

Capnia, Inc.
Form S-1/A
September 30, 2014
Table of Contents

As filed with the Securities and Exchange Commission on September 30, 2014.

Registration No. 333-196635

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 9

TO

FORM S-1

REGISTRATION STATEMENT

Under

The Securities Act of 1933

CAPNIA, INC.

(Exact name of Registrant as specified in its charter)

Delaware

3845

77-0523891

**(State or other jurisdiction of
incorporation or organization)**

**(Primary Standard Industrial
Classification Code Number)
3 Twin Dolphin Drive, Suite 160**

**(I.R.S. Employer
Identification Number)**

Redwood City, CA 94065

(650) 213-8444

**(Address, including zip code, and telephone number, including area code, of Registrant's principal executive
offices)**

Anish Bhatnagar

Chief Executive Officer

Capnia, Inc.

3 Twin Dolphin Drive, Suite 160

Redwood City, CA 94065

(650) 213-8444

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. x

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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 the 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 x (do not check if a smaller reporting company)

Smaller reporting company "

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered ⁽³⁾	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price ⁽¹⁾	Amount of Registration Fee ⁽⁸⁾
Units, each consisting of one share of common stock, \$0.001 par value per share, and a warrant to purchase one share of common stock ⁽²⁾⁽³⁾	2,127,500	\$ 6.50	\$ 13,828,750.00	\$ 1,781.15
Common stock included in the units ⁽³⁾⁽⁴⁾⁽⁵⁾	2,127,500			
Warrants included in the units ⁽³⁾⁽⁴⁾	2,127,500			
Shares of common stock underlying the warrants included in the units ⁽³⁾⁽⁵⁾⁽⁶⁾	2,127,500	\$ 5.00	\$ 10,637,500.00	\$ 1,370.11
Underwriters common stock purchase warrant ⁽⁷⁾	106,375			
Common stock underlying Underwriters common stock purchase warrants ⁽⁴⁾	106,375	\$ 5.50	\$ 585,062.50	\$ 75.36
Total	2,233,875		\$ 25,051,312.50	\$ 3,226.62

- (1) Estimated solely for the purpose of calculating the registration fee.
- (2) The units will consist of one share of common stock and one warrant to purchase one share of common stock.
- (3) Estimated pursuant to Rule 457(a) under the Securities Act of 1933, as amended. Includes the aggregate offering price of an additional 277,500 units the underwriters have the option to purchase in this offering to cover over-allotments, if necessary.
- (4) No fee required pursuant to Rule 457(g) under the Securities Act of 1933, as amended.
- (5) Pursuant to Rule 416 under the Securities Act of 1933, as amended, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.
- (6) We have calculated the proposed maximum aggregate offering price of the common stock underlying the warrants by assuming that such warrants are exercisable to purchase common stock at a price per share equal to \$5.00.
- (7) Represents warrants to purchase a number of shares of common stock equal to 10% of the units to be sold in this offering, including those that may be sold pursuant to the exercise of the over-allotment option and assuming a per share exercise price equal to 110% of the price per share of the common stock underlying each unit sold in this offering.
- (8) The Registrant previously paid \$3,562.40 in connection with previous filings of this Registration Statement.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated September 30, 2014

1,850,000 Units, Each Consisting Of

One Share of Common Stock and a

Warrant to Purchase One Share of Common Stock

This is the initial public offering of securities of Capnia, Inc. We are offering 1,850,000 units, each unit consisting of one share of our common stock and a warrant to purchase one share of common stock. Prior to this offering, there has been no public market for our securities. Each warrant entitles the holder to purchase one share of our common stock at \$5.00 per share, subject to adjustment as described herein. Each warrant will become exercisable immediately following issuance and will expire on _____, 2019. We estimate the initial public offering price to be \$6.50 per unit. We have applied for listing of our units, common stock and warrants on the NASDAQ Capital Market under the trading symbols CAPNU, CAPN and CAPNW, respectively. No assurance can be given that our application will be approved. If the application is not approved, we will not complete this offering.

The units will begin trading on or promptly after the date of this prospectus. The units will automatically separate and each of the common stock and warrants will trade separately on the first trading day following the expiration of the underwriters' 45-day over-allotment option, unless Maxim Group LLC, the representative of the underwriters, determines that an earlier date is acceptable based on its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular.

We are an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, as such, may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our securities involves a high degree of risk. See Risk Factors beginning on page 12.

	Per Unit	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds, before expenses	\$	\$

(1) See the heading entitled "Underwriting" on page 149 of this prospectus for additional disclosure regarding compensation to the underwriters payable by us.

Entities associated with our existing stockholders Vivo Ventures and our Chairman, Ernest Mario, have indicated to us their interest in purchasing up to \$6,000,000 of units in this offering at the offering price.

We have granted the underwriters an option, exercisable one or more times in whole or in part, to purchase up to 277,500 additional units from us at the public offering price, less the underwriting discount, within 45 days from the date of this prospectus to cover over-allotments, if any. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$, and the total proceeds to us, before expenses, will be \$. Prior to separation of the units, any exercise of the over-allotment will be settled in units, and subsequent to the separation of the units will be settled in shares of common stock and warrants, as applicable.

The underwriters expect to deliver the units against payment in New York, New York on , 2014.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Sole Book-Running Manager

Maxim Group LLC

Co-Managers

National Securities Corporation

The date of this prospectus is

Dawson James Securities, Inc.

, 2014.

Table of Contents

Commercial Launch Planned In Second Half of 2014

Table of Contents

TABLE OF CONTENTS

	Page
<u>Prospectus Summary</u>	1
<u>The Offering</u>	6
<u>Summary Financial and Other Data</u>	10
<u>Risk Factors</u>	12
<u>Cautionary Statement Concerning Forward-Looking Statements</u>	53
<u>Market, Industry and Other Data</u>	55
<u>Use of Proceeds</u>	56
<u>Dividend Policy</u>	57
<u>Capitalization</u>	58
<u>Dilution</u>	60
<u>Selected Financial Data</u>	63
<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	64
<u>Business</u>	78
<u>Management</u>	112
<u>Executive Compensation</u>	121
<u>Certain Relationships and Related Transactions</u>	133
<u>Security Ownership of Certain Beneficial Owners and Management</u>	137
<u>Description of Securities</u>	141
<u>Shares Eligible for Future Trading</u>	147
<u>Underwriting</u>	149
<u>Legal Matters</u>	153
<u>Experts</u>	153
<u>Where You Can Find More Information</u>	153

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the units offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of its date regardless of the time of delivery of this prospectus or of any sale of securities.

Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the U.S. Persons who come into possession of this prospectus and any free writing prospectus related to this offering in jurisdictions outside the U.S. are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.

Until _____, 2014 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in

addition to the dealers obligation to deliver a prospectus when acting as underwriter and with respect to their unsold allotments or subscriptions.

-i-

Table of Contents

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before deciding to invest in our securities, you should read this entire prospectus carefully, including the sections of this prospectus entitled Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes contained elsewhere in this prospectus. Unless the context otherwise requires, references in this prospectus to the company, Capnia, we, us and our refer to Capnia, Inc.

Overview

We develop medical diagnostics and therapeutics based on our proprietary technology for precision metering of gas flow. Our first 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 issued in the first quarter of 2014, and received CE Mark approval for sale in the European Union, or E.U., in the third quarter of 2013. CoSense is not yet commercially available and has thus not generated commercial sales to date; however, we are currently focused on launching CoSense commercially with the proceeds of this offering. We intend to begin selling CoSense in the second half of 2014. CoSense combines a portable detection device with a single-use disposable nasal cannula to measure carbon monoxide, or CO, in the portion of the exhaled breath that originates from the deepest portion of the lung, which is referred to as the end-tidal component of the breath.

With respect to therapeutics, we have previously obtained CE Mark approval in the E.U. for Serenz, an as-needed treatment for symptoms related to allergic rhinitis, or AR. Serenz has shown statistically significant improvements in AR symptoms in randomized, controlled Phase 2 clinical trials. In the U.S., where Serenz has not yet been approved, the FDA may require Phase 3 trials to be conducted prior to approval. Serenz is still in development and has not generated sales to date.

CoSense

Approximately 143 million babies are born annually worldwide, with approximately 9.2 million of these born in the U.S. and E.U. Over 60% of neonates present with jaundice at some point in the first five days of life. We believe CoSense has the potential to become a part of routine pre-discharge screening for all newborns, by aiding in the differential diagnosis of hemolysis in infants that present with, or are at risk of developing, jaundice. Red blood cell breakdown is a normal phenomenon, but in certain situations the breakdown is accelerated or is excessive and is referred to as hemolysis. The most common cause of hospital readmission during the neonatal phase is jaundice, and we expect that CoSense will help reduce such readmissions. Many causes of jaundice do not represent a significant health threat. However, when severe jaundice occurs in the presence of hemolysis, rapid diagnosis and treatment may be necessary for infants to avoid life-long neurological impairment or other disability. Also, unnecessary treatment increases hospital expenses, is stressful for both infant and parents and may increase morbidity. There is an unmet need, therefore, for more accurate diagnostics for hemolysis, particularly if they are non-invasive, rapid, and easy to use.

CoSense detects hemolysis by measuring CO in the end-tidal component of the breath, and the measurement we perform with CoSense is referred to as end-tidal carbon monoxide, or ETCO. The American Academy of Pediatrics, or AAP, guidelines, published in the journal Pediatrics in 2004, 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

Table of Contents

transfusion levels. These guidelines also note that ETCO is the only test that provides a *direct* measurement of bilirubin production because CO is a direct chemical byproduct of hemolysis. Therefore, ETCO provides a direct indication of the rate of bilirubin production from hemolysis. Measurement of serum bilirubin, whether performed via a transcutaneous bilirubinometer or via a conventional needle-stick assay, is only indicative of the bilirubin level at a point in time. It does not capture the rate of bilirubin production or the presence/absence of hemolysis, leaving the physician uncertain as to the patient's level of risk.

Today, no device is currently commercially available for accurately measuring the ETCO levels associated with the rate of hemolysis in clinical practice in neonates. As a result, we believe that CoSense will be the only device on the market that enables physicians to practice in accordance with the AAP guidelines when evaluating jaundiced neonates for potential treatment of hemolysis. Physicians are free to practice in accordance with their own judgment; however, we believe that the current AAP guidelines will be a significant factor in the adoption of CoSense.

Sales and marketing activities associated with the launch of CoSense will be the focus of our use of proceeds from this offering. We plan to hire our own sales force to market CoSense to hospitals and other medical institutions in the U.S. CoSense has the following advantages that we believe will drive its adoption by hospitals, other medical institutions and physicians:

rapid administration at the point-of-care, yielding results in approximately five minutes;

non-invasive and minimally disruptive to the neonate;

no requirement for specific breath maneuver;

simple user interface that allows the healthcare professional to use it correctly with minimal training;

no on-site calibration necessary; and

accuracy over a range of CO concentrations clinically relevant (less than 10 parts per million, or ppm) to detection of hemolysis.

In addition, we believe the CoSense device will be priced at a level that falls below the typical capital equipment purchasing threshold for a hospital or other medical institution in the U.S.

Our Sensalyze Technology Platform

CoSense is the first 510(k) cleared or CE mark approved device based on our Sensalyze Technology Platform. Once CoSense is generating sufficient revenue, we intend to use our research and development expertise to develop additional diagnostic devices that are based on this platform, with a particular emphasis on products that could be sold effectively by the same sales force deployed to commercialize CoSense. Our Sensalyze Technology Platform combines hardware, sensors, and software to provide the following novel capabilities:

identification of full breaths that follow a normal pattern, also known as physiologic breaths, even if the patient is breathing very rapidly a capability that is particularly relevant in infants;

capture of individual exhaled breaths, and segmentation of the breath into different components such as end-tidal, upper airway and lower airway, which may allow the localization of the source of a given analyte to a specific anatomic area; and

ability to move a specific micro-liter component of breath to a sensor module.

Table of Contents

When combined, these capabilities provide a novel platform for non-invasive detection of various analytes. Our current development pipeline includes proposed diagnostic devices for asthma in children, assessment of blood carbon dioxide, or CO₂, concentration in neonates, and malabsorption in infants with colic. We may also license elements of our Sensalyze Technology Platform to other companies that have complementary development or commercial capabilities.

Serenz

Serenz, our therapeutic product candidate, is a treatment for symptoms related to AR, which, when triggered by seasonal allergens, is commonly known as hay fever or seasonal allergies. Several Phase 2 clinical trials have been conducted in which Serenz showed statistically significant improvements in total nasal symptom scores, or TNSS, in symptomatic patients when compared to controls. Serenz has not shown statistically significant improvements in trials in which it was used in a scheduled dosing paradigm (see Business Serenz Clinical Trials of Serenz Using Other Dosing Methods on pages 98-99 of this prospectus), and as a result we have pursued development of Serenz using an as-needed dosing regimen. AR is typically an episodic disorder with intermittent symptoms. However, there is no treatment currently available that provides truly rapid relief of symptoms, other than topical decongestants, which can have significant side effects. The more optimal therapeutic for an episodic disorder is one that will treat symptoms when they occur, and can therefore be taken only as needed. We believe that Serenz has an ideal profile for an as-needed therapeutic for AR and may provide advantages over regularly dosed, slow to act currently marketed products.

Our Serenz technology is based upon the observation that nasal, non-inhaled CO₂ delivered at a low flow rate into the nasal cavity can alleviate the symptoms of AR, via a mechanism of action that is not yet known. Serenz is a convenient, hand-held device that delivers a low flow of CO₂ to the nasal mucosa.

In clinical trials to date, Serenz has shown a large effect size, a rapid onset of effect within 30 minutes after administration and a mild side effect profile. We believe that such a therapeutic index positions Serenz well to be a potential first-line treatment for any AR sufferer. Serenz can be taken as a stand-alone treatment or as an adjunct to other medications, and can be used on an as-needed basis.

We currently plan to commercialize Serenz in the E.U. via distributorship arrangements. In the U.S., we believe that Serenz may be classified as either a medical device or a drug-device combination. If Serenz is classified as a drug-device combination, Phase 3 trials would likely be required to obtain approval. We currently believe that these trials, if required, would be 400 to 600 patients in size and would take approximately a year to complete once started, which would significantly increase both the investment in and timeframe for regulatory approval. We therefore intend to determine the appropriate regulatory approval pathway for Serenz in dialogue with the U.S. Food and Drug Administration, or FDA. We believe a partner or distributorship arrangement for commercialization will maximize the value of Serenz. In 2013, we out-licensed Serenz to Block Drug Company, a wholly-owned subsidiary of GlaxoSmithKline, or GSK, realizing revenue in the form of a non-refundable up-front payment of \$3.0 million. In June 2014, the agreement with GSK terminated and GSK returned the licensed rights to Serenz back to us. We believe GSK's decision to terminate the agreement was due to GSK's belief that the product would be classified as a drug-device combination by the FDA, and the additional expense associated with such a classification. Potential partners may perceive this history as negatively impacting the Serenz program, which could impair our ability to partner it in the future. We do not expect that the net proceeds from this offering, will be sufficient to enable us to fund both the commercialization of our CoSense product and additional activities that advance Serenz toward product launch, and will therefore focus the use of proceeds from this offering on CoSense commercialization.

Risks Associated With Our Business

Our business is subject to numerous risks and uncertainties related to: the development and commercialization of CoSense, our reliance on third parties for manufacturing, our financial condition and need

Table of Contents

for additional capital, the operation of our business, our intellectual property, government regulation and this offering and ownership of our securities. These risks include those highlighted in the section entitled "Risk Factors" immediately following this prospectus summary, including the following:

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. As of June 30, 2014, on an unaudited basis, we had an accumulated deficit of \$60.7 million. 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.

CoSense, or any of our planned 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.

We have not commercialized any product in the past, and the challenges involved in establishing a new sales operation may expose us to a higher than usual level of risk with respect to commercializing CoSense.

While we have obtained approval to market CoSense in the U.S. and the E.U., our other products, including our AR treatment product, Serenz, have not yet received approval for sale in the U.S. We may be required to conduct additional clinical trials prior to obtaining approval for Serenz or for other future products. We may not obtain such approvals for sale on a predictable timeframe, or at all.

Neither CoSense, nor its associated consumables, have ever been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. The commercial manufacturers may not be successful in achieving the levels of production volume, quality, or manufacturing costs necessary to support commercial success of CoSense.

We previously out-licensed Serenz to a partner, who terminated the agreement and returned the rights to Serenz back to us in June 2014.

As of December 31, 2013, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

After this offering, 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. If Vivo Ventures and its affiliates purchase units in this offering, for which they have expressed interest, sufficient to obtain ownership of more than 50% of our common stock, they would have control over key decision making.

Participation in this offering by our existing stockholders Vivo Ventures and our Chairman, Ernest Mario, would reduce the available public float for our securities.

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.

Our business depends on our continuing to satisfy the FDA and any other applicable U.S. and international regulatory requirements with respect to medical diagnostics or therapeutics, including requirements which may change or be created in the future.

Table of Contents

We have obtained certain key intellectual property relating to CoSense from BioMedical Drug Development, Inc., or BDDI, and any breach of our asset purchase agreement with BDDI would prevent or otherwise materially adversely affect our ability to proceed with any development or potential commercialization of CoSense.

We need to obtain or maintain patents or other appropriate protection for the intellectual property utilized in our current and planned product offerings, and we must avoid infringement of third-party intellectual property.

Corporate information

We were incorporated in Delaware in August of 1999. Our principal executive offices are located at 3 Twin Dolphin Drive, Suite 160, Redwood City, CA 94065, and our telephone number is (650) 213-8444. Our website address is *www.capnia.com*. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus, or in deciding whether to purchase our securities.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. 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 this offering, (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.

Capnia, CoSense, Serenz, Sensalyze, our logo and our other trade names, trademarks and service marks appearing in this prospectus are our property. Other trade names, trademarks and service marks appearing in this prospectus are the property of their respective holders.

Table of Contents

THE OFFERING

Securities offered by Capnia	1,850,000 units, each unit consisting of one share of common stock and a warrant to purchase one share of common stock.
Common stock to be outstanding after this offering	6,672,670 shares
Terms of warrants issued as a part of the units	Exercise price \$5.00 per share of common stock. Exercisability each warrant is exercisable for one share of common stock, subject to adjustment as described herein. Exercise period each warrant will become exercisable immediately following issuance and will expire on , 2019.
Underwriters over-allotment option	We have granted the underwriters the right to purchase up to 277,500 additional units from us at the public offering price less the underwriting discount within 45 days from the date of this prospectus to cover over-allotments. Prior to separation of the units, any exercise of the over-allotment will be settled in units, and subsequent to the separation of the units will be settled in shares of common stock and warrants, as applicable.
Separation of common stock and warrants issued as part of the units	The units will begin trading on or promptly after the date of this prospectus. The units will automatically separate and each of the common stock and warrants will trade separately on the first trading day following the expiration of the underwriters 45-day over-allotment option, unless Maxim Group LLC, the representative of the underwriters, determines that an earlier date is acceptable based on its assessment of the relative strengths of the securities markets and small capitalization companies in general, and the trading pattern of, and demand for, our securities in particular.

Use of proceeds

We estimate that our net proceeds from this offering will be approximately \$9.5 million, or approximately \$11.2 million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of \$6.50 per unit, which is the estimated initial public offering price set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use approximately \$6.3 million of the net proceeds from this offering to fund our planned

Table of Contents

commercial launch of CoSense, and related costs, and the balance to fund working capital, capital expenditures, and other general corporate purposes. This may include the acquisition or licensing of other products, businesses or technologies, although we have no plans regarding any specific acquisition candidates at this time. See [Use of Proceeds](#) for additional information.

Lock-up

Prior to the completion of this offering, we and each of our officers, directors, and 1.0% or greater stockholders will agree, subject to certain exceptions, not to sell, offer, agree to sell, contract to sell, hypothecate, pledge, grant any option to purchase, make any short sale of, or otherwise dispose of or hedge, directly or indirectly, any units, shares of common stock or warrants, or any securities convertible into or exercisable or exchangeable for units, shares of common stock or warrants, whether any such transaction described above is to be settled by delivery of units, shares of common stock or warrants, in cash or otherwise, for a period of 180 days after the date of the final prospectus relating to this offering. See [Underwriting](#) for additional information.

Underwriters' compensation warrants

We will issue to the underwriters, upon closing of this offering, compensation warrants entitling the underwriters to purchase a number of shares of common stock equal to 5% of the aggregate number of units issued in this offering, including units issued pursuant to the exercise of the over-allotment option. The underwriters' warrants will have a term of five years and may be exercised commencing 181 days after the date of effectiveness of the Registration Statement on Form S-1 of which this prospectus forms a part. The underwriters' warrants may be exercised on a cashless basis.

Risk factors

See [Risk Factors](#) beginning on page 12 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

Proposed NASDAQ Capital Market symbol

We have applied for the listing of our units, common stock and warrants on The NASDAQ Capital Market under the trading symbols CAPNU, CAPN and CAPNW, respectively.

Table of Contents

The number of shares of our common stock to be outstanding after this offering is based on 1,401,114 shares of our common stock outstanding as of June 30, 2014 (which includes 865,429 shares of preferred stock to be converted into common stock at the close of the offering), and excludes the following:

240,906 shares of our common stock issuable upon the exercise of stock options outstanding as of June 30, 2014 at a weighted-average exercise price of \$3.59 per share;

1,437,165 shares of common stock, subject to increase on an annual basis, reserved for future issuance under our 2014 Equity Incentive Plan, which will become effective in connection with the completion of this offering;

139,839 shares of our common stock, subject to increase on an annual basis, reserved for future issuance under our 2014 Employee Stock Purchase Plan;

9,259 shares of our common stock issuable upon the exercise of warrants to purchase convertible preferred stock outstanding as of June 30, 2014, which warrants will automatically convert into warrants to purchase common stock immediately prior to the completion of this offering, with an exercise price per share equal to the fair market-value of the Company's common stock, assuming such shares are publicly traded;

523,867 shares of our common stock issuable upon the exercise of warrants issued in connection with our 2010/2012 convertible promissory notes outstanding as of June 30, 2014, which warrants will automatically convert into warrants to purchase common stock immediately prior to the completion of this offering, with an exercise price of \$4.87 per share, which is 75% of the assumed initial public offering price of the common stock underlying the units sold in this offering;

1,850,000 shares of our common stock issuable upon the exercise of warrants that are part of the units sold in this offering;

92,500 shares of common stock issuable upon the exercise of the underwriters' compensation warrants; and

788,566 shares of our common stock issuable upon exercise of stock options to be granted to certain of our directors, officers and employees upon the completion of this offering, and which shall have an exercise price per share equal to at least 110% of the fair market value of the common stock on the date of grant.

Unless otherwise indicated, all information in this prospectus reflects and assumes the following:

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a 1-for-12 reverse split of our common stock and convertible preferred stock effected on July 28, 2014, applied retroactively for all periods presented;

the automatic conversion of all outstanding shares of our convertible preferred stock in connection with this offering into an aggregate of 865,429 shares of our common stock immediately prior to the closing of this offering;

the automatic conversion of the outstanding 2010/2012 convertible promissory notes in connection with this offering into an aggregate of 3,036,131 shares of our common stock immediately prior to the closing of this offering;

Table of Contents

the automatic conversion of the outstanding April 2014 convertible promissory notes in connection with this offering into an aggregate of 385,425 units, which shall consist of 385,425 shares of common stock and warrants to purchase 385,425 shares of common stock, immediately prior to the closing of this offering;

the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the closing of this offering; and

no exercise of the underwriters' over-allotment option.

Table of Contents**SUMMARY FINANCIAL AND OTHER DATA**

The following tables summarize our financial data and should be read together with the sections in this prospectus entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

We have derived the statement of operations data for the years ended December 31, 2012 and 2013 and the balance sheet data as of December 31, 2012 and 2013 from our audited financial statements included elsewhere in this prospectus. The summary consolidated financial data for the six months ended June 30, 2013 and 2014 are derived from our unaudited consolidated financial statements appearing elsewhere in this prospectus. The unaudited consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly our financial position as of June 30, 2014 and the results of operations for the six months ended June 30, 2013 and 2014. Our historical results are not necessarily indicative of the results that should be expected in the future.

	Year Ended December 31,		Six Months Ended June 30,	
	2012	2013	2013	2014
	(in thousands, except share and per share data)			
Statement of Operations Data:				
Revenue	\$	\$ 3,000	\$ 3,000	
Operating expenses:				
Research and development	2,470	2,380	1,275	921
Sales and marketing				12
General and administrative	1,127	1,467	1,020	1,058
Total operating expenses	3,597	3,847	2,295	1,991
Operating income (loss)	(3,597)	(847)	705	(1,991)
Interest income	3	2	1	1
Interest expense	(2,866)	(2,860)	(1,900)	(1,059)
Other income (expense), net	(22)	(2)	51	(578)
Net loss and comprehensive loss	\$ (6,482)	\$ (3,707)	\$ (1,143)	\$ (3,627)
Net loss per common share, basic and diluted ⁽¹⁾	\$ (12.46)	\$ (6.92)	\$ (2.13)	\$ (6.77)
Shares used to compute net loss per common share, basic and diluted	520,312	535,648	535,611	535,685
Pro forma net loss per common share, basic and diluted ⁽¹⁾ (unaudited)		\$ (2.65)		\$ (2.59)

Shares used to compute pro forma net loss
per common share, basic and diluted⁽¹⁾
(unaudited)

1,401,077

1,401,114

(1) See Note 13 to our financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma net loss per share, basic and diluted, and the number of shares used in the computation of the per share amounts.

Table of Contents

	As of June 30, 2014	As of June 30, 2014 Pro Forma ⁽¹⁾	As of June 30, 2014 Pro Forma As Adjusted ⁽²⁾⁽³⁾
	(in thousands)		
	(unaudited)		
Balance Sheet Data:			
Cash and cash equivalents	\$ 1,208	1,208	10,953
Working capital (deficit)	446	446	10,191
Total assets	2,154	2,154	11,218
Convertible promissory notes, net of discounts	14,852		
Convertible preferred stock	23,808		
Accumulated deficit	(60,727)	(62,437)	(62,437)
Total stockholders' equity (deficit)	(40,127)	1,168	10,232

- (1) The pro forma column reflects (i) the filing of an amendment to our amended and restated certificate of incorporation on July 28, 2014; (ii) the automatic conversion of outstanding shares of our convertible preferred stock as of June 30, 2014 into an aggregate of 865,429 shares of common stock immediately prior to the closing of this offering; (iii) the automatic conversion of the 2010/2012 convertible promissory notes into 3,036,131 shares of common stock as if they had converted as of June 30, 2014; and (iv) the automatic conversion of the April 2014 convertible promissory notes in connection with this offering into an aggregate of 385,425 units, as if they had converted as of June 30, 2014 which shall consist of 385,425 shares of common stock and warrants to purchase 385,425 shares of common stock, including the acceleration of the amortization of debt discounts upon conversion.
- (2) The pro forma as adjusted column reflects (i) the pro forma adjustments described in footnote (1) above, (ii) the sale by us of 1,850,000 units in this offering at an assumed initial public offering price of \$6.50 per unit, which is the estimated initial public offering price set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, (iii) capitalization of \$681,017 of deferred offering costs into additional paid-in capital, and (iv) the issuance of \$0.3 million in convertible promissory notes in August 2014 and the automatic conversion of those notes into 54,874 units, which shall consist of 54,874 shares of common stock and warrants to purchase 54,874 shares of common stock, as if they had occurred as of June 30, 2014, and the receipt of approximately \$0.3 million of gross proceeds from such sale.
- (3) A \$1.00 increase (decrease) in the assumed initial public offering price of \$6.50 per unit would increase (decrease) each of cash and cash equivalents, working capital and total assets by \$1.7 million and decrease (increase) total stockholders' equity (deficit) by \$1.7 million, assuming the number of units we are offering, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of units we are offering. An increase (decrease) of 1,000,000 units in the number of units we are offering would increase (decrease) each of cash and cash equivalents, working capital and total assets by approximately \$6.0 million and decrease (increase) total stockholders' equity (deficit) by approximately \$6.0 million, assuming the assumed initial public offering price per unit, as set forth on the cover page of this prospectus, remains the same. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price, number of units offered and other terms of this offering determined at pricing.

Table of Contents

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider carefully the following risks, together with all the other information in this prospectus, including our financial statements and notes thereto, before you invest in our securities. If any of the following risks actually materializes, our operating results, financial condition and liquidity could be materially adversely affected. As a result, the trading price of our securities could decline and you could lose part or all of your investment.

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 this offering. As of June 30, 2014 (unaudited), we had an accumulated deficit of \$60.7 million.

We expect that our future financial results will depend primarily on our success in launching, selling and supporting CoSense and other products using our Sensalyze Technology Platform. 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;

establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing to maintain that supply;

Table of Contents

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.

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 this offering, 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;

Table of Contents

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;

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.

Table of Contents

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 June 30, 2014, on an unaudited basis, we had approximately \$1.2 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;

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;

Table of Contents

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 described in Note 1 of our accompanying audited financial statements, our auditors have included a going concern provision in their opinion on our financial statements, expressing substantial doubt that we can continue as an ongoing business for the next twelve months. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we cannot secure the financing needed to continue as a viable business, our stockholders may lose some or all of their investment in us.

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.

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

Table of Contents

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 this offering;

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.

In addition, although treatment guidelines recommend ETCO testing, physicians are free to practice in accordance with their own judgment, and may not adopt ETCO testing to the extent recommended by the guidelines, or at all. AAP guidelines recommend ETCO measurement be performed to assess the presence of hemolysis in neonates requiring phototherapy, neonates unresponsive to phototherapy or readmitted for

Table of Contents

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 tests that payors and physicians could view as functionally equivalent to our current or

Table of Contents

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, 2012, our research and development expenses were \$2.5 million, and 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;

Table of Contents

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.

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

Table of Contents

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.

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;

Table of Contents

the cost of clinical studies or the manufacturing of our planned products may be greater than we anticipate;

third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

we might have to suspend or terminate clinical studies of our planned products for various reasons, including a finding that our planned products have unanticipated serious side effects or other unexpected characteristics or that the patients are being exposed to unacceptable health risks;

regulators may not approve our proposed clinical development plans;

regulators or independent institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical study or conduct a clinical study at a prospective study site;

regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements; and

the supply or quality of our planned products or other materials necessary to conduct clinical studies of our planned products may be insufficient or inadequate.

If we or any future collaboration 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

Table of Contents

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;

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.

Table of Contents

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

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

We may attempt to form partnerships in the future with respect to Serenz or other future products, but we may not be able to do so, which may cause us to alter our development and commercialization plans, and may cause us to terminate the Serenz program.

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

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

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

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

The risk of failure of clinical development is high. It is impossible to predict when or if this or any planned products will prove safe enough to receive regulatory approval. Undesirable side effects caused by Serenz or any of our planned products could cause us or regulatory authorities to interrupt, delay or halt clinical trials. 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;

Table of Contents

regulatory authorities may withdraw their approvals of such product;

regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;

the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;

the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;

we may be required to change the way the product is administered or conduct additional clinical trials;

we could be sued and held liable for harm caused to subjects or patients;

we may be subject to litigation or product liability claims; and

our reputation may suffer.

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

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

Alternatives exist for 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.

Table of Contents

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 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

Table of Contents

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;