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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended September 30, 2014

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

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**CAPNIA, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction of  
incorporation or organization)

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

3 Twin Dolphin Drive,  
Redwood City, CA  
(Address of principal executive offices)

94065  
(Zip Code)

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

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

Indicate by check mark whether the registrant has submitted electronically 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  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

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

As of December 15, 2014 there were 6,769,106 shares of the registrant's common stock, par value \$0.001 per share, outstanding.

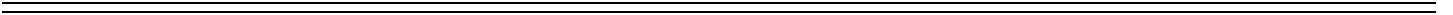


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**PART I—FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**Capnia, Inc.**  
**Condensed Balance Sheets**  
*(In thousands except share and per share data)*

	September 30, 2014 (unaudited)	December 31, 2013
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 64	\$ 1,269
Restricted cash	20	20
Accounts receivable	37	150
Prepaid expenses and other current assets	186	85
Total current assets	307	1,524
Long-term assets		
Deferred offering costs	1,353	—
Property and equipment, net	36	63
Total assets	<u>\$ 1,696</u>	<u>\$ 1,587</u>
<b>Liabilities, convertible preferred stock and stockholders' deficit</b>		
Current liabilities		
Accounts payable	\$ 1,238	\$ 58
Accrued liabilities	358	129
Convertible promissory notes and accrued interest	—	13,992
Total current liabilities	1,596	14,179
Long-term liabilities		
Convertible promissory notes and accrued interest, net of discounts	15,604	—
Convertible preferred stock warrant liability	3,066	1,464
Commitments and contingencies		
Convertible Preferred Stock		
Series A convertible preferred stock, \$0.001 par value, 40,000 shares authorized, 31,250 shares issued and outstanding at December 31, 2013 and September 30, 2014; (aggregate liquidation preference of \$1,500)	1,500	1,500
Series B convertible preferred stock, \$0.001 par value, 320,000 shares authorized, 119,140 shares issued and outstanding at December 31, 2013 and September 30, 2014; (aggregate liquidation preference of \$6,863)	6,863	6,863
Series C convertible preferred stock, \$0.001 par value, 1,500,000 shares authorized, 715,039 shares issued and outstanding at December 31, 2013 and September 30, 2014; (aggregate liquidation preference of \$15,445)	15,445	15,445
Stockholders' deficit		
Common stock, \$0.001 par value, 10,000,000 shares authorized at September 30, 2014 and December 31, 2013; 535,685 shares issued and outstanding at September 30, 2014 and December 31, 2013	1	1
Additional paid-in-capital	20,741	19,235
Accumulated deficit	(63,120)	(57,100)
Total stockholders' deficit	(42,378)	(37,864)
Total liabilities and stockholders' deficit	<u>\$ 1,696</u>	<u>\$ 1,587</u>

*See accompanying notes to condensed financial statements*

**Capnia, Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
*(In thousands except share and per share data)*  
*(unaudited)*

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Revenue	\$ —	\$ —	\$ —	\$ 3,000
Expenses				
Research and development	717	745	1,633	2,020
Sales and marketing	84	—	96	—
General and administrative	<u>522</u>	<u>248</u>	<u>1,585</u>	<u>1,267</u>
Total expenses	<u>1,323</u>	<u>993</u>	<u>3,314</u>	<u>3,287</u>
Operating income (loss)	(1,323)	(993)	(3,314)	(287)
Interest and other income (expense)				
Interest income	—	—	1	1
Interest (expense)	(752)	(571)	(1,811)	(2,550)
Other income (expense), net	<u>(318)</u>	<u>(26)</u>	<u>(895)</u>	<u>103</u>
Net loss and comprehensive loss	<u>\$ (2,393)</u>	<u>\$ (1,590)</u>	<u>\$ (6,019)</u>	<u>\$ (2,733)</u>
Basic and diluted net loss per common share	<u>\$ (4.47)</u>	<u>\$ (2.97)</u>	<u>\$ (11.24)</u>	<u>\$ (5.10)</u>
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	<u>535,685</u>	<u>535,685</u>	<u>535,685</u>	<u>535,611</u>

*See accompanying notes to condensed financial statements*

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

	<b>Nine Months Ended</b>	
	<b>September 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$(6,019)	\$(2,733)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	20	32
Stock-based compensation expense	21	35
Loss on disposition of property and equipment	8	—
Change in fair value of preferred stock warrants	888	79
Non-cash interest expense relating to warrants and convertible promissory notes	1,811	2,471
Change in operating assets and liabilities:		
Accounts receivable	112	(97)
Other receivables	—	151
Prepaid expenses and other assets	(101)	9
Accounts payable	103	(106)
Accrued liabilities	229	(4)
<b>Net cash used in operating activities</b>	<b><u>(2,928)</u></b>	<b><u>(163)</u></b>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	—	(1)
<b>Net cash used in investing activities</b>	<b><u>—</u></b>	<b><u>(1)</u></b>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of warrants	2	—
Proceeds from issuance of convertible notes payable	1,997	—
Deferred Offering Costs Paid	(276)	—
<b>Net cash provided by financing activities</b>	<b><u>1,723</u></b>	<b><u>—</u></b>
Net decrease in cash and cash equivalents	<u>(1,205)</u>	<u>(164)</u>
Cash and cash equivalents, beginning of period	<u>1,269</u>	<u>2,155</u>
<b>Cash and cash equivalents, end of period</b>	<b><u>\$ 64</u></b>	<b><u>\$ 1,992</u></b>
<b>Supplemental disclosures of noncash investing and financing information</b>		
Issuance of warrants in connection with notes payable	<u>\$ 713</u>	<u>\$ —</u>
Beneficial conversion feature in connection with convertible promissory notes	<u>\$ 1,484</u>	<u>\$ —</u>
Deferred Offering Costs accrued and included in Accounts Payable	<u>\$ 1,077</u>	<u>\$ —</u>

*See accompanying notes to condensed financial statements.*

**Capnia, Inc.**  
**September 30, 2014**

**Notes to Condensed 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 diagnostics and therapeutics based on its proprietary technology for precision metering of gas flow.

The Company's first diagnostic product, CoSense®, aids in diagnosis of excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, hemolysis is a dangerous condition which can lead to long-term developmental disability. CoSense received initial 510(k) clearance for sale in the U.S. in the fourth quarter of 2012, with a more specific Indication for Use related to hemolysis issued in the first quarter of 2014, and received CE Mark approval for sale in the European Union ("E.U.") in the third quarter of 2013. The Company initiated commercialization of CoSense in October 2014 using its own sales efforts. In addition, the Company is applying its research and development efforts to additional diagnostic products based on its Sensalyze™ Technology Platform, a portfolio of proprietary methods and devices which enables CoSense and can be applied to detect a variety of analytes in exhaled breath.

The Company has also obtained CE Mark approval in the E.U. for Serenz™, a therapeutic product candidate for the treatment of symptoms related to allergic rhinitis ("AR"). The Company out licensed Serenz to Block Drug Company, a wholly-owned subsidiary of GlaxoSmithKline ("GSK") in 2013, realizing revenue in the form of a non-refundable up-front payment of \$3.0 million. In June 2014, the GSK agreement terminated and the licensed rights to Serenz were returned to the Company.

***Initial Public Offering***

On November 18, 2014, the Company completed its initial public offering ("IPO"), pursuant to which the Company issued 1,650,000 units (each unit consisting of one share of common stock, one Series A warrant and one Series B warrant) and received net proceeds of approximately \$8.2 million, after deducting underwriting discounts and commissions and IPO related expenses. In connection with the completion of the Company's IPO, all shares of convertible preferred stock converted into 865,429 shares of common stock and all of the Company's convertible preferred stock warrants were converted into warrants to purchase shares of common stock. In addition, the outstanding convertible notes and accrued interest issued during 2010 and 2012 converted into an aggregate of 3,165,887 shares of common stock and the issuance of 523,867 warrants to purchase common stock. The outstanding convertible notes issued during April, August and October, 2014 converted into an aggregate of 552,105 units in the IPO. As this was a subsequent event, as of September 30, 2014 all of the convertible preferred stock and convertible notes are shown on the balance sheet at their pre-converted amounts.

**Note 2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying condensed 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 balance sheet at December 31, 2013 has been derived from the audited financial statements at that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

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The unaudited interim condensed financial statements have been prepared on the same basis as the audited financial statements and, in the opinion of management, reflect all adjustments of a normal recurring nature considered necessary to present fairly its financial position as of September 30, 2014 and results of its operations and comprehensive loss for the three months and nine months ended September 30, 2014 and 2013, and cash flows for the nine months ended September 30, 2014 and 2013. 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 financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2013 included in the Company's Prospectus filed pursuant to Rule 424(b)(4) on November 12, 2014 with the SEC (the "Prospectus").

### ***Significant Risks and Uncertainties***

The Company has experienced losses since its inception and, as of September 30, 2014, has an accumulated deficit of approximately \$63.1 million and cash and cash equivalents of approximately \$0.1 million. The Company received payments totaling approximately \$3.0 million pursuant to the license agreement with GSK pertaining to Serenz. This agreement terminated in June 2014, and the Company does not expect additional revenue to result from it. The Company plans to commercialize Serenz in the E.U. via a partnership or distributorship arrangements. In the U.S., the Company intends to determine the regulatory approval pathway for Serenz in dialogue with the FDA, and subsequently to seek partnership or distributorship arrangements for commercialization.

The Company initiated its commercialization of CoSense® starting in October of 2014, and will likely achieve profitability only if it can generate sufficient revenue from sales of the Company's CoSense instruments and consumables, or from license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships. Although management has been successful in raising capital in the past, most recently in April 2014, August 2014, October 2014 and November 2014 (See Note 14), there can be no assurance that the Company will be successful, or that any needed financing will be available in the future at terms acceptable to the Company.

As of September 30, 2014, there was substantial doubt about the Company's ability to continue as a going concern, if we did not secure additional financing. As a result, the Company's independent registered public accounting firm included an explanatory paragraph in its report on the Company's 2013 financial statements with respect to this uncertainty. However, as described more fully below, since September 30, 2014, we completed our IPO and received net proceeds of \$8.2 million, after deducting underwriting discounts and commissions and IPO related expenses. We believe that the Company's cash resources are sufficient to meet its cash needs for at least the next 12 months.

### ***Use of Estimates***

The preparation of 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 and the valuation of debt and equity instruments and stock-based compensation.



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### ***Fair Value of Financial Instruments***

The carrying amounts of the Company's financial instruments, including cash and cash equivalents, contracts receivable, prepaid and other current assets, accounts payable, accrued liabilities, and certain related-party convertible notes payable approximate fair value due to their short-term maturities.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company's cash and cash equivalents are held in institutions in the U.S. and include deposits in a money market fund which was unrestricted as to withdrawal or use.

### ***Deferred initial public offering costs***

Deferred initial public offering costs as of September 30, 2014 consist of costs directly related to the offering of equity securities such as legal fees, external auditor fees, accounting fees for work associated with the IPO, printing and registration related fees. There were no such costs as of December 31, 2013.

### ***Prepaid Expenses and Other Current Assets***

Prepaid expenses and other current assets consist of payments primarily related to insurance and short-term deposits. Prepaid expenses are initially recorded upon payment and are expensed as goods or services are received.

### ***Property and Equipment, Net***

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized.

### ***Impairment of Long-Lived Assets***

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets held and used is measured by comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of their carrying cost or fair value less cost to sell. The Company has not recognized losses related to impairment since inception.

### ***Related-Party Convertible Promissory Notes***

The Company has issued convertible promissory notes pursuant to a number of private placements since 2010. These convertible promissory notes were issued with separate warrants to purchase shares of the Company's convertible preferred stock. These warrants have been treated as liabilities. The convertible promissory notes and accrued interest were convertible into the Company's capital stock or, for promissory notes issued in 2014, units to be sold in the IPO. The fair value of the warrants was determined using a Monte Carlo simulation and allocated as a debt discount using the intrinsic value allocation method. The discount has been amortized using the effective interest method over the term of the related convertible promissory notes.

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The Company applies the accounting standards for derivatives and hedging and for distinguishing liabilities from equity when accounting for hybrid contracts that feature conversion options. The Company accounts for convertible debt instruments when the Company has determined that the embedded conversion options should not be bifurcated from their host instruments in accordance with ASC 470-20 "Debt with Conversion and Other Options." The Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt (see Note 5).

### ***Convertible Preferred Stock Warrant Liability***

The Company has issued freestanding warrants to purchase shares of its convertible preferred stock. At September 30, 2014, the Company has classified the fair value of these warrants as liabilities on the balance sheet as they correspond to the treatment of the preferred stock as temporary equity. The Company accounts for the warrants as a derivative instrument. Changes in the fair value of the warrants are presented separately as other expense (income) in the Company's statements of operations for each reporting period. The Company uses the Monte Carlo simulation model to determine the fair value of the warrants. As a result, the valuation of this derivative instrument is subjective because the option-valuation model requires the input of highly subjective assumptions, including the expected stock price volatility and the probability of a future occurrence of a fundamental transaction. Changes in these assumptions can materially affect the fair value estimate and, such impacts can, in turn, result in material non-cash charges or credits, and related impacts on earnings or loss per share, in the statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the expiration of the warrants or their exercise, at which time the liability will be reclassified into stockholders' deficit. The Company records any change in fair value as a component of other income or expense. At the time of the IPO, all of the warrants to purchase preferred stock converted into warrants to purchase common stock, which are no longer subject to adjustment to fair value.

### ***Convertible Preferred Stock***

Upon the occurrence of certain change in control events that are outside of the control of the Company, including sale or transfer of control of the Company, holders of the convertible preferred stock can force the Company to redeem these shares. The holders of convertible preferred stock are entitled to require the Company to redeem their shares upon the approval of at least two thirds of the holders of shares of the convertible preferred stock then outstanding. Accordingly, these shares are considered contingently redeemable and are classified as temporary equity on the accompanying balance sheets. At the time of the IPO, all outstanding shares of preferred stock converted into common stock, and reclassified to permanent equity.

### ***Revenue Recognition***

The Company recognized revenue during the year ended December 31, 2013 pursuant to its license agreement with GSK. The revenue was recognized because there was persuasive evidence of an arrangement, the price was fixed or determinable, and collectability was reasonably assured. The up-front payment for revenue recognized in 2013 was received prior to December 31, 2013 and was nonrefundable. No revenue was recognized during the nine months ended September 30, 2014. The agreement was terminated in the second quarter of 2014, and the Company does not have any further monetary obligations with respect to this agreement.

### ***Research and Development***

Research and development costs are charged to operations as incurred. Research and development costs consist primarily of salaries and benefits, consultant fees, prototype expenses, certain facility costs and other costs associated with clinical trials, net of reimbursed amounts.

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Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are expensed to research and development costs when incurred.

### ***Income Taxes***

The Company accounts for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the amounts at which assets and liabilities are recorded for financial reporting purposes and the amounts recorded for income tax purposes. Deferred income taxes are classified as current or non-current, based on the classifications of the related assets and liabilities giving rise to the temporary differences. A valuation allowance is provided against the Company's deferred income tax assets when their realization is not reasonably assured.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

### ***Stock-Based Compensation***

For stock options granted to employees, the Company recognizes compensation expense for all stock-based awards based on the estimated fair value on the date of grant. The value of the portion of the award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The fair value of stock options is determined using the Black-Scholes option pricing model. The determination of fair value for stock-based awards on the date of grant using an option pricing model requires management to make certain assumptions regarding a number of complex and subjective variables.

Stock-based compensation expense related to stock options granted to non-employees is recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The awards generally vest over the time period the Company expects to receive services from the non-employee.

### ***Comprehensive Income (Loss)***

Comprehensive income (loss) is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There have been no items qualifying as other comprehensive income (loss) and, therefore, for all periods presented, the Company's comprehensive income (loss) was the same as its reported net income (loss).

### ***Net Income (Loss) per Share of Common Stock***

Basic net income (loss) per common share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net income (loss) per share calculation, convertible preferred stock, convertible promissory notes, stock options and convertible preferred

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stock warrants are considered to be potentially dilutive securities. Because the Company has reported a net loss for the three and nine months ended September 30, 2014 and 2013, diluted net loss per common share is the same as basic net loss per common share for those periods.

Effective as of the completion of the IPO, all of the Company's preferred stock was converted to common stock. For purposes of calculating net loss per common share for the three and nine month periods ended September 30, 2014, the preferred stock that converted to common stock in the IPO was not included in the net loss per common share calculation as it did not convert until November 2014.

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,	
	2014	2013	2014	2013
Convertible preferred stock	865,429	865,429	865,429	865,429
Warrants to purchase convertible preferred stock	Adjustable	Adjustable	Adjustable	Adjustable
Stock issuable upon conversion of convertible notes	Adjustable	Adjustable	Adjustable	Adjustable
Options to purchase common stock	240,906	228,223	240,906	228,223
Warrants to purchase common stock	9,259	9,259	9,259	9,259

### **Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

On June 10, 2014, the FASB issued ASU 2014-10, *Elimination of Certain Financial Reporting Requirements, Including Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation*. The pending content resulting from the issuance of ASU 2014-10 eliminates the definition of development stage entity, thereby removing the distinction between the development stage entities and other reporting entities. As a consequence, inception-to-date presentation and other incremental disclosure requirements in ASC Topic 915 for entities previously considered development stage entities are eliminated. For public business entities, the ASU's elimination of the inception-to-date information and the other disclosures in Topic 915 is effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. For other entities, this portion of the ASU is effective for annual reporting periods beginning after December 15, 2014, and interim reporting periods beginning after December 15, 2015. While the changes resulting from the issuance of ASU 2014-10 are not yet effective, early adoption of either the amendments to Topic 915 or Topic 810 is permitted for any annual or interim period for which a reporting entity's financial statements have not yet been issued (public business entities) or made available for issuance (other entities.)

The Company adopted ASU 2014-10 as of June 30, 2014, and therefore is no longer considered in the development stage. The Company continues to engage in research and development activities; however, the adoption of this ASU allows the Company to remove the inception to date information and all references to development stage in the accompanying financial statements.

The Company has considered all other recently issued accounting pronouncements and does not believe the adoption of such pronouncements will have a material impact on its financial statements.

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**Note 3. Fair Value of Financial Instruments**

The carrying value of the Company's cash and cash equivalents, other receivable, prepaid expenses and other current assets, accounts payable, accrued liabilities, approximate fair value due to the short-term nature of these items. Convertible preferred stock call option liability and convertible preferred stock warrant liability are carried at fair value. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the convertible promissory notes approximates their fair value.

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

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

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

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

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

	Fair Value Measurements at December 31, 2013			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market fund	<u>\$1,256,752</u>	<u>\$1,256,752</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities</b>				
Convertible preferred stock warrant liability	<u>\$1,464,877</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,464,877</u>
	Fair Value Measurements at September 30, 2014			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market fund	<u>\$ 30,000</u>	<u>\$ 30,000</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Liabilities</b>				
Convertible preferred stock warrant liability	<u>\$3,066,258</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$3,066,258</u>

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The fair value measurement of the convertible preferred stock warrant liability is based on significant inputs not observed in the market and thus represents a Level 3 measurement. The Company's estimated fair value of the convertible preferred stock warrant liability is calculated using a Monte Carlo simulation and key assumptions including the probabilities of settlement scenarios, enterprise value, time to liquidity, risk-free interest rates, discount for lack of marketability and volatility (see Note 6). The estimates are based, in part, on subjective assumptions and could differ materially in the future. Generally, increases or decreases in the fair value of the underlying convertible preferred stock would result in a directionally similar impact in the fair value measurement of the warrant liability.

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

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows:

	<b>Convertible preferred stock warrant liability</b>
Balance at December 31, 2013	\$1,463,877
Issuance of convertible preferred stock warrants	714,699
Change in fair value recorded in other expense (income), net	887,682
Balance at September 30, 2014	<u>\$3,066,258</u>

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In connection with the completion of the Company's IPO in November 2014, all of the outstanding warrants to purchase convertible preferred stock converted into warrants to purchase shares of common stock.

**Note 4. Property and Equipment, Net**

Property and equipment consisted of the following:

	<u>December 31,</u> <u>2013</u>	<u>September 30,</u> <u>2014</u>
Furniture and fixtures	\$ 180,238	\$ 139,695
Computer hardware	27,555	27,555
Leasehold improvements	10,726	4,074
	<u>\$ 218,519</u>	<u>\$ 171,324</u>
Less accumulated depreciation and amortization	<u>(155,352)</u>	<u>(136,061)</u>
Total	<u>\$ 63,167</u>	<u>\$ 35,263</u>

Depreciation and amortization expense was \$32,000 and \$20,000 for the nine months ended September 30, 2013 and September 30, 2014, respectively.

**Note 5. Related Party Convertible Promissory Notes**

*2014 Convertible Promissory Notes*

In April 2014, the Company entered into convertible promissory notes with various investors for a total principal amount of \$1,747,681. These notes bear interest at the rate of 2% per annum in the event that the note is automatically converted into units, equal to one share of common stock and a warrant to purchase one share of common stock, upon the Company's Contemplated IPO, prior to the maturity date. At September 30, 2014, accrued interest for these convertible promissory notes totaled \$14,761. The convertible notes' principal amount, plus any accrued interest thereon, is due on September 30, 2015 following the occurrence of demand by two-thirds of the holders of the total principal amounts of convertible promissory notes outstanding. The outstanding principal and interest is convertible into the type of equity securities sold by the Company in the next round of equity financing under certain conditions, or into shares of Series C preferred stock. The convertible notes participate pari passu with the 2010 and 2012 convertible promissory notes upon repayment of the outstanding convertible promissory notes.

In connection with the April 2014 convertible notes, the Company issued a warrant for the purchase of preferred stock. The number of shares for which the warrant may be exercised is to be determined by dividing an amount equal to 25% of the unpaid principal by the exercise price prior to the expiration of this warrant. The exercise price for the warrant is 75% of the price per share of the next financing securities issued in the next financing or \$16.20 per share if converted into the Series C preferred stock. The warrants are exercisable: (1) after the earlier of (a) the closing date of a next financing that occurs prior to the Company's consummation of the IPO or (b) the note maturity date and (2) prior to the expiration of this warrant. The estimated fair value of the warrants at issuance was determined to be \$600,148, which was recorded as a debt discount and amortized using the effective interest rate method over the term of the convertible notes. The Company estimated the fair value of its preferred stock warrant liability at issuance utilizing a Monte Carlo simulation based on expected volatility of 35%, expected time to liquidity of event of 5.00 years and risk-free interest rate of 1.62%.

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After allocating \$600,148 to the warrants issued in connection with the April 2014 convertible notes as discussed above, the Company determined the fair value of the conversion option to be \$1,347,406, which was recorded as a debt discount to the convertible notes and within additional paid-in capital. The debt discount was amortized using the effective interest rate method over the term of the convertible notes. The discount to convertible notes for the intrinsic value of conversion options embedded in debt instruments is based upon the differences between the fair value of the underlying preferred stock at the commitment date of the note transaction and the effective conversion price embedded in the note.

In relation to the April 2014 convertible notes payable, the Company recognized interest expense for the nine months ended September 30, 2014 of \$14,761, which was included in the balance of convertible promissory notes and accrued interest on the accompanying balance sheets at September 30, 2014. Additionally, the Company recorded interest expense in connection with the amortization of the debt discount recorded for the nine months ended September 30, 2014 of \$572,516.

In August 2014, the Company entered into convertible promissory notes with various investors for a total principal amount of \$249,693. These notes bear interest at the rate of 2% per annum in the event that the note is automatically converted into units, equal to one share of common stock and a warrant to purchase one share of common stock, upon the Company's Contemplated IPO, prior to the maturity date. At September 30, 2014, accrued interest for the August 2014 convertible promissory notes totaled \$575. The convertible notes' principal amount, plus any accrued interest thereon, is due on September 30, 2015 following the occurrence of demand by two-thirds of the holders of the total principal amounts of convertible promissory notes outstanding. The outstanding principal and interest is convertible into the type of equity securities sold by the Company in the next round of equity financing under certain conditions, or into shares of Series C preferred stock. The convertible notes participate *pari passu* with the 2010 and 2012 convertible promissory notes upon repayment of the outstanding convertible promissory notes.

In connection with the August 2014 convertible notes, the Company issued a warrant for the purchase of preferred stock. The number of shares for which the warrant may be exercised is to be determined by dividing an amount equal to 25% of the unpaid principal by the exercise price prior to the expiration of this warrant. The exercise price for the warrant is 75% of the price per share of the next financing securities issued in the next financing or \$16.20 per share if converted into the Series C preferred stock. The warrants are exercisable: (1) after the earlier of (a) the closing date of a next financing that occurs prior to the Company's consummation of the IPO or (b) the note maturity date and (2) prior to the expiration of this warrant. The estimated fair value of the warrants at issuance was determined to be \$113,295, which was recorded as a debt discount and amortized using the effective interest rate method over the term of the convertible notes. The Company estimated the fair value of its preferred stock warrant liability at issuance utilizing a Monte Carlo simulation based on expected volatility of 35%, expected time to liquidity of event of 5.00 years and risk-free interest rate of 1.62%.

After allocating \$113,295 to the warrants issued in connection with the April 2014 convertible notes as discussed above, the Company determined the fair value of the conversion option to be \$136,705, which was recorded as a debt discount to the convertible notes and within additional paid-in capital. The debt discount was amortized using the effective interest rate method over the term of the convertible notes. The discount to convertible notes for the intrinsic value of conversion options embedded in debt instruments is based upon the differences between the fair value of the underlying preferred stock at the commitment date of the note transaction and the effective conversion price embedded in the note.

In relation to both the April and August 2014 convertible notes payable, the Company recognized interest expense for the nine months ended September 30, 2014 of \$15,336 which was included in the balance of convertible promissory notes and accrued interest on the accompanying balance sheets at September 30, 2014. Additionally, the Company recorded interest expense in connection with the amortization of the debt discount recorded for the nine months ended September 30, 2014 of \$25,246.



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[Table of Contents](#)**Note 6. Convertible Preferred Stock Warrants**

In 2010 and 2012, in conjunction with the related party convertible note financings, the Company issued preferred stock warrants. The Company re-measures the associated fair value of the convertible preferred stock warrant liability at each reporting period.

As of December 31, 2013 and as of September 30, 2014, the Company used a Monte Carlo simulation to calculate the fair value of its convertible preferred stock warrant liability using the following inputs:

	<u>December 31, 2013</u>	<u>September 30, 2014</u>
Volatility	38% - 47%	38% - 66%
Expected Term (years)	0.75 - 2.00	4.00 - 8.00
Expected dividend yield	0.0%	0.0%
Risk-free rate	0.12% - 0.38%	1.54% - 2.13%

In addition to the assumptions above, the Company's estimated fair value of the convertible preferred stock warrant liability is calculated using other key assumptions including the probability and value of the next equity financing, enterprise value, and discount for lack of marketability. Management, with the assistance of an independent valuation firm, makes these subjective determinations based on available current information; however, as such information changes, so might management's determinations and such changes could have a material impact of future operating results.

As of September 30, 2014, outstanding convertible preferred stock warrants consisted of:

<u>Issuance date</u>	<u>Contractual Term</u>	<u>Exercise price per share</u>	<u>Number of shares underlying warrant</u>	<u>Fair Value at December 31, 2013</u>	<u>Fair Value at September 30, 2014</u>
January 2009	10 years	\$ 21.60	9,259	\$ 42,444	\$ 3,597
February and March 2010	10 years	Adjustable	Adjustable	461,421	530,197
November 2010	10 years	Adjustable	Adjustable	263,875	303,609
January 2012	10 years	Adjustable	Adjustable	263,978	453,036
July 2012	10 years	Adjustable	Adjustable	432,159	743,184
April 2014	10 years	Adjustable	Adjustable		904,380
August 2014	10 years	Adjustable	Adjustable		128,255
Total				<u>\$ 1,463,877</u>	<u>\$ 3,066,258</u>

For the above warrants issued between February 2010, July 2012 and April 2014, the number of shares for which the warrants may be exercised are to be determined by dividing the unpaid principal by (a) 75% of the price per share of the equity securities issued in the next equity financing or (b) if converting into Series C preferred stock, \$16.20 per share. The exercise price for these warrants is determined by dividing the unpaid principal and accrued interest by 75% of the price per share of common stock issued in such financing or \$16.20 per share if converted into the Series C preferred stock.

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As of December 31, 2013 and as of September 30, 2014, all warrants issued from February 2010 through August 2014 by the Company were issued to related parties consisting of investors and the Chairman of the Board. No convertible preferred stock warrants expired or were exercised during 2013 or during the nine months ended September 30, 2014.

**Note 7. Credit Facility**

On September 29, 2014, the Company established a line of credit in the amount of up to \$0.1 million. The line of credit bears a fixed interest rate of 6.0% per annum simple interest. The line of credit has a two-year repayment term, with prepayment at the Company's option with no penalty. The line of credit shall be payable out of cash received in the Company's accounts receivable following their commencement of commercial sales.

**Note 8. Commitments and Contingencies**

*Facility Leases*

The Company leases its headquarters facility under a non-cancelable operating lease agreement set to expire in May 2015. The Company previously leased two other facilities under non-cancelable operating lease agreements that expired in January 2014 and May 2014, respectively. Rent expense was \$234,000 and \$177,000 during the nine months ended September 30, 2013 and September 30, 2014, respectively.

As of September 30, 2014, the Company's future minimum commitments under non-cancelable operating lease are approximately \$73,000.

*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 2010 the Company entered into an asset purchase agreement with BioMedical Drug Development, Inc. Pursuant to the agreement, the Company made a payment of \$150,000 for the acquisition of intellectual property which the Company used to develop its product, CoSense. As part of the terms of the agreement, the Company is contingently committed to make development and sales-related milestone payments of up to \$200,000 under certain circumstances, as well as single-digit-percentage royalties relating to potential planned product sales of CoSense. The amount, timing and likelihood of these payments are unknown, as they are dependent on the occurrence of future events that may or may not occur. In 2013 and during the nine months ended September 30, 2014, the Company made no payments and incurred no liabilities in connection with the agreement, and there are no outstanding payments due as of December 31, 2013 and as of September 30, 2014.

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**Note 9. Capital Stock**

***Common Stock:***

The Company is authorized to issue 10,000,000 shares of common stock as of September 30, 2014 with a par value of \$0.001 per share. As of December 31, 2013 and as of September 30, 2014, the Company had 535,685 shares of common stock issued and outstanding.

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when and if declared by the Board of Directors, subject to the prior rights of all classes of stock outstanding. The holders of common stock, voting as a separate class, are entitled to elect one member of the Board of Directors.

***Convertible Preferred Stock:***

The Company is authorized to issue 1,860,000 shares of convertible preferred stock as follows at December 31, 2013 and September 30, 2014:

<u>Series</u>	<u>Par Value</u>	<u>Shares Authorized</u>	<u>Shares Outstanding</u>
A	\$ 0.001	40,000	31,250
B	0.001	320,000	119,140
C	0.001	1,500,000	715,039
		<u>1,860,000</u>	<u>865,429</u>

In connection with the completion of the Company's IPO on November 18, 2014, all shares of convertible preferred stock converted into 865,429 shares of common stock and all of the Company's convertible preferred stock warrants were converted into warrants to purchase common stock. As of September 30, 2014, the holders of Series A, Series B and Series C convertible preferred stock, had the rights, preferences, privileges and restrictions as follows:

***Voting:***

The holders of each share of Series A, Series B and Series C would have been entitled to voting rights equal to the number of shares of common stock into which each share of preferred stock would have been converted. So long as at least 1,000,000 shares are outstanding, the holders of Series A, Series B and Series C, voting together as a single class, would have been entitled to elect three members of the Board of Directors. The holders of common stock, voting as a separate class, would have been entitled to elect one member of the Board of Directors. The holders of Series A, Series B, Series C and common stock, voting together as a single class on an as converted basis, would have been entitled to elect the remaining members of the Board of Directors.

Certain actions would have required the vote or written consent of at least two-thirds of the holders of preferred stock, including, but not limited to, the following: any amendment, alteration or repeal of the Certificate of Incorporation or the Bylaws of the Company that alters or changes the rights or restrictions of the preferred stock; any increase or decrease in the authorized number of shares of preferred stock; any distributions with respect to common stock or preferred stock; any agreement by the Company or its stockholders regarding asset transfer or acquisition; creation of any new class or series of shares having rights, preferences or privileges and voting rights for the Board of Directors, which are better than existing preferred stock.

***Dividends:***

The holders of Series A, Series B and Series C would have been entitled to receive non-cumulative dividends as adjusted for stock splits, dividends, reclassifications or the like, prior and in preference to any

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declaration or payment of any dividends to the holders of common stock, when and if declared by the Board of Directors, at a rate of \$3.84, \$4.61, and \$1.73, respectively, per share, as adjusted, per annum. No dividends have been declared or paid to date.

*Conversion:*

Each share of Series A, Series B and Series C would have been convertible to common stock, at the option of the holder, at any time after the date of issuance. Each share of Series A, Series B and Series C converts into that number of shares of common stock determined in accordance with the conversion ratio (i) immediately prior to the closing of a public offering of common stock provided that the offering price per share is not less than \$75.60 (adjusted for recapitalizations) and gross proceeds to the Company are not less than \$30,000,000 or (ii) upon the written request by the Company from the holders of two thirds of the preferred stock outstanding. The initial conversion ratio would have been one share of common stock for each share of preferred stock. The initial conversion price would have been equal to the original issuance price of Series A, Series B and Series C, as adjusted. At December 31, 2013 and September 30, 2014, the conversion price is \$48.00, \$57.60 and \$21.60 per share, for Series A, Series B and Series C, respectively.

*Liquidation:*

In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of Series A, Series B and Series C would have been entitled to receive, prior to and in preference to holders of common stock, an amount per share equal to \$48.00, \$57.60 and \$21.60, respectively, as adjusted for stock splits, stock dividends, reclassifications or the like. If, upon occurrence of such an event, the assets and funds distributed among the holders of Series A, Series B and Series C are insufficient to permit the above payment to such holders, then the entire assets and funds of the Company legally available for distribution would have been distributed ratably among the holders of Series A, Series B and Series C in proportion to the preferential amount each such holder is otherwise entitled to receive.

Following the above payments, the remaining assets and surplus funds of the Company, if any, would have been distributed ratably among the holders of Series A, Series B, Series C and common stock based on the number of shares of common stock held on an as-if converted basis.

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*Redemption:*

The holders of Series A, Series B and Series C would have been entitled to require the Company to redeem their shares, at any time after March 20, 2012, upon the approval of at least two thirds of the holders of shares of Series A, Series B and Series C then outstanding, voting together as a single class. The redemption would have been affected in two annual payments beginning no later than 45 days after the Company receives the redemption notice. The redemption price would have been equal to \$48.00, \$57.60 and \$21.60 per share for Series A, Series B and Series C, respectively, as adjusted, plus all declared or accrued but unpaid dividends. As of December 31, 2013 and as of September 30, 2014, the total redemption price for Series A, Series B and Series C shares outstanding was \$23,808,048.

**Note 10. Stock Option Compensation**

***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 2010 Plan and 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. Fair value is determined by the Board of Directors. The vesting period is normally monthly over a period of four years from the vesting date. The term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options.

The Company recognized stock-based compensation expense related to options granted to employees for the nine-month periods ended September 30, 2013 and September 30, 2014 of \$34,810 and \$20,944, 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 December 31, 2013 and nine month ended September 30, 2014.

The Company did not grant any stock options in 2013. The Company granted 12,683 options to purchase common stock in February 2014. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for the nine-month period ended September 30, 2014:

	<b>Nine Months Ended September 30, 2014</b>
Expected life (years)	5.0 - 8.0
Risk-free interest rate	1.6% - 2.3%
Volatility	35% - 59%
Dividend rate	0%

The most recent independent third-party valuation of the Company’s common stock found \$7.56 to be the fair market value as of December 31, 2013 and \$7.56 per share to be the fair market value as of September 30, 2014.

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Expected volatility is based on volatilities of a group of public companies operating in the Company's industry. The expected life of stock options represents the average of the contractual term of the options and the weighted-average vesting period, as permitted under the simplified method. The Company has elected to use the simplified method, as the Company does not have enough historical exercise experience to provide a reasonable basis upon which to estimate the expected term and the stock option grants are considered "plain vanilla" options. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant.

The following table summarizes stock option transactions for the years ended December 31, 2013, and for the nine month period ended September 30, 2014 as issued under the Plans:

	<u>Options Available</u>	<u>Number of Shares</u>	<u>Average Exercise Price</u>
Balances, December 31, 2013	124,824	239,606	3.36
Granted	(12,683)	12,683	7.56
Cancelled	11,382	(11,382)	3.96
Balances, September 30, 2014	123,523	240,906	3.59

At December 31, 2013 and at September 30, 2014, there were 232,302 and 228,224 shares, respectively, vested with a weighted-average exercise price of \$3.36 and \$3.59 per share, respectively, and a weighted average contractual life of 4.86 and 4.4 years, respectively. There were no stock options issued during the nine months ended September 30, 2014.

Future stock-based compensation for unvested employee options granted and outstanding as of December 31, 2013 and as of September 30, 2014 is \$8,287 and \$38,028, respectively, to be recognized over a remaining requisite service period of 0.4 and 3.0 years, respectively.

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.

### **Note 11. GSK License Agreement**

In 2013, the Company entered into a license agreement with GSK in which GSK was to develop and commercialize the Company's product, Serenz, on a world-wide basis. In 2013, the Company recognized license revenue of \$3,000,000 due to a non-refundable payment upon execution of the agreement. In June 2014, the GSK agreement terminated and the licensed rights to Serenz were returned to the Company. Accordingly, the Company does not expect additional revenue to result from this agreement. Because the upfront payment was non-refundable, the Company is not obligated to return any of the funds as a result of the termination of the agreement. The Company does not have any continuing obligations under the GSK agreement.

### **Note 12. 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 conversion of preferred stock. For the three and nine months ended September 30, 2014, 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 for each of those periods.

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The following is a reconciliation of the number of shares used in the calculation of basic earnings per share and diluted earnings per share during the three and nine months ended September 30, 2013 and 2014:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Net loss	<u>\$(1,590,223)</u>	<u>\$(2,393,808)</u>	<u>\$(2,733,261)</u>	<u>\$(6,019,420)</u>
Weighted-average shares used in computing basic and diluted net loss per common share	535,685	535,685	535,611	535,685
Basic and diluted net loss per common share	\$ (2.97)	\$ (4.47)	\$ (5.10)	\$ (11.24)

**Note 13. Subsequent Events**

On October 30, 2014, the Company received cash proceeds of approximately \$490,000 in exchange for convertible promissory notes and warrants to purchase convertible preferred stock issued to existing investors referred to herein as the October 2014 notes. These notes were issued on the same terms and conditions as the April 2014 and August 2014 notes, and represent a continuation of the second tranche issued pursuant to the Promissory Note and Warrant Purchase Agreement entered into with various investors in April 2014 and August 2014 (See note 5).

On November 18, 2014, the Company completed its IPO, pursuant to which the Company issued 1,650,000 units (each unit consisting of one share of common stock, one Series A warrant and one Series B warrant) and received net proceeds of approximately \$8.2 million, after deducting underwriting discounts and commissions and IPO related expenses. In connection with the completion of the Company's IPO, all shares of convertible preferred stock converted into 865,429 shares of common stock and all of the Company's convertible preferred stock warrants were converted into warrants to purchase common stock. In addition, the outstanding convertible notes of \$10.2 million issued during 2010 and 2012 and accrued interest of \$5.2 million converted into an aggregate of 3,165,887 shares of common stock and the issuance of 523,867 warrants to purchase common stock. The outstanding convertible notes of approximately \$2.5 million issued during April, August and October, 2014 and accrued interest of approximately \$21,000 converted into an aggregate of 552,105 units in the IPO.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operation**

*The interim 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, 2013, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, contained in the Prospectus filed with the SEC pursuant to Rule 424(b)(4) on November 12, 2014. 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 develop diagnostics and therapeutics based on our proprietary technology for precision metering of gas flow. Our first diagnostic product, CoSense®, aids in the diagnosis of hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, hemolysis is a dangerous condition which can lead to long-term developmental disability. CoSense received initial 510(k) clearance for sale in the U.S. in the fourth quarter of 2012, with a more specific Indication for Use related to hemolysis in the first quarter of 2014 and received CE Mark approval for sale in the E.U. in the third quarter of 2013. We initiated our commercialization of CoSense in October 2014 using our own sales efforts, and intend to direct a significant portion of the use of proceeds of the IPO to sales and marketing of CoSense. We are also applying our research and development efforts to additional diagnostic products based on our Sensalyze™ Technology Platform, a portfolio of proprietary methods and devices which enables CoSense and can be applied to detect a variety of analytes in exhaled breath.

Prior to 2010, our efforts were primarily focused on development of therapeutics rather than diagnostics. We have previously obtained CE Mark approval in the E.U. for Serenz, an as-needed treatment for AR that has shown statistically significant improvements in AR symptoms in randomized, controlled Phase 2 clinical trials completed by us. We outlicensed Serenz™ to GSK in 2013, realizing revenue in the form of a non-refundable up-front payment of \$3.0 million. In June 2014, the agreement terminated and GSK returned the licensed rights to Serenz back to us. We have no further monetary obligations to GSK related to the terminated agreement. We intend to engage in further research and development of Serenz prior to obtaining a partner for the final development and commercialization of the product.

In November, 2014, we completed our IPO, pursuant to which we issued 1,650,000 units (each unit consisting of one share of common stock, one Series A warrant and one Series B warrant) and received net proceeds of approximately \$8.2 million, after deducting underwriting discounts and commissions and IPO related expenses. In connection with the completion of our IPO, all shares of convertible preferred stock converted into 865,429 shares of common stock and all of our convertible preferred stock warrants were converted into warrants to purchase common stock. In addition, the outstanding convertible notes and accrued interest issued during 2010 and 2012 converted into an aggregate of 3,165,887 shares of common stock and the issuance of 523,867 warrants to purchase common stock. The outstanding convertible notes issued during April, August and October, 2014 converted into an aggregate of 552,105 units in the IPO.

We have not generated net income from operations and as of September 30, 2014, we had an accumulated deficit of \$63.1 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 CoSense and 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. The GSK agreement terminated in June 2014, and we may not generate future licensing revenue. We may never be successful in commercializing our CoSense product 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.



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[Table of Contents](#)**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 financial statements, which have been prepared in accordance with GAAP. The preparation of these 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 2 of the accompanying unaudited condensed financial statements and in Note 1 to our audited financial statements contained in the Prospectus.

During the nine months ended September 30, 2014, there were no material changes to our critical accounting policies. Our critical accounting policies are described under *Management's Discussion and Analysis of Financial Condition and Results of Operations* in the Prospectus.

**Results of Operations*****Comparison of the Three and Nine Month Periods Ended September 30, 2013 and 2014***

	Three Months Ended		Change	Nine Months Ended		Change
	September 30,			September 30,		
	2014	2013		2014	2013	
	(in thousands)					
Revenue	\$ —	\$ —	\$ —	\$ —	\$ 3,000	\$(3,000)
Operating expenses:						
Research and development	717	745	(28)	1,633	2,020	(387)
Sales and marketing	84	—	84	96	—	96
General and administrative	522	248	274	1,585	1,267	318
Total	<u>1,323</u>	<u>993</u>	<u>330</u>	<u>3,314</u>	<u>3,287</u>	<u>27</u>
Income (Loss) from operations	(1,323)	(993)	(330)	(3,314)	(287)	(3,027)
Interest income	—	—	1	1	1	—
Interest expense	(752)	(571)	(181)	(1,811)	(2,471)	660
Other income (expense), net	<u>(318)</u>	<u>(26)</u>	<u>(293)</u>	<u>(895)</u>	<u>24</u>	<u>(919)</u>
Net loss	<u>\$ (2,393)</u>	<u>\$ (1,590)</u>	<u>\$ (803)</u>	<u>\$ (6,019)</u>	<u>\$ (2,733)</u>	<u>\$ (3,286)</u>

***Revenue***

No revenue was recognized in the three or nine months ended September 30, 2014. The \$3.0 million of revenue recognized in the nine months ended September 30, 2013 represented the revenue recognized from the non-refundable up-front payment pursuant to our license agreement with GSK.

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***Research and development expense***

Research and development expense was constant for the three months ended September 30, 2014, as compared to the same period in 2013. Research and development expense decreased \$0.4 million for the nine months ended September 30, 2014, as compared to the same period in 2013. The decrease was primarily due to employee related expenses due to lower headcount in 2014 versus 2013.

***Sales and marketing expense***

Sales and marketing expense increased \$0.1 million for the three months and \$0.1 million for the nine months ended September 30, 2014, as compared to the same periods in 2013. These increases were primarily due to the addition of the Vice President of Sales in June 2014 and commercial launch activities for CoSense.

***General and administrative expense***

General and administrative expense increased \$0.3 million for the three and nine months ended September 30, 2014, as compared to the same periods in 2013. The increase was primarily due to increase in consulting costs and employee related expenses due to increased executive headcount in 2014 versus 2013.

***Interest income***

Interest income and other, net was not material and remained relatively consistent for both the three and nine months ended September 30, 2013 and 2014.

***Interest expense***

Interest expense increased \$0.2 million in the three months ended September 30, 2014, as compared to the same period in 2013. This increase was primarily due to the higher debt balance from the April 2014 convertible notes and increased amortization on the debt discount associated with these notes. Interest expense decreased \$0.6 million for the nine months ended September 30, 2014 compared to the same period in 2013. The decrease was primarily due to the fact that the discounts for the 2010 and 2012 convertible notes were fully amortized as of December 31, 2013.

***Other income (expense), net***

Other expense increased \$0.3 million for the three months and \$0.9 million for the nine months ended September 30, 2014, compared to the same periods in 2013. These increases were primarily due to the increase in the fair value of the preferred stock warrant liability.

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**Liquidity and Capital Resources**

	Nine-Month Periods Ended	
	September 30,	
	2014	2013
	(in thousands)	
<b>Cash Flows from Continuing Operations:</b>		
Net cash provided by (used in) operating activities	\$ (2,928)	\$ (163)
Net cash used in investing activities	—	(1)
Net cash provided by financing activities	<u>1,723</u>	<u>—</u>
Net increase (decrease) in cash and cash equivalents	<u>\$ (1,205)</u>	<u>\$ (164)</u>

***Cash provided by (used in) operating activities***

During the nine months ended September 30, 2014, net cash used in operating activities was \$2.9 million, which was primarily due to the use of funds in our operations related to the development of our products. Net cash used in operating activities in the nine months ended September 30, 2013 was primarily due to the use of funds in our operations related to the development of our products, offset by the receipt of \$3.0 million from GSK.

***Cash used in investing activities***

Cash used in investing activities consisted primarily of investment in equipment.

***Cash provided by (used in) financing activities***

During the nine months ended September 30, 2014, cash provided by financing activities was \$1.7 million, consisting primarily of net proceeds of \$1.9 from issuance of convertible promissory notes in April and August 2014, offset by IPO related expenses paid.

As of September 30, 2014, we had cash and cash equivalents of approximately \$0.1 million, including the net proceeds we received from our convertible note financing in April and August 2014. As of September 30, 2014, there was substantial doubt about our ability to continue as a going concern, if we did not secure additional financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our 2013 financial statements with respect to this uncertainty. However, as described more fully below, since September 30, 2014, we completed our IPO and received net proceeds of \$8.2 million, after deducting underwriting discounts and commissions and IPO related expenses. We believe that our cash resources are sufficient to meet our cash needs for at least the next 12 months.

**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, 2014. For additional information regarding market risk, refer to the *Qualitative and Quantitative Disclosures About Market Risk* section of the Prospectus.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

A company's internal control over financial reporting is a process designed by, or under the supervision of, that company's principal executive and principal financial officers, or persons performing similar functions, and effected by that company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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 policies or procedures may deteriorate.

In connection with our preparation for the IPO, we concluded that there was a material weakness in our internal control over financial reporting that caused the restatement of our previously issued financial statements as of and for the year ended December 31, 2012, and the deficiencies extended through the year ended December 31, 2013. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The following material weakness was identified: We did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements. As of December 31, 2013, our financial operations staff consisted of one part-time consultant.

During 2014 and in preparation for the IPO, we initiated various remediation efforts, including initiation of hiring processes for additional personnel with the appropriate public company and technical accounting expertise, and other actions that are more fully described below. As such remediation efforts are still ongoing, we have concluded that the material weakness has not been remediated. Our remediation efforts to date have included the following:

*Addition of Employee Resources*—We are in the process of adding appropriate full-time resources to our finance team and are have hired additional external consultants with public company and technical accounting experience to facilitate accurate and timely accounting closes, and to accurately prepare and review financial statements and related footnote disclosures. For example, we hired a new Chief Financial Officer on July 7, 2014. Our finance team is being expanded to include external consultants with significant financial and accounting technical experience.

*Other Actions to Strengthen the Internal Control Environment*—As a result of the additional resources added to the finance function, we are allowing for separate preparation and review of the reconciliations and other account analyses. In addition, these additional finance resources are allowing us to develop a more structured close process, including enhancing our existing policies and procedures, to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including, but not limited to, those regarding proper financial statement classification, recognition of accruals to ensure proper period-end cutoff of expenses and assessing more judgmental areas of accounting.

The actions that have been taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have implemented a plan to remediate this weakness, we cannot assure you that we will be able to remediate this weakness, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

Notwithstanding the material weakness that existed as of September 30, 2014, December 31, 2012 and December 31, 2013, our management has concluded that the condensed financial statements included elsewhere in this quarterly report present fairly, in all material respects, our financial position, results of operation and cash flows in conformity with GAAP.

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If we fail to fully remediate this material weakness or fail to maintain effective internal controls in the future, it could result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis, which could cause investors to lose confidence in our financial information or cause our stock price to decline. Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and, under the JOBS Act, will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings

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

### Item 1A. RISK FACTORS

#### Risks related to our financial condition and capital requirements

*We have a limited operating 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 only one product approved for sale, and have generated no 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 operating history. Other than CoSense®, which has received 510(k) clearance from the FDA and CE Mark clearance in the E.U., we have no other products currently approved. 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 device product development is highly speculative, because it entails substantial upfront capital expenditures and significant risk that any potential 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 some time after the completion of the IPO. As of September 30, 2014, we had an accumulated deficit of \$63.1 million.

We expect that our future financial results will depend primarily on our success in launching, selling and supporting CoSense and other products. This will require us to be successful in a range of activities, including manufacturing, marketing and selling CoSense. 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 no source of product revenue and may never become profitable.*

To date, we have not generated any revenues from commercial product sales, and have not generated sufficient revenues from licensing activities to achieve profitability. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability, alone or with any future collaborators, to successfully commercialize products, including CoSense, 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 products, if any;
- set a commercially viable price for our products;

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- 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 distribution partners for CoSense or Serenz to help us market, sell and distribute our approved products in other markets;
- demonstrate the safety and efficacy of Serenz to the satisfaction of FDA and obtain regulatory approval for Serenz and planned products, if any, for which there is a commercial market;
- 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, including that CoSense, Serenz or any planned products may not advance through development or achieve the endpoints of applicable clinical trials, 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 or any planned products, we anticipate incurring significant costs associated with commercializing these products.

Even if we are able to generate revenues from the sale of CoSense, 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.

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*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, after the closing of the IPO, 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, including substantial hiring of sales and marketing personnel;
- 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 CoSense and any planned products, which may vary depending on FDA guidelines and 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 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 of Serenz or any of our planned products;
- the level of demand for CoSense, and for Serenz and any planned products, should they receive approval, 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 CoSense, Serenz or any of our planned products;
- our ability to commercialize CoSense 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;



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- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

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

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

The commercialization of CoSense, as well as the completion of the development and the potential commercialization of planned products, will require substantial funds. As of September 30, 2014, we had approximately \$0.1 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 CoSense, including marketing, manufacturing, and distribution;
- the cost of preparing to manufacture CoSense instruments and consumables on a larger scale;
- the degree and rate of market acceptance of CoSense, and the revenue that we are able to collect from sales of CoSense as a result;
- our ability to set a commercially attractive price for CoSense devices and consumables, 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 a partner for Serenz on attractive economic terms, or engage in commercial sales of Serenz on our own or through 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;

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- 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.

We do not have any material committed external source of funds or other support for our commercialization and development efforts. Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, 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.

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.***

As of September 30, 2014, there was substantial doubt about our ability to continue as a going concern, if we did not secure additional financing. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our 2013 financial statements with respect to this uncertainty. However, as described more fully below, since September 30, 2014, we completed our IPO and received net proceeds of \$8.2 million, after deducting underwriting discounts and commissions and IPO related expenses. We believe that our cash resources are sufficient to meet our cash needs for at least the next 12 months.

### **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. If we are unable to sell sufficient numbers of our CoSense instruments and disposables, our revenues may be insufficient to achieve profitability.***

CoSense is our sole product approved for sale. As a result, we will derive substantially all of our revenues from sales of CoSense devices and consumables for the foreseeable future. If we cannot generate sufficient revenues from sales, we may be unable to finance our continuing operations.

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***We have not commercialized any product in the past, and may not be successful in commercializing CoSense.***

We have no history of successful product launches. Our efforts to launch CoSense into the neonatology marketplace are subject to a variety of risks, any of which may prevent or limit sales of the CoSense instruments and consumables. 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 CoSense from the marketplace by regulatory authorities.

***If we are unable to execute our sales and marketing strategy for CoSense, 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 CoSense, and our 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 CoSense and build that market 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 current test and our planned tests.

Our ability to successfully market CoSense and our future diagnostic products will depend on numerous factors, including:

- the outcomes of clinical utility studies of such diagnostics in collaboration with key thought leaders to demonstrate our products' value in informing important medical decisions such as treatment selection;
- the success of the sales force which we intend to hire with some of the proceeds of the IPO;
- 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.

Failure to achieve widespread market acceptance of CoSense and our other planned products would materially harm our business, financial condition and results of operations.

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

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

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In addition, although treatment guidelines recommend end-tidal carbon monoxide, or 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. 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. Furthermore, AAP guidelines are updated approximately every ten years, and the current guidelines were published in 2004, so the 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 CoSense, or our 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 CoSense and our other planned products can provide reliable, high-quality diagnostic results. 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 CoSense or our 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 our sole final-assembly manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell CoSense and to pursue our research and development efforts may be jeopardized.***

We currently manufacture CoSense instruments and consumables. These are comprised of components sourced from a variety of contract manufacturers, with final assembly and calibration completed at our facility in Redwood City, California. We have recently moved these facilities from our prior location, a move which may be disruptive and risks interruption of manufacturing activities. We do not have any backup final-assembly facilities. We depend on contract manufacturers for our CoSense components, and for some of these we rely on a sole supplier. The San Francisco Bay area has experienced serious fires and power outages in the past, and is considered to lie in an area with significantly above-average earthquake risk. Our facilities and equipment, or those of our sole-source suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including fire, earthquake, flooding and power outages. Any of these may render it difficult or impossible for us to manufacture products for some period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of our planned products, may result in the loss of customers or harm to our reputation or relationships with scientific or clinical collaborators; we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

***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 principal competition 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 CoSense or our planned products. These include General Electric Healthcare, 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

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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.***

In recent years, we have incurred significant costs in connection with the development of CoSense. For the year ended December 31, 2013, our research and development expenses were \$2.4 million. 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 nitric oxide and other analytes. We will also incur significant expenses to establish a sales and marketing organization, 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 a CE Mark, clearing the device for commercial sale. However, upon our license of the product to Block Drug Company, a wholly-owned subsidiary of GlaxoSmithKline, or GSK, we discontinued the contract manufacturing relationships that formed a key element of the CE Mark documentation. An application for revival of the CE Mark will need to be submitted to the Notified Body for approval prior to commercialization of Serenz in the E.U. Furthermore, neither we, nor any future collaboration partner, can commercialize Serenz in any country outside of the E.U. without obtaining regulatory approval from comparable foreign regulatory authorities. 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 novo* 510(k) pathway, or traditional 510(k). Additional randomized, controlled clinical trials 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 partner 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.

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***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 efficacy 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 efficacy 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 efficacy 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 efficacy 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 efficacy 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.



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If we or any future collaboration partner are required to conduct additional clinical trials or other testing of Serenz or any planned products beyond those that we contemplate, 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.

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 efficacy of Serenz for treatment of 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, 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;

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- their efficacy 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 of marketing and distribution support; 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 CoSense, 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 organization or outsource these functions to third parties. We intend to commercialize CoSense with our own specialty sales force in the U.S., Canada and potentially other geographies. If we obtain regulatory approval, we intend to commercialize Serenz through third-party partners or distributors.

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.

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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. They 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 marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

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

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

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***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 CoSense and for Serenz, 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 CoSense 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 commercialize CoSense, Serenz, or any planned products, or to obtain a partner to commercialize Serenz, the products 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 CoSense or any planned 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.

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 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

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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.

Similar risks apply to the reimbursement of Serenz.

### ***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 CoSense and any planned products in human clinical studies. The marketing, sale and use of CoSense 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 CoSense 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 \$5.0 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 Chief Financial Officer, Anthony Wondka, our Vice President of Research and Development, Gina Phelps, our Vice President of Sales, and Antoun Nabhan, our Vice President of Corporate Development. 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

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Officer, Vice President of Sales, Vice President of Corporate Development and Vice President of Research and Development have employment agreements, however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We have secured a \$1,000,000 “key person” life insurance policy on our Chief Executive Officer, Dr. Anish Bhatnagar but do not otherwise maintain “key person” life insurance on any of our employees.

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

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.

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

***Our inability to attract, hire and retain a sufficient number of qualified sales professionals would hamper our ability to increase demand for CoSense, to expand geographically and to successfully commercialize any other products we may develop.***

To succeed in selling CoSense and any other products that we are able to develop, we must develop a sales force in the U.S. and internationally by recruiting sales representatives with extensive experience in neonatology and close relationships with neonatologists, pediatricians, nurses, and other hospital personnel. To achieve our marketing and sales goals, we will need to build our sales and commercial infrastructure, with which to date we have had little experience. Sales professionals with the necessary technical and business qualifications are in high demand, and there is a risk that we may be unable to attract, hire and retain the number of sales professionals with the right qualifications, scientific backgrounds and relationships with decision-makers at potential customers needed to achieve our sales goals. We expect to face competition from other companies in our industry, some of whom are much larger than us and who can pay greater compensation and benefits than we can, in seeking to attract and retain qualified sales and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer.

***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 CoSense instruments and consumables, 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 CoSense or the development and commercialization of planned products.***

We perform final assembly of CoSense instruments 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 CoSense instrument and consumables. 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

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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 the CoSense instruments and consumables 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 CoSense are currently sole-source, 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 planned 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 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.

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

Our business strategy contemplates international expansion, including partnering with medical device distributors, and introducing CoSense 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 test and our planned future tests 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.***

The diagnostic 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 device 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



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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 CoSense, 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 CoSense, 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 planned 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 planned 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 CoSense or our other planned 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 planned product, repeat or conduct new clinical studies or require a new engineering iterations of a planned product for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or planned 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 planned 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 planned 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 planned products, increases in our costs to develop the planned products or the termination of development of a planned product.

***Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on our chief executive officer and the other principal members of our executive team. Under the terms of their employment, our executives may terminate their employment with us at any time. The loss of the services of any of these people could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

***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, 2014, we had eight employees and seven 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;

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- 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 CoSense 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.***

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 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

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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 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.

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***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. For example, we entered into an asset purchase agreement with BDDI on May 11, 2010, pursuant to which we have ongoing payment obligations relating to CoSense. A breach of this agreement would therefore materially adversely affect our ability to commercialize CoSense as currently planned. BDDI has the right to terminate the agreement upon 60 days' written notice in the event that we fail to make any royalty payment when due and do not remedy such failure after notice. Termination of this agreement, or reduction or elimination of our rights under it or any other agreement, may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business and financial condition.

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.

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

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

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

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

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

In addition to our patented technology and products, we rely upon confidential proprietary information, including trade secrets, unpatented know-how, technology and other proprietary information, to develop and maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information, however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to

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the same extent as the laws of the U.S. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

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

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

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

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents or applications will be due to be paid by us to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents or applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and this circumstance would have a material adverse effect on our business.



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### ***Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.***

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

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

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

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

### **Risks related to government regulation**

#### ***The regulatory approval process is expensive, time consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of Serenz or our planned products.***

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, which regulations differ from country to country. We are not permitted to market our planned products in the U.S. until we received the requisite approval or clearance from the FDA. We have not submitted an application or received marketing approval for Serenz or any planned products. Obtaining PMA or 510(k) clearance for a medical device from the FDA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including the following:

- warning letters;
- civil or criminal penalties and fines;
- injunctions;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical studies;

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- voluntary or mandatory product recalls and publicity requirements;
- refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;
- restrictions on operations, including costly new manufacturing requirements; or
- seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our planned products in the U.S. or abroad, we may be required to demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such planned products are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we believe the preclinical or clinical data for our planned products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our planned products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications.

Regulatory approval from the FDA is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical studies, or perform additional preclinical studies and clinical studies. The number of preclinical studies and clinical studies that will be required for FDA approval varies depending on the planned product, the disease or condition that the planned product is designed to address and the regulations applicable to any particular planned product. The FDA can delay, limit or deny approval of a planned product for many reasons, including, but not limited to, the following:

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

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

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

Once regulatory approval has been obtained, the approved product and its manufacturer are subject to continual review by the FDA or non-U.S. regulatory authorities. Our regulatory approval for CoSense, as well as any regulatory approval that we receive for Serenz or for any planned products may be subject to limitations on the indicated uses for which the product may be marketed. Future approvals may contain requirements for potentially costly post-marketing follow-up studies to monitor the safety and efficacy of the approved product. In addition, we are subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the labeling, packaging, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. In addition, we are required to comply with cGMP regulations regarding the manufacture of Serenz, which include requirements related to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture drug products, and these facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a third party discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturer or us, including requiring withdrawal of the product from the market or suspension of manufacturing.

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

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

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

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

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

- imposes a tax of 2.3% on the retail sales price of medical devices sold after December 31, 2012;
- could result in the imposition of injunctions;
- requires collection of rebates for drugs paid by Medicaid managed care organizations; and
- requires manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discounts off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

While the U.S. Supreme Court upheld the constitutionality of most elements of the PPACA in June 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the PPACA. At this time, it remains unclear whether there will be any changes made to the PPACA, whether to certain provisions or its entirety. At this time, we believe the 2.3% tax on sales of medical devices will be applicable to sales of CoSense devices, and may be applicable to CoSense consumables and Serenz devices. We cannot assure you that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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

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

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

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

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

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

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

- the federal healthcare program Anti-Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

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

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

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

### **Risks related to the IPO and ownership of our securities**

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

Our stock price is likely to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the IPO price. The market price for our common stock may be influenced by many factors, including the following:

- our ability to successfully commercialize, and realize revenues from sales of, CoSense;

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

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

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

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

In connection with the IPO, we, our officers and directors and holders of 1% or more of our currently outstanding shares of common stock have agreed, subject to limited exceptions, not to sell or transfer any shares of common stock for 180 days after the date of the Prospectus without the consent of Maxim Group LLC, or Maxim. However, Maxim may release these shares from any restrictions at any time. We cannot predict what effect, if any, market sales of shares held by any stockholder or the availability of shares for future sale will have on the market price of our common stock.

Approximately 1,436,161 shares of common stock may be sold in the public market by existing stockholders after the date of the final Prospectus and an additional 4,822,670 shares of common stock may be sold in the public market by existing stockholders on or about 181 days after the date of the final Prospectus, subject to volume and other limitations imposed under the federal securities laws. Sales of substantial amounts of our common stock in the public market after the completion of the IPO, or the perception that such sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through offerings of our common stock.

We have issued Series A warrants and Series B warrants to purchase a total of 3,795,000 shares of common stock in the IPO each subject to adjustment. The number of shares of common stock exercisable for Series B warrants could increase if the market price of our stock decreases; see the Prospectus and the section entitled "Description of Securities." We have also issued compensation warrants to the underwriters in the IPO to purchase an additional 82,500 shares of our common stock and additional compensation warrants to the underwriters to purchase 12,375 shares of our common stock if the over-allotment option is exercised in full. In addition, as of September 30, 2014, we had outstanding options to purchase 240,906 shares of our common stock and outstanding warrants to purchase an aggregate of 918,551 shares of our common stock. We will also have outstanding other options that were granted upon the completion of the IPO which would result in the issuance of an additional 913,701 shares of common stock. We have registered for offer and sale the shares of common stock that are reserved for issuance pursuant to outstanding options. Shares covered by such registration statements upon the exercise of stock options generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act of 1933, as amended. The issuance or sale of such shares could depress the market price of our common stock.

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth

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company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of the IPO, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.0 billion, (3) the date on which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of the prior June 30th, and (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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

***After the IPO, our executive officers, directors and principal stockholders will continue to maintain the ability to control or significantly influence all matters submitted to stockholders for approval and under certain circumstances Vivo Ventures and its affiliates may have control over key decision making.***

Upon the completion of the IPO in November 2014, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before the IPO beneficially own shares, in the aggregate, representing approximately 60% of our common stock. In addition, entities associated with our existing stockholders Vivo Ventures and our Chairman, Ernest Mario, purchased \$5.5 million of units in the IPO at the offering price. This resulted in insider ownership upon the completion of the IPO of approximately 77%, including ownership of approximately 66% by entities associated with Vivo Ventures based on their purchasing \$3.85 million of units in the IPO at the offering price, and ownership of approximately 18% by Ernest Mario based on purchasing \$1.65 million of units in the IPO at the offering price. As a result, they are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

***Although we have elected not to take advantage of the “controlled company” exemption to the corporate governance rules for NASDAQ-listed companies, for which we will be eligible upon the closing of the IPO, we may in the future avail ourselves of this exemption, which could make our common stock less attractive to some investors or otherwise harm our stock price.***

Upon the completion of the IPO in November 2014, Vivo Ventures and its affiliates now hold more than 50% of our outstanding common stock. Because they control a majority of our outstanding voting power, we are a “controlled company” under the corporate governance rules for NASDAQ-listed companies and will not be required to have a majority of our board of directors be independent, nor will we be required to have a compensation committee or an independent nominating function. Although our current intention is to not avail ourselves of the controlled company exemption, we are eligible to do so because we have a stockholder with control over a majority of our outstanding common stock. If in the future we determined to avail ourselves of these corporate governance exemptions, under circumstances where the interests of our controlling stockholder may differ from those of other stockholders, the other stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance rules for NASDAQ-listed companies, and our status as a controlled company could make our common stock less attractive to some investors or otherwise harm our stock price.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as



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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404, beginning as early as our annual report on Form 10-K for the fiscal year ended December 31, 2014. In addition, we will be required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with our annual report on Form 10-K following the date on which we are no longer an emerging growth company. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

***We have identified a material weakness in our internal control over financial reporting as of December 31, 2013, and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remedy our material weaknesses, or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Prior to the completion of the IPO, we have been a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for the IPO, we determined that material adjustments to various accounts were necessary, which required us to restate the financial statements for the year ended December 31, 2012, which had been previously audited by another independent audit firm. These adjustments leading to a restatement of those financial statements led us to conclude that we had a material weakness in internal

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control over financial reporting as of December 31, 2012. The material weakness that we identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements. We also found that the weakness persisted through the year ending December 31, 2013. As of that time, our financial operations staff consisted of one part-time consultant.

This material weakness contributed to adjustments to previously issued financial statements principally, but not limited to, the following areas: equity accounting in connection with our issuance of Series A, B, and C convertible preferred stock and related warrants, and period-end cutoff for development-related expenses.

For a discussion of our remediation plan and the actions that we have executed during 2014, see Item 4. The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have implemented a plan to remediate this weakness we cannot assure you that we will be able to remediate this weakness, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. If we are unable to successfully remediate this material weakness, and if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable NASDAQ listing requirements.

Our failure to remediate the material weakness identified above or the identification of additional material weaknesses in the future, could adversely affect our ability to report financial information, including our filing of quarterly or annual reports with the SEC on a timely and accurate basis. Moreover, our failure to remediate the material weakness identified above or the identification of additional material weaknesses, could prohibit us from producing timely and accurate consolidated financial statements, which may adversely affect our stock price and we may be unable to maintain compliance with NASDAQ listing requirements.

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

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

***A significant number of our shares of our common stock became eligible for sale upon the completion of the IPO, and a significant number of additional shares of our common stock may become eligible for sale at a later date, and their sale could depress the market price of our common stock.***

We have issued Series A warrants and Series B warrants to purchase a total of 3,795,000 shares. In the event that the market price of our common stock falls below \$6.50 at any time between four and fifteen months after the issuance of the Series B warrants, the Series B warrants will become exercisable on a cashless basis for a number of common shares that increases as the market price of our common stock decreases, and exercisable at a discount to the tracking price of our common stock at the time. This may result in a number of shares issued, pursuant to the cashless exercise of Series B warrants, significantly in excess of the original 1,897,500 shares. If the price of our common stock were to fall to \$1.00 per share, the minimum share price necessary for continued listing on the NASDAQ Capital Market, at any time more than four months, and less than fifteen months, after the IPO, the number of shares for which the Series B warrants may be exercised would exceed eighteen million shares. This would result in majority ownership of our common stock by Series B warrant holders, if all the Series B warrant holders exercised their warrants at that time. Under certain other circumstances, exercises of the Series A and Series B warrants may be on a cashless basis, resulting in dilutive issuance of common shares of the company without cash proceeds to the company.

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We have also issued compensation warrants to the underwriters in the IPO to purchase an additional 82,500 shares of our common stock and additional compensation warrants to the underwriters to purchase 12,375 shares of our common stock if the over-allotment option is exercised in full. In addition, as of September 30, 2014, we had outstanding options to purchase 240,906 shares of our common stock and outstanding warrants to purchase an aggregate of 918,551 shares of our common stock. We also have outstanding other options that were granted upon the completion of the IPO, that would result in the issuance of an additional 913,701 shares of common stock.

As of completion of the IPO on November 18, 2014, we had \$15,409,955 in aggregate principal amount and accrued interest outstanding under the 2010/2012 convertible promissory notes and \$2,512,078 in aggregate principal amount and accrued interest outstanding under the April, August and October 2014 convertible promissory notes. The 2010/2012 convertible promissory notes automatically converted into shares of our common stock upon the completion of the IPO. The 2014 convertible promissory notes automatically converted into units of common stock and warrants issued in the IPO. At the IPO price of \$6.50 per unit, the 2010/2012 convertible promissory notes automatically converted into 3,165,887 shares of common stock and the April, August and October 2014 convertible promissory notes automatically converted into 552,105 units (which consisted of 552,105 shares of common stock, Series A warrants to purchase 552,105 shares of common stock, and Series B warrants to purchase 552,105 shares of common stock).

As of September 30, 2014, options to purchase 240,906 shares of our common stock were issued and outstanding with a weighted average exercise price of \$3.59 per share. Options to purchase 240,906 of such shares are currently exercisable or will be exercisable and we granted additional options to purchase 913,701 shares of common stock upon the completion of the IPO.

The sale or even the possibility of sale of the shares of common stock described above could substantially reduce the market price for our common stock or our ability to obtain future financing.

***As our warrantholders convert their notes and warrants into shares of our common stock, our stockholders will be diluted, and certain features of the Series B warrants may substantially accelerate the issuance of dilutive shares.***

The exercise of some or all of our warrants results in issuance of common shares that dilute the ownership interests of existing stockholders. Any sales of the common stock issuable upon exercise of the warrants could adversely affect prevailing market prices of our common stock. In addition, the Series B warrants contain a provision that will allow exercise of these warrants for a number of shares that increases as the trading market price of our common stock decreases. The potential for such dilutive exercise of the Series B warrants may depress the price of our common stock regardless of our business performance, and could encourage short selling by market participants, especially if the trading price of our common stock drops below the IPO offering price in the period between four and fifteen months after the IPO.

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

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

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

We have listed our common stock and Series A warrants on the NASDAQ Capital Market. We might not be able to maintain the listing standards of that exchange, which includes requirements that we maintain our shareholders' equity, total value of shares held by unaffiliated shareholders, and market capitalization above certain specified levels. In particular, since we do not expect to become profitable for some time after completion of the IPO, there is a risk that our shareholders' equity could fall below the \$2.5 million level required by the NASDAQ Capital Market. If we fail to conform to the NASDAQ listing requirements on an ongoing basis, our common stock might cease to trade on the NASDAQ Capital Market exchange, and may move to the Over the Counter Bulletin Board or the "pink sheets" exchange maintained by Pink OTC Markets, Inc. The OTC Bulletin Board and the "pink sheets" are generally considered to be markets that are less efficient, and to provide less liquidity in the shares, than the NASDAQ Capital Market.

***If the trading price of our common stock declines between the four-month and fifteen-month anniversary of the IPO, we may not have registered sufficient shares to cover all shares of common stock that might be issued upon exercise of warrants.***

Our common stock may also decline to a point that the number of shares of common stock issuable upon exercise of Series B warrants exceeds the number of shares we have registered for public sale under any registration statement in effect at the time. If we are not successful in registering these additional shares in a timely fashion, warrant holders might receive, upon exercise of Series B warrants, common stock that is not freely tradable.

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

The warrants offered as part of the units do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, following issuance of the warrants, Series A warrant holders may exercise their right to acquire the common stock and pay an exercise price of \$6.50 per share prior to the expiration of the five-year term on November 12, 2019, after which date any unexercised Series A warrants will expire and have no further value. Series B warrant holders may exercise their right to acquire the common stock and pay an exercise price of \$6.50 per share prior to the expiration of their 15-month term on February 12, 2016, after which date any unexercised Series B warrants will expire and have no further value. In certain circumstances, the Series A and Series B warrants may be exercisable on a cashless basis, and certain other circumstances may affect the number of shares into which the Series B warrants may be exercisable. Moreover, following the IPO, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

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

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our common stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

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

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

- our board of directors will be divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;
- our board of directors will have the right to elect directors to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our board of directors;
- our stockholders will not be able to act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by our board of directors, the chairman of our board, the chief executive officer or the president;
- our certificate of incorporation will prohibit cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- future amendments of our certificate of incorporation and bylaws will require the approval of 66 2/3% of our outstanding voting securities;
- our stockholders will be required to provide advance notice and additional disclosures in order to nominate individuals for election to our board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors will be able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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

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

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately \$0.6 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately \$0.5 million (as of September 30, 2014, based on the IPO price of \$6.50 per unit) in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing

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stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

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

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

*(a) Recent Sales of Unregistered Equity Securities*

In November 2014, upon the closing of our IPO, all shares of our then-outstanding convertible preferred stock automatically converted into shares of common stock. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act pursuant to Section 3(a)(9) and Section 4(a)(2) of the Securities Act.

*(b) Use of Proceeds*

On November 18, 2014, we closed our IPO and issued 1,650,000 units, each of which consisted of one share of common stock, one Series A warrant and one Series B warrant, at an initial offering price of \$6.50 per unit. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-196635), which was declared effective by the SEC on November 12, 2014, and a registration statement on Form S-1 under Rule 462(b) of the Securities Act of 1933, as amended (File No. 333-200164), which was effective immediately upon filing on November 12, 2014. The sole book-running manager for the IPO was Maxim Group LLC with Dawson James Securities, Inc. being the co-manager. The aggregate offering price to the public for the shares sold in the IPO was \$10.8 million. We received net proceeds from the IPO of approximately \$8.2 million, after deducting underwriting discounts and commissions of approximately \$0.8 million and expenses of approximately \$1.8 million payable by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus.

*(c)*

Not applicable.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: December 18, 2014

**CAPNIA, INC.**

By: /s/ David D. O'Toole

David D. O'Toole  
Chief Financial Officer

**(principal financial and accounting officer)**



## EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from			
		Registrant's Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
3.2	Amended and Restated Certificate of Incorporation of Capnia, Inc.	S-1/A	August 7, 2014	3.2	
3.4	Amended and Restated Bylaws of Capnia, Inc.	S-1/A	July 1, 2014	3.4	
10.1	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	June 10, 2014	10.1	
10.2	1999 Incentive Stock Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.2	
10.3	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	June 10, 2014	10.3	
10.4	2014 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.4	
10.5	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.5	
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. § 1350.				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

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

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

I, Anish Bhatnagar, certify that:

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

Date: December 18, 2014

/s/ Anish Bhatnagar

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

## CERTIFICATION OF THE CHIEF FINANCIAL OFFICER

## PURSUANT TO

## SECURITIES EXCHANGE ACT RULES 13A-14(A) AND 15D-14(A)

I, David D. O'Toole, certify that:

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

Date: December 18, 2014

/s/ David D. O'Toole

David D. O'Toole

Chief Financial Officer

(principal financial and accounting officer)

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

In connection with the Quarterly Report of Capnia, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2014, as filed with the Securities and Exchange Commission (the "Report"), Anish Bhatnagar, President, Chief Executive Officer of the Company, and David D. O'Toole, Chief Financial Officer of the Company, respectively, do each hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: December 18, 2014

/s/ Anish Bhatnagar

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

/s/ David D. O'Toole

David D. O'Toole  
Chief Financial Officer  
(principal financial and accounting officer)

