
Accounts receivable	137	156
Restricted cash	35	35
Inventory	703	551
Prepaid expenses and other current assets	217	167
Total current assets	6,507	6,404
Long-term assets		
Property and equipment, net	116	86
Goodwill	718	718
Other intangible assets, net	842	917
Other assets	126	76
Total assets	$ 8,309	$ 8,201
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 862	$ 695
Accrued compensation and other current liabilities	915	1,634
Series B warrant liability	—	865
Total current liabilities	1,777	3,194
Long-term liabilities		
Series A warrant liability	509	1,213
Series C warrant liability	115	462
Other long-term liabilities	196	109
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred Stock, $.001 par value, 10,000,000 shares authorized:		
Series A convertible preferred stock, 10,000 shares designated; zero and 4,555 issued and outstanding at September 30, 2016 and December 31, 2015, respectively	—	—
Series B convertible preferred stock, 13,780 and zero shares designated at September 30, 2016 and December 31, 2015, respectively; 13,780 and zero shares issued and outstanding at September 30, 2016 and at December 31, 2015, respectively	—	—
Common stock, $0.001 par value, 100,000,000 shares authorized, 15,761,530 and 14,017,909 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	15	14
Additional paid-in-capital	101,395	89,456
Accumulated deficit	(95,698)	(86,247)
Total stockholders' equity	5,712	3,223
Total liabilities and stockholders' equity	$ 8,309	$ 8,201

See accompanying notes to condensed consolidated financial statements

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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,	
	2016	2015	2016	2015
Government grant revenue	—	155	—	220
Product revenue	329	92	1,167	146
Total revenue	329	247	1,167	366
Cost of product revenue	399	56	1,287	96
Gross profit (loss)	(70)	191	(120)	270
Expenses				
Research and development	1,131	1,193	4,231	3,252
Sales and marketing	342	467	1,457	1,239
General and administrative	1,398	1,714	4,846	4,432
Total expenses	2,871	3,374	10,534	8,923
Operating loss	(2,941)	(3,183)	(10,654)	(8,653)
Interest and other income (expense)				
Interest expense, net	—	—	—	(1)
Change in fair value of warrants liabilities (expense)	200	73	1,323	(1,177)
Cease-use expense	—	—	(94)	—
Other expense	(9)	(183)	(27)	(183)
Inducement charge for Series C warrants	—	—	—	(3,050)
Interest and other income (expense), net	191	(110)	1,202	(4,411)
Net loss	(2,750)	(3,293)	(9,452)	(13,064)
Loss on extinguishment of convertible preferred stock	(3,651)	—	(3,651)	—
Net loss attributable to common stockholders	$(6,401)	$ (3,293)	$(13,103)	$(13,064)
Net loss per share attributable to common stockholders, basic and diluted	$(0.41)	$ (0.33)	$(0.85)	$(1.60)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	15,761,530	10,040,079	15,363,648	8,178,897

See accompanying notes to condensed consolidated financial statements

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(9,452)	$(13,064)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	94	59
Loss on disposition of property and equipment	1	—
Stock-based compensation expense	560	746
Change in fair value of common stock warrants	(1,323)	1,177
Inducement charge for Series C warrants	—	3,050
Non-cash expense of issuing shares to Aspire Capital	—	183
Change in fair value of contingent consideration	35	—
Change in operating assets and liabilities:		
Accounts receivable	19	(94)
Inventory	(152)	(267)
Prepaid expenses and other assets	(50)	27
Other long-term assets	(50)	—
Accounts payable	175	542
Accrued compensation and other current liabilities	(719)	720
Other long-term liabilities	52	—
Net cash used in operating activities	(10,810)	(6,921)
Cash flows from investing activities:		
Cash paid for purchase of assets of NeoForce Group, Inc.	—	(1,000)
Increase in restricted cash	—	(91)
Cash paid for patent acquisition	—	(150)
Purchase of property and equipment	(39)	(48)
Net cash used in investing activities	(39)	(1,289)
Cash flows from financing activities:		
Proceeds from sale of Series A preferred convertible stock	5,071	—
Series A preferred convertible stock transaction costs paid	(71)	—
Proceeds from sale of Series B preferred convertible stock	13,479	—
Redemption of Series A preferred convertible stock in conjunction with issuance of Series B Convertible Preferred	(7,780)	—
Proceeds from issuance of common stock		1,434
Proceeds from exercise of common stock options	70	294
Proceeds from exercise of Series A warrants	—	156
Proceeds from exercise of Series B warrants (Private Transaction)	—	3,832
Proceeds from exercise of Series B warrants (Tender offer)		6
Proceeds from other exercise of Series B warrants	—	189
Series B warrant transaction costs paid	—	(306)
Initial public offering costs paid	—	(530)
Repayment of credit line	—	(102)
Net cash provided by financing activities	10,769	4,973
Net decrease in cash and cash equivalents	(80)	(3,237)

Cash and cash equivalents, beginning of period	5,495	7,957
Cash and cash equivalents, end of period	$5,415	$4,720
Supplemental disclosures of noncash investing and financing information		
Conversion of Series A preferred to common stock	2,220	—
Patent costs included in Accrued liabilities	—	300
Stock issuable in consideration for Patent purchase	—	112
De-recognition of Series B warrant liability (cash exercise)	—	6,747
De-recognition of Series B warrant liability (cashless exercise)	593	9,475
De-recognition of Series A warrant liability (cash exercise)	—	42
Reduction in initial public offering costs payable	—	45
Cashless exercise of 2010/2012 warrants	—	13
De-recognition of Series B warrants contributed back to the Company	—	3
Series B transaction costs in accounts payable	52	—
Fixed asset purchases in accounts payable	11	—

See accompanying notes to condensed consolidated financial statements.

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Capnia, Inc.
September 30, 2016
Notes to Condensed Consolidated Financial Statements
(unaudited)

Note 1. Description of Business

Capnia, Inc. (the “Company”) was incorporated in the State of Delaware on August 25, 1999, and is located in Redwood City, California. The Company develops and commercializes neonatology devices and diagnostics. The Company also has a therapeutics platform based on its proprietary technology for precision metering of gas flow.

On September 8, 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 develops innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets.

On April 27, 2015, the Company established Capnia UK Limited, a wholly owned foreign subsidiary in the United Kingdom. Capnia UK Limited began sales and marketing operations in the first quarter of 2016.

The Company's most recent product to launch commercially is Serenz® Allergy Relief, or Serenz, which has a CE Mark certification for sale in the European Union, or E.U. Serenz is a proprietary handheld device that delivers non-inhaled CO_2 topically to the nasal mucosa. Serenz is used only when needed, and does not need to be used on a scheduled basis. Pilot commercial sales of Serenz began in the U.K. and Ireland in the second quarter of 2016.

The Company is also selling 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 has CE Mark certification for sale in the E.U. In addition, through the Company's wholly owned subsidiary NFI, the Company also develops and globally markets assets relating to innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets. NFI’s primary product is the NeoPip T-piece resuscitator and related consumable, which delivers consistent pre-set inspiratory pressure and positive end-expiratory pressures. Other NFI products include temperature probes, scales, surgical tables and patient surfaces.

Note 2. Liquidity, Financial Condition and Management’s Plans

The Company had a net loss of approximately $9.5 million for the nine months ended September 30, 2016 and has an accumulated deficit of approximately $95.7 million at September 30, 2016 from having incurred losses since its inception. The Company has approximately $4.7 million of working capital at September 30, 2016 and used approximately $10.8 million of cash in its operating activities during the nine months ended September 30, 2016. The Company has financed its operations principally through issuances of debt and equity securities.

On July 24, 2015, the Company entered into a Common Stock Purchase Agreement (the "Aspire Purchase Agreement") with Aspire Capital, LLC ("Aspire") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $10.0 million in value of shares of the Company’s Common Stock over the 24-month term of the Aspire Purchase Agreement. From July 24, 2015 through September 30, 2016, the Company had issued an aggregate of 506,585 shares of Common Stock to Aspire in exchange for approximately $1.4 million. Under the 2016 Sabby Purchase Agreement entered into on June 29, 2016, as described below, the Company is unable to access funds from Aspire Capital pursuant to the Aspire Purchase Agreement until January 24, 2017, 120 days after the date the SEC declared the registration statement effective covering the securities being issued under the 2016 Sabby Purchase Agreement.

On October 12, 2015, the Company entered into a Securities Purchase Agreement (the “ 2015 Sabby Purchase Agreement”) with funds managed by Sabby Management, LLC ("Sabby"), to purchase up to $10 million worth of

Series A Convertible Preferred Stock (the “Series A Convertible Preferred Stock”). The sale of the Series A Convertible Preferred Stock closed in two separate closings. On October 15, 2015, the date of the first closing, the Company received proceeds of approximately $4.1 million, net of $0.4 million in estimated expenses. On January 8, 2016, the date of the second closing, the Company received proceeds of approximately $5.0 million, net of $0.5 million in estimated expenses.

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On June 29, 2016, the Company entered into a second Securities Purchase Agreement (the "2016 Sabby Purchase Agreement") with Sabby, pursuant to which the Company agreed to sell to Sabby, in a private placement, an aggregate of up to 13,780 shares of Series B Convertible Preferred Stock at an aggregate purchase price of $13,780,000, which shares are convertible into 13,780,000 shares of Common Stock (the "Series B Convertible Preferred Stock"), based on a fixed conversion price of $1.00 per share on an as-converted basis. 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 transactions required under the 2016 Sabby Purchase Agreement, the Company was obligated to repurchase from Sabby an aggregate of 7,780 shares of Series A Convertible Preferred Stock held by Sabby for an aggregate amount of $7,780,000, which shares were originally purchased by Sabby under the 2015 Sabby Purchase Agreement and which shares represent 4,205,405 shares of Common Stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock closed in two separate closings. On July 5, 2016, the date of the first closing, the Company received proceeds of approximately $1.3 million, net of $0.1 million in estimated expenses. On September 29, 2016, the date of the second closing, the Company received proceeds of approximately $4.4 million, net of $0.3 million in estimated expenses. After the repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, the Company received approximately $5.6 million of net proceeds from the 2016 Sabby Purchase Agreement.

The Company expects to continue incurring losses for the foreseeable future and may be required to raise additional capital to pursue its product development initiatives and penetrate markets for the sale of its products. Management believes that the Company's commercial products, including CoSense, the other neonatology products and Serenz, and the distribution strategies implemented will begin to generate meaningful revenue and corresponding cash in the near term. In addition, the Company has been successful over the last 12 months in raising additional capital including the completed closings pursuant to the 2015 Sabby Purchase Agreement and the 2016 Sabby Purchase Agreement on June 29, 2016. 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, 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 new products 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 to commercialize its products, which is critical to the realization of its business plan and the future operations of the Company.

These conditions raise substantial doubt about our ability to continue as a going concern.

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, 2016 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, 2015. 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 GAAP for complete financial statements. The condensed consolidated balance sheet at December 31, 2015 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, 2016 and

results of its operations for the three and nine months ended September 30, 2016 and 2015 and cash flows for the nine months ended September 30, 2016 and 2015. 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.

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, 2015 included in the Company's Annual Report on Form 10-K.

Use of Estimates

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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 December 31, 2015 and September 30, 2016, the Company's inventory was comprised of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	$ 385	$ 106
Work-in-process	164	399
Finished goods	154	46
Total inventory	$ 703	$ 551

Inventory is stated at the lower of cost or market under the first-in, first-out (FIFO) method. The Company recorded a lower of cost or market write down to inventory of $72 thousand during the nine months ended September 30, 2016.

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.

Goodwill
The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing its reporting unit's carrying value to its implied fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. There was no impairment of goodwill for the nine months ended September 30, 2016. Such goodwill is not deductible for tax purposes and represents the value placed on entering new markets and expanding market share.

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 principally consist of Series A, Series B, 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.

Due to certain provisions contained in the Series B Warrant agreement that provides for the Company potentially issuing an unlimited number of shares upon exercise, the Company had adopted a sequencing policy that reclassified contracts, with the exception of stock options, from equity to assets or liabilities for those with the latest inception date first. The Company had

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evaluated the issuance of securities as to reclassification as a liability under this sequencing policy through February 12, 2016, the date that the Series B Warrants expired.

Recent Accounting Pronouncements

There have been no new accounting pronouncements or changes to accounting pronouncements during the nine months ended September 30, 2016 as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015 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.

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

	Fair Value Measurements at September 30, 2016			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$4,879	$4,879	$ —	$—
Liabilities				
Series A warrant liability	$509	$509	$ —	$—
Series C warrant liability	115	—	—	115
Total liabilities	$624	$509	$ —	$115

	Fair Value Measurements at December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$3,804	$3,804	$ —	$—
Liabilities				
Series A warrant liability	$1,213	$1,213	$ —	$—
Series B warrant liability	865	—	—	865
Series C warrant liability	462	—	—	462
Total common stock warrant liability	$2,540	$1,213	$ —	$1,327

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 B and 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 B Warrant liability is calculated using a Monte Carlo simulation. Key assumptions include the volatility of the Company's stock, the expected warrant term, expected dividend yield and risk-free interest rates (see Note 5). 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 5). The Level 3 estimates are based, in part, on subjective assumptions.

The agreement to pay the annual royalty in the NeoForce acquisition 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 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 thousand at the date of acquisition and $188 thousand as of 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.

On January 13, 2016 we entered into an agreement to sublease our excess space located in Redwood City. By the end of February we 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.

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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 B Warrant		Series C Warrant	
	Number of Warrants	Liability	Number of Warrants	Liability	Number of Warrants	Liability
Balance at December 31, 2015	2,425,605	$1,213	116,580	$ 865	590,415	$ 462
Change in value of Series A Warrants	—	(704)	—	—	—	—
De-recognition of Series B Warrant liability upon cashless exercise of warrants (485,202 shares issued)	—	—	(102,300)	(593)	—	—
De-recognition of Series B Warrant liability upon expiration	—	—	(14,280)	—	—	—
Change in value of Series B Warrants	—	—	—	(272)	—	—
Change in value of Series C Warrants	—	—	—	—	—	(347)
Balance at September 30, 2016	2,425,605	$509	—	$ —	590,415	$ 115

Note 5. Warrant Liabilities

Warrants terms

The Company has issued Series A Warrants, Series B 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

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The Company has issued 2,449,605 Series A Warrants to purchase shares of its Common Stock at an exercise price of $6.50 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. 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 24,000 Series A Warrants have been exercised. As of September 30, 2016, the fair value of the 2,425,605 outstanding Series A Warrants was approximately 509 thousand, and the decrease of $704 thousand in fair value during the nine months ended September 30, 2016 was recorded as other income in the statement of operations.

Series B Warrants

The Company issued 2,449,605 Series B Warrants to purchase shares of its Common Stock at an exercise price of $6.50 per share in connection with the IPO.

Between January 1, 2016 and the expiration date of the Series B Warrants of February 12, 2016, certain holders of Series B warrants cashless exercised a total of 102,300 Series B Warrants resulting in the issuance of 485,202 shares of Common Stock and the derecognition of approximately $593 thousand in Series B Warrant liability. The remaining Series B Warrant liability was reduced to zero upon expiration resulting in the recording of $272 thousand in other income in the statement of operations. The remaining Series B Warrants expired unexercised on February 12, 2016.

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 589510 shares of the Company’s Common Stock at an exercise price of $6.50 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 $6.25 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 $6.25 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 905 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 590,415 shares of the Company’s Common Stock. As of September 30, 2016, the fair value of the Series C Warrants was determined to be $115 thousand. The decline in the fair value of the Series C Warrants of $347 thousand 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:

	September 30, 2016	December 31, 2015
Volatility	90 %	90 %
Expected Term (years)	3.42	4.17

Expected dividend yield	—	%	—	%
Risk-free rate	0.93	%	1.76	%

Note 6. Commitments and Contingencies

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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 leases approximately 2,100 square feet of office space for its operations in Ivyland, Pennsylvania under a month-to-month lease.

Rent expense was $462 thousand and $221 thousand during the nine months ended September 30, 2016 and 2015, 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 thousand at the date of acquisition and $188 thousand at September 30, 2016. The long-term portion of the royalty obligation, $144 thousand, is classified as part of other long-term liabilities while the remaining current portion is included in accrued compensation and other current liabilities.

Note 7. Stockholders’ Equity

Convertible Preferred Stock

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

The Company issued a total of 10,000 Series A Convertible Preferred Stock under the 2015 Sabby Purchase Agreement, with a par value of $0.001 and a stated value of $1,000 per share. The Series A Convertible Preferred Stock did not have an expiration date and were not redeemable at the option of the holders. During the three months ended March 31, 2016 and June 30, 2016, the holders of the Series A Convertible Preferred Stock converted 1,665 and 555, respectively, shares of Series A Convertible Preferred Stock resulting in the issuance of 900,000 and 300,000 shares of Common Stock, respectively. Under the 2016 Sabby Purchase Agreement, the remaining 7,780 shares of Series A Convertible Preferred Stock were repurchased.

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. 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 $2.46 to $1.75 per share on the effective date of the 2016 Sabby Purchase Agreement.

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The Company has recognized the repurchase of the Series A Convertible Preferred Stock as an extinguishment of the Series A Convertible Preferred Stock. The Company compared the fair value of the Series B Convertible Preferred Stock immediately after the two close dates under the 2016 Sabby Purchase Agreement to the carrying value of the Series A Convertible Preferred Stock immediately prior to the two close dates under the 2016 Sabby Purchase Agreement. The Company recorded the excess of the aggregate fair value of the Series B Convertible Preferred Stock, $3.4 million, as a loss on extinguishment. In addition, the Company estimated the effect of modifying the exercise price on the existing Series D warrants to be $203 thousand. The Company therefore recorded a total of $3.7 million extinguishment loss to net loss applicable to common stockholders.

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 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.

The Company recognized stock-based compensation expense related to options granted to employees for the nine months ended September 30, 2016 and 2015 of $560 thousand and $746 thousand, respectively. The 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, 2016 and September 30, 2015.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research & Development	$41	$27	$116	$99
Sales & Marketing	11	17	22	51
General & Administrative	154	100	422	596
Total	$206	$144	$560	$746

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 139,839 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; 279,680 shares; or
- such amount as determined by our Board of Directors.

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As of September 30, 2016 there were no purchases by employees under this plan.

Series D Warrants

As part of the 2015 Sabby Purchase Agreement, the Company previously issued 2,810,811 Series D Warrants, with an exercise price of $2.46, which the exercise price of 2,702,704 Series D Warrants were subsequently amended to $1.75 per share and a term of five years expiring on October 15, 2020. The exercise price of the remaining 108,108 Series D Warrants issued to Maxim LLC, as placement agent, was $2.46, and are exercisable beginning on April 15, 2016 and through and including October 15, 2020. The Company's Series D Warrants contain standard anti-dilution provisions for stock dividends, stock splits, subdivisions, combinations and similar types of recapitalization events. They also contain a cashless exercise feature that provides for their net share settlement at the option of the holder in the event that there is no effective registration statement covering the continuous offer and sale of the warrants and underlying shares. The Company is required to comply with certain 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 herein. The Company evaluated the registration payment arrangement stipulated in the terms of this securities agreement and determined that it is probable that the Company will maintain an effective registration statement and has therefore not allocated any portion of the proceeds to the registration payment arrangement. The Series D Warrant agreement specifically provides that under no circumstances will the Company be required to settle any Series D Warrant exercise for cash, whether by net settlement or otherwise.
As part of the 2016 Sabby Purchase Agreement, the Company issued to Maxim LLC, as its placement agent, 120,000 Series D Warrants, with an exercise price of $1.75 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, 2016, the Company had 480147 Common Stock warrants outstanding originally issued in conjunction with the 2010/2012 convertible notes, with an exercise price of $4.87 and a term of 10 years expiring in November 2024. The Company also has outstanding 9,259 Common Stock warrants issued in 2009, with an exercise price of $21.60 and a term of 10 years, expiring in January 2019 and 82,500 Common Stock warrants issued to the underwriter in our IPO, with an exercise price of 7.14 and a term of 10 years, expiring in November 2024.

Note 8. Net loss per share

Basic net loss per share is computed by dividing net loss by the weighted-average number of Common Stock actually outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of Common Stock outstanding and dilutive potential Common Stock that would be issued upon the exercise of Common Stock warrants and options. For the three months ended September 30, 2016 and 2015 and the nine months ended September 30, 2016 and 2015, 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.

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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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Convertible preferred stock of 13,780 shares	13,780,000	—	13,780,000	—
Warrants issued to 2010/2012 convertible note holders to purchase common stock	480,147	480,147	480,147	480,147
Options to purchase common stock	2,938,152	1,863,171	2,938,152	1,863,171
Warrants issued in 2009 to purchase common stock	9,259	9,259	9,259	9,259
Warrants issued to underwriter to purchase common stock	82,500	82,500	82,500	82,500
Series A Warrants to purchase common stock	2,425,605	2,425,605	2,425,605	2,425,605
Series B Warrants to purchase common stock	—	527,573	—	527,573
Series C Warrants to purchase common stock	590,415	590,415	590,415	590,415
Series D Warrants to purchase common stock	2,930,812	—	2,930,812	—

Note 9. Subsequent Events

On October 24, 2016, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market (“Nasdaq”) indicating that, based upon the closing bid price of the Company’s common stock for the last 30 consecutive business days, the Company 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). The letter also indicated that the Company will be provided with a compliance period of 180 calendar days, or until April 24, 2017, in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(A). The letter further provided that if, at any time during the 180-day period, the closing bid price of the Company’s common stock is at least $1.00 for a minimum of ten consecutive business days, Nasdaq will provide the Company with written confirmation that it has achieved compliance with the minimum bid price requirement. If the Company does not regain compliance by April 24, 2017, an additional 180 days may be granted to regain compliance if the Company (i) meets the continued listing requirement for market value of publicly held shares and all other initial listing standards for Nasdaq (except for the bid price requirement) and (ii) provides written notice of its intention to cure the deficiency during the second 180-day compliance period.

On November 7, 2016, the two funds managed by Sabby converted 200 shares of their Series B Convertible Stock into 200,000 shares of Common Stock.

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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, 2015, 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, 2015. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are subject to risks and uncertainties, including those set forth in Part II – Other Information, Item 1A. Risk Factors below and elsewhere in this report that could cause actual results to differ materially from historical results or anticipated results.

Overview

We are a diversified healthcare company that develops and commercializes innovative diagnostics, devices and therapeutics addressing unmet medical needs. We have a number of commercial products based on our proprietary technologies, including those which utilize precision metering of gas flow. Our most recent product to launch commercially utilizing our precision metering of gas flow technology is Serenz® Allergy Relief, or Serenz, which has a CE Mark certification for sale in the E.U. Serenz is a proprietary handheld device that delivers non-inhaled CO_2 topically to the nasal mucosa. Serenz is used only when needed, and does not need to be used on a scheduled basis. Pilot commercial sales of Serenz began in the U.K. and Ireland in the second quarter of 2016.

We are also selling 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. In addition, through our wholly owned subsidiary NFI, we also develop and globally market assets relating to innovative pulmonary resuscitation solutions for the inpatient and ambulatory neonatal markets. NFI's primary product is the NeoPip T-piece resuscitator and related consumable, which delivers consistent pre-set inspiratory pressure and positive end-expiratory pressures. Other NFI products include temperature probes, scales, surgical tables and patient surfaces.

Our therapeutic technology consists of the use of nasal, non-inhaled CO_2 for the treatment of the symptoms of allergic rhinitis, or AR, as well as for the treatment of pain associated with migraine, cluster headache and trigeminal neuralgia, or TN. Serenz is a treatment for symptoms related to AR, which, when triggered by seasonal allergens, is commonly known as hay fever or seasonal allergies. We are also pursuing new initiatives for the development of our precision metering of gas flow technology for the treatment of trigeminally-mediated pain disorders such as cluster headache and TN. On December 18, 2015, the U.S. Food and Drug Administration, or FDA, granted us orphan drug designation for our nasal, non-inhaled CO_2 technology for the treatment of TN in the U.S. We filed an investigational new drug application, or IND, with the FDA and started enrolling TN patients in a pilot clinical trial in 2016.

We continue to focus our research and development efforts on diagnostic products based on our Sensalyze™ Technology Platform, a portfolio of patented and proprietary methods and systems, which enables CoSense to measure ETCO and that can be applied to detect a variety of analytes in exhaled breath, as well as other products for the neonatology market. Our current development pipeline includes proposed diagnostic devices for asthma in children, assessment of blood CO_2 concentration in neonates and malabsorption. We may also license elements of our Sensalyze Technology Platform to other companies that have complementary development or commercial capabilities.

In July 2015, we commenced enrollment in a pilot, single-center, investigator-sponsored clinical trial evaluating our proprietary nasal, non-inhaled CO_2 technology for the treatment of cluster headaches. The primary efficacy endpoint

of the trial is the greatest change from pre-treatment headache pain intensity to post treatment. We expect to report top-line data from this trial in 2016.

In January of 2016, we entered into a distribution agreement with Bemes, Inc., or Bemes, a leading medical equipment Master Distributor, to market and distribute CoSense and Precision Sampling Sets or PSS. Under the terms of the agreement, Bemes will have the exclusive right for sales, marketing, distribution and field service activities for CoSense in the United States. Bemes and its network of sub distributors will allow nationwide distribution of CoSense with 44 sales representatives covering almost every state.

In March 2015, holders of 589,510 Series B Warrants exercised their Series B Warrants for cash, and we received approximately $3.8 million in gross proceeds. In conjunction with these exercises, we issued the same number of Series C

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Warrants to purchase Common Stock at an exercise price of $6.25 per share which are exercisable through March 4, 2020. In April 2015, we filed a registration statement to offer and exchange to the remaining Series B Warrant holders to cash exercise their existing Series B Warrants and receive a Series C Warrant. We also received approximately $0.2 million from holders of Series B Warrants who exercised their Series B Warrants for cash during the nine months ended March 31, 2015.

On July 24, 2015, we entered into the Aspire Purchase Agreement with Aspire, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $10.0 million in value of shares of our Common Stock over the 24-month term of the Purchase Agreement. Since July 24, 2015, we issued an aggregate of 506,585 shares of Common Stock to Aspire in exchange for approximately $1.4 million.

On October 12, 2015, we entered into the 2015 Sabby Purchase Agreement with funds managed by Sabby to purchase up to $10 million of Series A Convertible Preferred Stock together with related Series D Warrants to purchase shares of our Common Stock. The sale of the Series Convertible A Preferred Stock occurred in two separate closings. On October 15, 2015, the date of the first closing under the 2015 Sabby Purchase Agreement, we received proceeds of approximately $4.1 million, net of $0.4 million in estimated expenses. On January 8, 2016, the date of the second closing under the 2015 Sabby Purchase Agreement, we received proceeds of approximately $5 million, net of $0.5 million in estimated expenses.

On June 29, 2016, we entered into the 2016 Sabby Purchase Agreement with Sabby, pursuant to which we agreed to sell to Sabby, in a private placement, an aggregate of up to 13,780 shares of our Series B Convertible Preferred Stock at an aggregate purchase price of $13,780,000, which shares are convertible into 13,780,000 shares of our Common Stock, based on a fixed conversion price of $1.00 per share on an as-converted basis. 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 2016 Sabby Purchase Agreement, we also repurchased an aggregate of 7,780 shares of Series A Convertible Preferred Stock held by Sabby for an aggregate amount of $7,780,000, which shares were originally purchased by Sabby under the 2015 Sabby Purchase Agreement and which shares represent 4,205,405 shares of Common Stock on an as-converted basis. The sale of the Series B Convertible Preferred Stock occurred in two separate closings. On July 5, 2016, the date of the first closing under the 2016 Sabby Purchase Agreement, the Company received proceeds of approximately $1.3 million, net of $0.1 million in estimated expenses. On September 29, 2016, the date of the second closing under the 2016 Sabby Purchase Agreement, the Company received proceeds of approximately $4.4 million, net of $0.3 million in estimated expenses. After repurchase of the Series A Convertible Preferred Stock and estimated transaction expenses, the Company received approximately $5.6 million of net proceeds.

During the year ended December 31, 2015 and the nine months ended September 30, 2016, we received $0.3 million and $0.1 million, respectively, from the exercise of stock options.

As of September 30, 2016, we had an accumulated deficit of $95.7 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 neonatology products, therapeutic products, other diagnostic 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, $1.6 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.

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 condensed consolidated financial statements.

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Results of Operations

Comparison of the nine months ended September 30, 2016 and 2015

	Nine Months Ended September 30,		Increase (decrease)	
	2016	2015	Amount	Percentage
	(in thousands)			
Government grant revenue	$—	$220	$(220)	(100)%
Product revenue	1,167	146	$1,021	699 %
Total revenue	1,167	366	801	219 %
Cost of goods sold	1,287	96	1,191	1,241 %
Gross profit (loss)	(120)	270	(390)	(144)%
Operating expenses:				
Research and development	4,231	3,252	979	30 %
Sales and marketing	1,457	1,239	218	18 %
General and administrative	4,846	4,432	414	9 %
Total	10,534	8,923	1,611	18 %
Loss from operations	(10,654)	(8,653)	(2,001)	23 %
Change in fair value of warrants	1,323	(1,177)	2,500	(212)%
Inducement charge for Series C Warrants	—	(3,050)	3,050	(100)%
Cease-use expense	(94)	—	(94)	N/A
Interest expense, net	—	(1)	1	(100)%
Other income (expense), net	(27)	(183)	156	(85)%
Interest and other income (expense), net	1,202	(4,411)	5,613	(127)%
Net loss	$(9,452)	$(13,064)	$3,612	(28)%

Revenue

Total revenue in the nine months ended September 30, 2016 increased 219% as compared to the nine months ended September 30, 2015. During the nine months ended September 30, 2016, we recognized $344 thousand of product revenue from sales of CoSense and Precision Sampling Sets and $820 thousand from NFI products. In the nine months ended September 30, 2015, we recognized $85 thousand of product revenue from sales of CoSense and Precision Sampling Sets and $61 thousand from NFI products. NeoForce was acquired in September 2015 and thus the $61 thousand represents one month's revenue. Grant revenue was $220 thousand for the nine months ended September 30, 2015 and $0 in the nine months ended September 30, 2016.

Research and development expense

Research and development expense in the nine months ended September 30, 2016 increased $979 thousand as compared to the nine months ended September 30, 2015. The increase was primarily due to increased headcount, development materials for the improvement of our CoSense product, costs associated with the launch of Serenz in the E.U. and an increase in costs for the TN and cluster headache clinical trials.

Sales and marketing expense

Sales and marketing expense in the nine months ended September 30, 2016 increased $218 thousand over the nine months ended September 30, 2015 primarily due to commercial activities associated with the continued commercialization of CoSense and the launch of Serenz in the E.U.

General and administrative expense

General and administrative expense in the nine months ended September 30, 2016 increased $414 thousand as compared to the nine months ended September 30, 2015. The increase was primarily due to an increase in IP legal fees, increased headcount associated with the NFI operations, and partially offset by external printing and filing costs

associated with SEC filings incurred in 2015.

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Other income (expense)

Other income (expense) in the nine months ended September 30, 2016 increased $5.6 million as compared to the nine months ended September 30, 2015. Of the $4.4 million expense in 2015, $3.1 million was due to the issuance of the Series C Warrants, a one-time charge which was treated as an inducement. The change in the fair value of the warrants decreased from an other expense of $1.2 million in the nine months ended September 30, 2015 to $1.3 million in other income in the nine months ended September 30, 2016. Other expense decreased $156 thousand primarily due to the value of shares issued to Aspire Capital in 2015.

Comparison of the three months September 30, 2016 and 2015

	Three Months Ended September 30,		Increase (decrease)	
	2016	2015	Amount	Percentage
	(in thousands)			
Government grant revenue	$—	$155	$(155)	(100)%
Product revenue	329	92	237	258 %
Total revenue	329	247	82	33 %
Cost of product revenue	399	56	343	613 %
Gross profit (loss)	(70)	191	(261)	(137)%
Operating expenses:				
Research and development	1,131	1,193	(62)	(5)%
Sales and marketing	342	467	(125)	(27)%
General and administrative	1,398	1,714	(316)	(18)%
Total	2,871	3,374	(503)	(15)%
Loss from operations	(2,941)	(3,183)	242	(8)%
Change in fair value of warrants	200	73	127	174 %
Other income (expense), net	(9)	(183)	174	(95)%
Interest and other income (expense), net	191	(110)	301	(274)%
Net loss	$(2,750)	$(3,293)	$543	(16)%

Revenue

Total revenue in the three months ended September 30, 2016 increased 33% as compared to the three months ended September 30, 2015. During the three months ended September 30, 2016, we recognized $71 thousand of product revenue from sales of CoSense and Precision Sampling Sets and $257 thousand from NFI products. During the three months ended September 30, 2015, we recognized $31 thousand of product revenue from the sales of CoSense and Precision Sampling Sets and $61 thousand (one month) from NFI products. Grant revenue was $155 thousand for the three months ended September 30, 2015 and $0 in the three months ended September 30, 2016.

Research and development expense

Research and development expense in the three months ended September 30, 2016 decreased 5% as compared to the three months ended September 30, 2015. The decrease was primarily due to decreased development materials for our CoSense product as we focus more on commercialization.

Sales and marketing expense

Sales and marketing expense in the three months ended September 30, 2016 decreased 27% over the three months ended September 30, 2015 primarily due to the shift in commercialization efforts from internal resources to the external distribution model.

General and administrative expense

General and administrative expense in the three months ended September 30, 2016 decreased 18% as compared to the three months ended September 30, 2015 due to external printing and filing costs associated with SEC filings in 2015.

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Other income (expense)

Other income in the three months ended September 30, 2016 increased $301 thousand as compared to the three months ended September 30, 2015. The change in the fair value of the warrants increased $127 thousand from the three months ended September 30, 2015 due to decreases in the warrant liability values. Other expense in 2015 was due to the value of the shares of Common Stock issued to Aspire Capital as part of the Aspire Purchase Agreement.

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,	
	2016	2015
	(in thousands)	
Cash Flows from Continuing Operations:		
Net cash used in operating activities	$(10,810)	$(6,921)
Net cash used in investing activities	(39)	(1,289)
Net cash provided by financing activities	10,769	4,973
Net decrease in cash and cash equivalents	$(80)	$(3,237)

Cash used in operating activities

During the nine months ended September 30, 2016, net cash used in operating activities was $10.8 million, which was primarily due to the use of funds for operations, including costs incurred to launch Serenz in the E.U., as well as adjustments for non-cash items including the $1.3 million change in fair value of warrants and $0.6 million of stock based compensation expense, decreases in accounts payable and accrued liabilities of $0.5 million and increases of inventory of $0.2 million.

During the nine months ended September 30, 2015, net cash used in operating activities was $6.9 million, which was primarily due to the use of funds in our operations, as well as adjustments for non-cash items including the $4.2 million change in fair value of warrants and the Series C Warrants inducement charge and the $0.7 million of stock based compensation expense, offset by increases in accounts payable and accrued liabilities of $1.3 million.

Cash used in investing activities

During the nine months ended September 30, 2016, we used $39 thousand in investing activities. Cash used in investing activities in the nine months ended September 30, 2016 consisted primarily of investment in equipment.

During the nine months ended September 30, 2015, the Company used $1.0 million to acquire NeoForce. Cash used in investing activities in the nine months ended September 30, 2015 consisted primarily of investment in equipment, change unrestricted cash and payment to acquire patents.

Cash provided by financing activities

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

During the nine months ended September 30, 2015 cash provided by financing activities was $5.0 million, consisting primarily of $4.2 million in proceeds from issuance of Common Stock as a result of the exercise of Series A Warrants and Series B Warrants, issuance of Common Stock to Aspire Capital for $1.4 million and the $0.3 million received

from the exercise of Common Stock options, offset by payment of IPO costs and Series B transaction costs of $0.7 million and the repayment of the outstanding balance on our line of credit of $0.1 million.
As of September 30, 2016, we had cash and cash equivalents of approximately $5.4 million.

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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, 2016. 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 and Chief Financial Officer has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

(b) Changes in Internal Control over Financial Reporting

There have been no changes to our internal control over financial reporting that occurred during the third fiscal quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material litigation or other material legal proceedings.

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 and the other information in this prospectus. 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

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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 and diagnostics 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, 2016, we had an accumulated deficit of $95.7 million.

We expect that our future financial results will depend primarily on our success in launching, selling and supporting our neonatology and other products. This will require us to be successful in a range of activities, including manufacturing, marketing and selling our neonatology 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.

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

To date, we have not generated significant revenues from our products or Serenz, and have not generated sufficient revenues from licensing activities 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, including our neonatology products, Serenz, or any planned 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 neonatology products and our other future products, if any;
• set a commercially viable price for our neonatology product and our other 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 for our neonatology products and distribution partners for Serenz in the E.U to help us market, sell and distribute our approved products in other markets;
• demonstrate the safety and effectiveness of Serenz to the satisfaction of FDA and obtain regulatory approval for Serenz;
• complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;
• complete development activities, including any potential Phase 3 clinical trials of Serenz, 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 Serenz in the U.S. or any or 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 complete the development and regulatory process for Serenz in the U.S. or any planned products worldwide, we anticipate incurring significant costs associated with commercializing these products.

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Even if we are able to generate significant revenue from the sale of our neonatology products, Serenz or any planned products that may be approved, 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;
• the cost of manufacturing our Serenz and our neonatology 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 for Serenz in the U.S. and any planned products or competing planned products;
• 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 Serenz or any of our planned products;
• the level of demand for our neonatology products, and for Serenz and any planned products, should they receive approval, in the U.S., or, if applicable, globally,which 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 neonatology products, Serenz or any of our planned products;
• our ability to commercialize our neonatology products or any planned product 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.

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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 commercialization of our products, as well as the completion of the development and the potential commercialization of planned products, will require substantial funds. As of September 30, 2016, we had approximately $5.4 million in cash and cash equivalents. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

• the cost of activities and added personnel associated with the commercialization of our products, including marketing, manufacturing, and distribution;
• the cost to manufacture our products on a larger scale;
• the degree and rate of market acceptance of our products, and the revenue that we are able to collect as a result;
• our ability to set a commercially attractive price for our products, and our customers' perception of the value relative to the prices we set;
• our ability to clarify the regulatory path in the U.S. for Serenz, and the potential requirement for additional pivotal clinical studies;
• the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities for Serenz and other planned products;
• our ability to obtain additional partners for Serenz in the E.U. on attractive economic terms, or engage in commercial sales of Serenz on our own or through distributors, or maintain existing distributors;
• the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights and/or the loss of those rights;
• our ability to enter into distribution, collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
• the emergence of competing technologies or other adverse market developments;
• the costs of attracting, hiring and retaining qualified personnel;
• unforeseen developments during our clinical trials;
• unforeseen changes in healthcare reimbursement for any of our approved products;
• our ability to maintain commercial scale manufacturing capacity and capability with a commercially acceptable cost structure;
• unanticipated financial resources needed to respond to technological changes and increased competition;
• enactment of new legislation or administrative regulations;
• the application to our business of new regulatory interpretations;
• claims that might be brought in excess of our insurance coverage;
• the failure to comply with regulatory guidelines; and
• the uncertainty in industry demand.

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 Serenz, CoSense, or potential 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 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 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 Aspire

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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 $2.63 per share. Even if we are able to access the full $10.0 million under the Aspire Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans. In addition, as a result of the 2016 Sabby Purchase Agreement, from 120 days after September 26, 2016, the day the registration statement was declared effective by the SEC, we are not able to access any additional funds under the Aspire Purchase Agreement.

On July 5, 2016 and September 29, 2016, we issued $3,151,000 and $10,629,000 worth of shares of Series B Convertible Preferred Stock, respectively, which are convertible into 13,780,000 shares of our Common Stock, pursuant to the 2016 Sabby Purchase Agreement.

In addition, at the first closing held on July 5, 2016 under the 2016 Sabby Purchase Agreement and the second closing held on September 29, 2016 under the 2016 Sabby Purchase Agreement, we repurchased $1,779,012 and $6,000,988, respectively, worth of Series A Convertible Preferred Stock held by Sabby.

Risks related to the development and commercialization of our products

Our success depends heavily on the successful commercialization of our CoSense device to aid in diagnosis of neonatal hemolysis and of our Serenz device to relieve the nasal symptoms of allergic rhinitis. If we are unable to sell sufficient numbers of our products, our revenues may be insufficient to achieve profitability.

With the exception of revenue generated from the sale of products acquired from NFI, we will derive substantially all of our revenues from sales of CoSense devices and consumables globally and our Serenz devices in the E.U. for the foreseeable future. If we cannot generate sufficient revenues from sales, we may be unable to finance our continuing operations.

We may not be successful in commercializing our approved products.

Our efforts to launch CoSense into the neonatology marketplace and Serenz in the E.U. are subject to a variety of risks, any of which may prevent or limit sales of CoSense and Serenz. Furthermore, commercialization of products into the medical marketplace 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 neonatology products and for Serenz, 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 Serenz, our neonatology, and 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 Serenz in the E.U. and for our neonatology products 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 Serenz in the E.U., as well as products globally 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.

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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 Serenz, and our neonatology and other products, and would materially harm our business, financial condition and results of operations.

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

To generate demand for our neonatology and other planned products, we will need to educate physicians, neonatologists, pediatricians, 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 CoSense 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.

In addition, although treatment guidelines recommend ETCO testing, physicians are free to practice in accordance with their own judgment, and may not adopt ETCO testing to the extent recommended by the guidelines, or at all. While the current AAP guidelines recommend ETCO measurement be performed to assess the presence of hemolysis in neonates requiring phototherapy, neonates unresponsive to phototherapy or readmitted for phototherapy, and neonates with bilirubin levels approaching exchange transfusion levels. AAP guidelines are updated approximately every ten years, and since the current guidelines were published in 2004, these guidelines may change in the near term.

If we cannot convince medical practitioners to order and pay for our current test and our planned tests, and if we cannot convince institutions to pay for our current test and our planned tests, we will likely be unable to create demand in sufficient volume for us to achieve sustained profitability.

If Serenz or our neonatology or other planned 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 Serenz in the E.U., and our neonatology and other planned products worldwide can provide reliable, high-quality diagnostic results or treatments. With respect to our neonatology and other diagnostic products, we believe that our customers are likely to be particularly sensitive to test defects and errors, and prior products made by other companies for the same diagnostic purpose have failed in the marketplace, in part as a result of poor diagnostic accuracy. As a result, the failure of our neonatology and other 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 we cannot compete successfully with other diagnostic modalities, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

Our principle competition for CoSense comes from mainstream diagnostic methods, used by physicians for many years, which focus on invasive blood tests such as the Coombs test, blood counts and serum bilirubin. In addition, transcutaneous monitors of bilirubin also create a competitive threat. It may be difficult to change the methods or behavior of neonatologists and pediatricians to incorporate CoSense in their practices in conjunction with, or instead of, blood tests.

In addition, several larger companies have extensive sales presence in the neonatology area and could potentially develop non-invasive diagnostic tests that compete with our neonatology or other planned products. These include

General Electric Healthcare, Fischer & Paykel, Philips, Draeger, Covidien, Masimo, Natus Medical, and CAS Medical. Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced tests that payors and physicians could view as functionally equivalent to our current or planned tests, which could force us to lower the list price of our tests. This would impact our operating margins and our ability to achieve and maintain profitability. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our current or planned tests, which could prevent us from increasing or sustaining our revenues or achieving or sustaining profitability.

We expect to continue to incur significant expenses to develop and market additional diagnostic tests, which could make it difficult for us to achieve and sustain profitability.

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In recent years, we have incurred significant costs in connection with the development of CoSense. For the three and nine months ended September 30, 2016, our research and development expenses were $1.1 million and $4.2 million, respectively. We expect our expenses to increase for the foreseeable future, as we conduct studies of CoSense and continue to develop our planned products, including tests for hydrogen nitric oxide and other analytes. We will also incur significant expenses to establish a sales and marketing infrastructure, and to drive adoption of and reimbursement for our products. As a result, we need to generate significant revenues in order to achieve sustained profitability.

Serenz may not be approved for sale in the U.S., or in any territory outside of the E.U.

Neither we nor any future collaboration partner can commercialize Serenz in the U.S. without first obtaining regulatory approval for the product from the FDA. In the E.U., we previously obtained CE Mark certification, clearing the device for commercial sale. We recently reactivated the CE Mark certification for Serenz. We commenced pilot sales of Serenz to pharmacies in the E.U. in the second quarter of 2016 to gather commercial feedback in preparation of a full launch of Serenz in 2017.

The approval route for Serenz in the U.S. may be through a device approval or a drug-device combination approval. If it is a device approval pathway, it may be either via the premarket approval, or PMA, process, a de novo510(k) pathway, or traditional 510(k). Additional randomized, controlled clinical trials and other development work may be necessary to obtain approval. The approval process may take several years to complete, and approval may never be obtained. Before obtaining regulatory approvals for the commercial sale of Serenz for treatment of AR, we must demonstrate with substantial evidence, gathered in preclinical and well-controlled clinical studies, that the planned product is safe and effective for use for that target indication. We may not conduct such a trial or may not successfully enroll or complete any such trial. Serenz may not achieve the required primary endpoint in the clinical trial, and Serenz may not receive regulatory approval. We must also demonstrate that the manufacturing facilities, processes and controls are adequate. Additionally, the FDA may determine that Serenz should be regulated as a combination product or as a drug, and in that case, the approval process would be further lengthened.

Moreover, obtaining regulatory approval for marketing of Serenz in one country does not ensure we will be able to obtain regulatory approval in other countries, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries.

Even if we or any future collaboration partners were to successfully obtain a regulatory approval for Serenz, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for Serenz in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient revenue to justify commercial launch. Also, any regulatory approval of Serenz, once obtained, may be withdrawn. Even if we obtain regulatory approval for Serenz in additional countries, the commercial success of the product will depend on a number of factors, including the following:

• establishment of commercially viable pricing, and obtaining approval for adequate reimbursement from third-party and government payors;
• our ability, or that of third-party manufacturers that we may retain, to manufacture quantities of Serenz using commercially viable processes at a scale sufficient to meet anticipated demand and reduce our cost of manufacturing, and that are compliant with current Good Manufacturing Practices, or cGMP, regulations;
• our success in educating physicians and patients about the benefits, administration and use of Serenz;
• the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;

• acceptance of Serenz as safe and effective by patients, caregivers and the medical community; and
• a continued acceptable safety profile of Serenz following approval.

Many of these factors are beyond our control. If we are unable to successfully commercialize Serenz, or unable to obtain a partner to commercialize it, we may not be able to earn any revenues related to Serenz. This would result in an adverse effect on our business, financial condition, results of operations and growth prospects.

One or more countries in the E.U. may reassess the Class 2a designation and determine that Serenz be regulated in a different manner.

Serenz has CE Mark certification in the E.U. based on it being treated as a Class 2a medical device in constituent E.U. countries. One or more countries in the E.U. may reassess the Class 2a designation and determine that Serenz be

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regulated differently and if this occurs, controlled clinical trials and other development work may be necessary to maintain regulatory clearances in any such jurisdictions. We may be required to demonstrate with substantial evidence, gathered in preclinical and well-controlled clinical studies, that Serenz is safe and effective for use. We may not be able to conduct such a trial or may not successfully enroll or complete any such trial. Serenz may not achieve the required primary endpoint in the clinical trial As a result, the regulatory process in any such jurisdictions may take several years to complete, and requisite clearances may never be obtained.

The regulatory approval process is expensive, time consuming and uncertain, and may prevent us or our partners from obtaining approval for the commercialization of Serenz or our other development candidates. Approval of Serenz in the U.S. or other territories may require that we, or a partner, conduct additional randomized, controlled clinical trials.

The regulatory pathway for approval of Serenz in the U.S. has not been determined. However, there is a significant risk that the FDA will require us to file for approval via the PMA pathway for devices, or may classify Serenz as a drug-device combination that must be approved via the new drug application, or NDA, pathway typically used for drug products. In either of these cases, the FDA may require that additional randomized, controlled clinical trials be conducted before an application for approval can be filed. These are typically expensive and time consuming, and require substantial commitment of financial and personnel resources from the sponsoring company. These trials also entail significant risk, and the data that results may not be sufficient to support approval by the FDA or other regulatory bodies.

Furthermore, regulatory approval of either a PMA or an NDA is not guaranteed, and the filing and approval process itself is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure may occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies. The FDA can delay, limit, or deny approval of a future product for many reasons, including but not limited to:

- a future product may not be deemed to be safe and effective;
- FDA officials may not find the data from clinical and preclinical studies sufficient;
- the FDA may 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 Serenz, or our future products, fail to demonstrate safety and effectiveness in further clinical studies that may be required, or do not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

The mechanism of action of Serenz has not been fully determined or validated.

The exact mechanism of action(s) of Serenz is unknown. Therapeutics are increasingly focused on target-driven development, and an understanding of a future product’s mechanism of action is typically believed to make development less risky. The FDA may view this as increasing the potential risks, and diminishing the potential benefits, of Serenz. In addition, potential partners may view this as a limitation of the program, and it may be more challenging for us to obtain a partnership on favorable terms as a result.

Because the results of preclinical testing and earlier clinical trials, and the results to date in various clinical trials, are not necessarily predictive of future results, Serenz may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the effectiveness and safety of an investigational product. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results to date in the various clinical studies performed with Serenz, we do not know whether pivotal clinical trials, if the FDA requires they be conducted, will demonstrate adequate effectiveness and safety to result in regulatory approval to market Serenz. Even if we, or a future partner, believe that the data is adequate to support an application for regulatory approval to market our planned products, the FDA or other applicable foreign regulatory authorities may not agree and may require additional clinical trials. If these subsequent clinical trials do not produce favorable results, regulatory approval for Serenz may not be achieved.

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There can be no assurance that Serenz will not exhibit new or increased safety risks in subsequent clinical trials. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many other companies that have believed their planned products performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their products.

Delays in the enrollment of patients in any of our clinical studies could increase development costs and delay completion of the study.

We or any future collaboration partner may not be able to initiate or continue clinical studies for Serenz if we are unable to locate and enroll a sufficient number of eligible patients to participate in these studies as required by the FDA or other regulatory authorities. Even if a sufficient number of patients can be enrolled in clinical trials, if the pace of enrollment is slower than we expect, the development costs for our planned products may increase and the completion of our studies may be delayed, or the studies could become too expensive to complete.

If clinical studies of Serenz or 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 Serenz or 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 Serenz or 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 Serenz or 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;
- 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.

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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 subsequent clinical trials demonstrate acceptable safety and effectiveness of Serenz for the relief of nasal symptoms related to AR, the FDA or similar regulatory authorities outside the U.S. may not approve Serenz for marketing or may approve it with restrictions on the label, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

It is possible that the FDA or similar regulatory authorities may not consider the results of the clinical trials to be sufficient for approval of Serenz for this indication. In general, the FDA suggests that sponsors complete two adequate and well-controlled clinical studies to demonstrate effectiveness because a conclusion based on two persuasive studies will be more compelling than a conclusion based on a single study. The FDA may nonetheless require that we may conduct additional clinical studies, possibly using a different clinical study design.

Moreover, even if the FDA or other regulatory authorities approve Serenz, the approval may include additional restrictions on the label that could make Serenz less attractive to physicians and patients compared to other products that may be approved for broader indications, which could limit potential sales of Serenz.

If we fail to obtain FDA or other regulatory approval of Serenz, or if the approval is narrower than what we seek, it could impair our ability to realize value from Serenz, and therefore may have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Even if Serenz or 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 Serenz or 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 Serenz or any planned products, if approved, 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 neonatology products, Serenz, or other planned products.

We are currently building a sales and marketing infrastructure and have no experience in the sale, marketing or distribution of diagnostic or therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing infrastructure or outsource these functions to third parties.

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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.

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 in the future with respect to Serenz or other future 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 the Serenz program.

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 Serenz. We may also attempt to find one or more strategic partners for the development or commercialization of one or more of our other future 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.

Serenz or our planned 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 this or any planned products will prove safe enough to receive regulatory approval. Undesirable side effects caused by Serenz or any of our planned 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 Serenz or 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;

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- 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 proposition that Serenz or our neonatology 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 neonatology products, Serenz, or any planned 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., while we expect payments for CoSense to be part of a Diagnosis-Related Group, or DRG, (also known as a bundled payment) we may have to obtain reimbursement for it from payors directly. There may be significant delays in obtaining reimbursement for CoSense, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, 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

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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 CoSense, 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 Serenz, our neonatology products and any planned products in human clinical studies. The marketing, sale and use of Serenz, our neonatology products and our planned 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 neonatology products or our planned 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, David D. O'Toole, our Senior Vice President, Chief Financial Officer, Anthony Wondka, our Senior Vice President of Research and Development, Otho Boone, our Vice President and General Manager of Neonatology, and Kristen Yen, our Vice President of Clinical & Regulatory. 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 Chief Executive Officer, Chief Financial Officer, Vice President & General Manager of Neonatology, Vice President of Clinical & Regulatory, and Senior Vice President of Research and Development 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.

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The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy.

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.

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 and medical device businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

We may encounter manufacturing problems or delays that could result in lost revenue. Additionally, we currently rely on third-party suppliers for critical materials needed to manufacture our Serenz devices, CoSense monitors and consumables, other neonatology products, as well as our planned products. Any problems experienced by these suppliers could result in a delay or interruption of their supply to us, and as a result, we may face delays in the commercialization of our neonatology products or the development and commercialization of planned products.

We perform final assembly of CoSense monitors and consumables at our facility in Redwood City, CA. We believe that we currently have adequate manufacturing capacity. If demand for our current products and our planned products increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. We currently have limited experience in commercial-scale manufacturing of our planned products, and we currently rely upon third-party contract manufacturing organizations to manufacture and supply components for our products. The manufacture of these products in compliance with the FDA’s regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations.

We currently purchase components for our products under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in manufacturing the instruments or consumables while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new materials or reagents and in increased operating costs. Further, any prolonged disruption in a supplier’s operations could have a significant negative impact on our ability to manufacture and deliver products in a timely manner. Some of the components used in our products are currently sole-sourced, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us because the number of third-party manufacturers with the necessary

manufacturing and regulatory expertise and facilities is limited. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities. It could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New manufacturers of any planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the product. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

We currently contract manufacture Serenz in China with a sole-source third party out-sourced manufacturing supplier. We do not have any backup manufacturing capability. If our sole-source supplier is harmed or rendered inoperable

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by natural or man-made disasters, including fire, earthquake, flooding and power outages, our supply of Serenz will be interrupted. Also there can be no guarantee that we can maintain a commercial relationship with this supplier on acceptable economic terms.

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. 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.

We have distribution partners for CoSense in China, India, Canada, Turkey, Denmark, Qatar and Saudi Arabia. We recently launched pilot sales of Serenz in the U.K. and Ireland. Our business strategy contemplates international expansion, including partnering with medical device distributors, and introducing our neonatology 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;
• 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.

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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, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's 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 the U.S. Department of Health and Human Services, or 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 neonatology products, Serenz, or any other planned product, 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 neonatology products, to Serenz, or with respect to planned products, for commercialization in or outside the U.S. Our likely collaborators for any distribution, marketing, licensing or other collaboration arrangements include large and mid-size medical device and diagnostic companies, regional and national medical device and diagnostic 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;

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• 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, 2016, we had 29 employees and 7 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 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 device 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.

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We rely on third parties, such as contract research organizations, or CROs, clinical data management organizations, medical institutions and clinical investigators, 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 to comply with regulations and with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical studies 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. 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 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 the medical device and diagnostic 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

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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 medical device and diagnostic 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

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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.