

Capnia, Inc.
Form 424B4
November 13, 2014
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**Filed Pursuant to Rule 424(b)(4)
Registration No. 333-196635**

**1,650,000 Units, Each Consisting Of
One Share of Common Stock, a Series A Warrant
to Purchase One Share of Common Stock, and a
Series B Warrant to Purchase One Share of Common Stock**

This is the initial public offering of securities of Capnia, Inc. We are offering 1,650,000 units, each unit consisting of one share of our common stock, one Series A warrant to purchase one share of common stock and one Series B warrant to purchase one share of common stock. Prior to this offering, there has been no public market for our securities. Each Series A warrant is immediately exercisable for one share of common stock at an expected initial exercise price of \$6.50 per share and will expire on November 12, 2019, and each Series B warrant is immediately exercisable at an expected initial exercise price of \$6.50 per share and will expire on February 12, 2016. Each is subject to adjustment as described herein. The initial public offering price is \$6.50 per unit. Our common stock and Series A warrants have been approved for listing on the NASDAQ Capital Market under the trading symbols CAPN and CAPNW, respectively. The units and the Series B warrants will not be listed on any trading market.

The units will immediately and automatically separate upon issuance, and each of the common stock and Series A warrants will trade separately on the first trading day following the effective date of the Registration Statement of which this prospectus is a part.

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 13.

	Per Unit	Total
Initial public offering price	\$ 6.50	\$ 10,725,000.00
Underwriting discounts and commissions ⁽¹⁾	\$ 0.4374	\$ 721,750.13
Proceeds, before expenses	\$ 6.0626	\$ 10,003,249.87

(1) The per unit calculation represents the average underwriting discounts and commissions per unit. See the heading entitled Underwriting on page 153 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 agreed to purchase \$5,500,000 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 an additional 247,500 shares of common stock at a price of \$6.49 per share and/or 247,500 additional Series A warrants at a price of \$0.005 per Series A warrant and/or 247,500 additional Series B warrants at a price of \$0.005 per Series B warrant less, in each case, 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 \$850,450,113, and the total proceeds to us, before expenses, will be \$11,483,299.87.

The underwriters expect to deliver the units against payment in New York, New York on November 18, 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-Manager

Dawson James Securities, Inc.

The date of this prospectus is November 12, 2014.

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Commercial Launch Initiated October 2014

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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 December 7, 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.

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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 became commercially available in the U.S. in October 2014 and has thus not generated commercial sales to date; however, we are currently focused on launching CoSense commercially with the proceeds of this offering. 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 transfusion levels. These guidelines also note that ETCO is the only test that provides a *direct* measurement of

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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, CoSense is the only device 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 is 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 price will be 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.

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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 101-102 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.

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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 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.

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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.

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The warrants to be issued in this offering contain cashless exercise provisions that may result in the issuance of a significant number of additional shares of common stock at a discount to the market price of these shares. If our common stock price declines below the offering price between the four-month and fifteen-month anniversaries of this offering, the number of shares issuable upon exercise of Series B warrants will increase, and the exercise price of Series B warrants will decrease, as the trading stock price further decreases. If the price of our common stock were to fall to \$1.00 per share, the minimum share price necessary for continued listing on the NASDAQ Capital Market, at any time more than four months, and less than fifteen months, after this offering, the number of shares for which the Series B warrants may be exercised would exceed eighteen million shares. (see Description of Securities, herein for more information)

Our common stock may also decline to a point that the number of shares of common stock issuable upon exercise of Series B warrants exceeds the number of shares we have registered for public sale under any registration statement in effect at the time. If we are not successful in registering these additional shares in a timely fashion, warrant holders might receive, upon exercise of Series B warrants, common stock that is not freely tradable. In addition, both the Series A warrants and Series B warrants will not be exercisable to the extent that, after exercise, a holder and/or its affiliates would beneficially own more than 4.99% of the common stock outstanding immediately after giving effect to such exercise; provided, however, that if a holder and/or its affiliates already own 4.99% on the date of this offering, then such limitation will not apply.

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.

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

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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.

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THE OFFERING

Securities offered by Capnia 1,650,000 units, each unit consisting of one share of common stock, a Series A warrant to purchase one share of common stock, and a Series B warrant to purchase one share of common stock.

Common stock to be outstanding after this offering 6,472,670 shares

Terms of Series A warrants issued as a part of the units Exercise price \$6.50 per share of common stock.

Exercisability each Series A warrant is exercisable for one share of common stock, subject to adjustment as described herein.

Exercise period each Series A warrant will become exercisable immediately following issuance and will expire on November 12, 2019.

Terms of Series B warrants issued as a part of the units Exercise price \$6.50 per share of common stock.

Exercisability each Series B warrant is exercisable for one share of common stock, subject to adjustment as described herein.

Exercise period each Series B warrant will become exercisable immediately following issuance and will expire on February 12, 2016.

Underwriters over-allotment option We have granted the underwriters the right to purchase up to an additional 247,500 shares of common stock at a price of \$6.49 per share and/or 247,500 additional Series A

warrants at a price of \$0.005 per Series A warrant and/or 247,500 additional Series B warrants at a price of \$0.005 per Series B warrant less, in each case, the underwriting discount within 45 days from the date of this prospectus to cover over-allotments.

Separation of common stock and warrants issued as part of the units

The units will automatically separate at issuance and each of the common stock and Series A warrants will trade separately on the first trading day following the effective date of the Registration Statement of which this prospectus is a part.

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Use of proceeds

We estimate that our net proceeds from this offering will be \$8.2 million, or \$9.7 million if the underwriters exercise their over-allotment option in full, at the initial public offering price of \$6.50 per unit, after deducting underwriting discounts and commissions and offering expenses payable by us.

We intend to use approximately \$5.6 million of the net proceeds from this offering to fund our planned 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 Series A warrants, Series B 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.

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Risk factors

See Risk Factors beginning on page 13 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

NASDAQ Capital Market symbols

We have been approved for the listing of our common stock and Series A warrants on The NASDAQ Capital Market under the trading symbols CAPN and CAPNW, respectively. The Units and the Series B warrants will not be listed on any trading market.

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 initial public offering price of the common stock underlying the units sold in this offering;

1,650,000 shares of our common stock issuable upon the exercise of Series A warrants that are part of the units sold in this offering, subject to adjustment as described herein;

1,650,000 shares of our common stock issuable upon the exercise of Series B warrants that are part of the units sold in this offering, subject to adjustment as described herein;

82,500 shares of common stock issuable upon the exercise of the underwriters' compensation warrants;
and

924,180 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.

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

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;

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, Series A warrants to purchase 385,425 shares of common stock and Series B 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.

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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
		\$ (2.65)		\$ (2.59)

Pro forma net loss per common share, basic and diluted⁽¹⁾ (unaudited)

Shares used to compute pro forma net loss per common share, basic and diluted ⁽¹⁾ (unaudited)	1,401,077	1,401,114
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(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.

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	As of June 30, 2014	As of June 30, 2014 Pro Forma ⁽¹⁾	As of June 30, 2014 Pro Forma As Adjusted ⁽²⁾
	(in thousands)		
	(unaudited)		
Balance Sheet Data:			
Cash and cash equivalents	\$ 1,208	1,208	10,131
Working capital (deficit)	446	446	9,368
Total assets	2,154	2,154	10,396
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	5,720

- (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, Series A warrants to purchase 385,425 shares of common stock and Series B 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 1,650,000 units in this offering at the initial public offering price of \$6.50 per unit after deducting underwriting discounts and commissions and offering expenses payable by us, (iii) capitalization of \$681,017 of deferred offering costs into additional paid-in capital, (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 109,748 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, (v) the issuance of \$0.5 million in convertible promissory notes in October 2014 and the automatic conversion of those notes into 105,536 units, which shall consist of 105,536 shares of common stock and warrants to purchase 211,072 shares of common stock, as if they had occurred as of June 30, 2014, and the receipt of approximately \$0.5 million of gross proceeds from such sale, and (vi) due to the cashless exercise feature of the Series B warrants, the value of the Series B warrants are treated as a derivative liability. See Description of Securities.

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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;

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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;

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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.

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

The commercialization of 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;

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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

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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

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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

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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;

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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

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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;

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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

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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.

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

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

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

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

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

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

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

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

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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.

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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

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provide. If we cannot successfully defend ourselves against claims that CoSense or our planned products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for any planned products that we may develop;

injury to our reputation and significant negative media attention;

withdrawal of patients from clinical studies or cancellation of studies;

significant costs to defend the related litigation and distraction to our management team;

substantial monetary awards to patients;

loss of revenue; and

the inability to commercialize any products that we may develop.

We currently hold \$5.0 million in product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

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

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

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

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

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

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

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

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

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

We currently purchase components for the CoSense instruments and consumables under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our

components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in manufacturing the instruments or consumables while finding another acceptable supplier, which could impact our results of operations. The changes could also result in increased costs associated with qualifying the new materials or reagents and in increased operating costs. Further, any prolonged disruption in a supplier's operations could have

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a significant negative impact on our ability to manufacture and deliver products in a timely manner. Some of the components used in our CoSense are currently sole-source, and substitutes for these components might not be able to be obtained easily or may require substantial design or manufacturing modifications. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us because the number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. The inclusion of substitute components must meet our product specifications and could require us to qualify the new supplier with the appropriate government regulatory authorities. It could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on our business. New manufacturers of any planned product would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing the planned product. Obtaining the necessary FDA approvals or other qualifications under applicable regulatory requirements and ensuring non-infringement of third-party intellectual property rights could result in a significant interruption of supply and could require the new manufacturer to bear significant additional costs that may be passed on to us.

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

As part of our business strategy, we may pursue acquisitions or licenses of assets or acquisitions of businesses. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our product offerings or sales and distribution resources. Our company has limited experience with acquiring other companies, acquiring or licensing assets or forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture. To finance such a transaction we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

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

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

multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

potential failure by us or our distributors to obtain regulatory approvals for the sale or use of our current test and our planned future tests in various countries;

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difficulties in managing foreign operations;

complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;

logistics and regulations associated with shipping products, including infrastructure conditions and transportation delays;

limits on our ability to penetrate international markets if our distributors do not execute successfully;

financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable, and exposure to foreign currency exchange rate fluctuations;

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

natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and

failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors activities.

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

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

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

The CoSense device also stores test results, a feature which assists medical professionals in interfacing the device with electronic medical records systems. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's healthcare

information by healthcare providers, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements for individuals whose health information has been inappropriately accessed or disclosed: notification requirements to federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health

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information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

Risks related to the operation of our business

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

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

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

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

collaborators may not pursue development and commercialization of CoSense or our other planned products, or may elect not to continue or renew efforts based on clinical study results, changes in their strategic focus for a variety of reasons, potentially including the acquisition of competitive products, availability of funding, and mergers or acquisitions that divert resources or create competing priorities;

collaborators may delay clinical studies, provide insufficient funding for a clinical study program, stop a clinical study, abandon a planned product, repeat or conduct new clinical studies or require a new engineering iterations of a planned product for clinical testing;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or planned products;

a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our planned products or that results in costly litigation or arbitration that diverts management attention and resources;

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collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable planned products; and

collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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

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

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

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

As of October 30, 2014, we had nine employees and six full-time or part-time consultants. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of engineering, product development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

managing our clinical trials effectively, which we anticipate being conducted at numerous clinical sites;

identifying, recruiting, maintaining, motivating and integrating additional employees with the expertise and experience we will require;

managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

managing additional relationships with various strategic partners, suppliers and other third parties;

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improving our managerial, development, operational and finance reporting systems and procedures; and
expanding our facilities.

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

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

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

different regulatory requirements for device approvals in foreign countries;

reduced protection for intellectual property rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

economic weakness, including inflation or political instability in particular foreign economies and markets;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

foreign taxes, including withholding of payroll taxes;

foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

workforce uncertainty in countries where labor unrest is more common than in the U.S.;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

Risks related to intellectual property

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

Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends upon our ability and the ability of our distributors, contract manufacturers, and suppliers to manufacture, market, and sell our planned products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our planned products or force us to cease some of our business operations, which could materially harm our business. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development

activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of

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such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

We are a party to intellectual property arrangements and expect that our future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, any licensor may have the right to terminate such agreements, in which event we may not be able to develop and market any product that is covered by such agreements. For example, we entered into an asset purchase agreement with BDDI on May 11, 2010, pursuant to which we have ongoing payment obligations relating to CoSense. A breach of this agreement would therefore materially adversely affect our ability to commercialize CoSense as currently planned. BDDI has the right to terminate the agreement upon 60 days written notice in the event that we fail to make any royalty payment when due and do not remedy such failure after notice. Termination of this agreement, or reduction or elimination of our rights under it or any other agreement, may result in our having to negotiate new or reinstated arrangements on less favorable terms, or our not having sufficient intellectual property rights to operate our business. The occurrence of such events could materially harm our business and financial condition.

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

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

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

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

Even if the patent applications we rely on issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or

products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the patents we rely on may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or

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identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new planned products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

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

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

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

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

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

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

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thus eroding our competitive position in the market. We seek to protect our confidential proprietary information, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. These agreements are designed to protect our proprietary information, however, we cannot be certain that our trade secrets and other confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets, or that technology relevant to our business will not be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees, consultants or collaborators that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could be disclosed, misappropriated or otherwise become known or be independently discovered by our competitors. In addition, intellectual property laws in foreign countries may not protect trade secrets and confidential information to the same extent as the laws of the U.S. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business.

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

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

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

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

Others may be able to make products that are similar to CoSense or other planned products, but that are not covered by claims in our patents;

The original filers of the patents we purchased from BDDI might not have been the first to make the inventions covered by the claims contained in such patents;

We might not have been the first to file patent applications covering an invention;

Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;

Pending patent applications may not lead to issued patents;

Issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

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Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

We may not develop or in-license additional proprietary technologies that are patentable; and

The patents of others may have an adverse effect on our business.

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

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

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

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

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

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

Depending upon the timing, duration and specifics of FDA marketing approval of our products, if any, one or more of the U.S. patents covering any such approved product(s) or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our planned products. Nevertheless, we may not be granted patent term extension either in the

U.S. or in any foreign country because of, for example, our failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.

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

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Risks related to government regulation

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

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

warning letters;

civil or criminal penalties and fines;

injunctions;

suspension or withdrawal of regulatory approval;

suspension of any ongoing clinical studies;

voluntary or mandatory product recalls and publicity requirements;

refusal to accept or approve applications for marketing approval of new drugs or biologics or supplements to approved applications filed by us;

restrictions on operations, including costly new manufacturing requirements; or

seizure or detention of our products or import bans.

Prior to receiving approval to commercialize any of our planned products in the U.S. or abroad, we may be required to demonstrate with substantial evidence from well-controlled clinical studies, and to the satisfaction of the FDA and other regulatory authorities abroad, that such planned products are safe and effective for their intended uses. Results from preclinical studies and clinical studies can be interpreted in different ways. Even if we believe the preclinical or

clinical data for our planned products are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering any of our planned products to humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications.

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

a planned product may not be deemed safe or effective;

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FDA officials may not find the data from preclinical studies and clinical studies sufficient;

the FDA might not approve our or our third-party manufacturer's processes or facilities; or

the FDA may change its approval policies or adopt new regulations.

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

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

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

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

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

We have had limited interactions with foreign regulatory authorities. The approval procedures vary among countries and can involve additional clinical testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Moreover, clinical studies or manufacturing processes conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign

regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and even if we file we may not receive necessary approvals to commercialize our products in any market.

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

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

imposes a tax of 2.3% on the retail sales price of medical devices sold after December 31, 2012;

could result in the imposition of injunctions;

requires collection of rebates for drugs paid by Medicaid managed care organizations; and

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

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

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

overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. We cannot predict whether any additional legislative changes will affect our business.

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

our ability to set a price that we believe is fair for our products;

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our ability to generate revenue and achieve or maintain profitability; and

the availability of capital.

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

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

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

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

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

indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs;

the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government, and which may apply to entities like us which provide coding and billing advice to customers;

federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

Risks related to this offering and ownership of our securities

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

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

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

the success of competitive products or technologies;

results of clinical studies of Serenz or planned products or those of our competitors;

regulatory or legal developments in the U.S. and other countries, especially changes in laws or regulations applicable to our products;

introductions and announcements of new products by us, our commercialization partners, or our competitors, and the timing of these introductions or announcements;

actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;

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variations in our financial results or those of companies that are perceived to be similar to us;

the success of our efforts to acquire or in-license additional products or planned products;

developments concerning our collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;

developments concerning our ability to bring our manufacturing processes to scale in a cost-effective manner;

announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;

our ability or inability to raise additional capital and the terms on which we raise it;

the recruitment or departure of key personnel;

changes in the structure of healthcare payment systems;

market conditions in the pharmaceutical and biotechnology sectors;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

trading volume of our common stock;

sales of our common stock by us or our stockholders;

general economic, industry and market conditions; and

the other risks described in this Risk Factors section.

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

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

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

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

Approximately 1,436,161 shares of common stock may be sold in the public market by existing stockholders after the date of this prospectus and an additional 4,822,670 shares of common stock may be sold in the public market by existing stockholders on or about 181 days after the date of this prospectus, subject to volume and other limitations imposed under the federal securities laws. Sales of substantial amounts of our common stock in the public market after the completion of this offering, or the perception that such sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through offerings of our common stock. See the section entitled Shares Eligible for Future Trading for a more detailed description of the restrictions on selling shares of our common stock after this offering.

We are issuing Series A warrants and Series B warrants to purchase a total of 3,300,000 shares of common stock in this offering (or 3,795,000 shares if the over-allotment option is exercised in full) each subject to adjustment described under Description of Securities elsewhere in this prospectus. The number of shares of common stock exercisable for Series B warrants could increase if the market price of our stock decreases; see the section entitled Description of Securities. We will also issue compensation warrants to the underwriters in this offering to purchase an additional 82,500 shares of our common stock and additional compensation warrants to the underwriters to purchase 12,375 shares of our common stock if the over-allotment option is exercised in full. In addition, as of June 30, 2014, we had outstanding options to purchase 240,906 shares of our common stock and outstanding warrants to purchase an aggregate of 918,551 shares of our common stock. We will also have outstanding other options that are expected to be granted upon the completion of this offering that, if granted, would result in the issuance of an additional 924,180 shares of common stock. We plan to register for offer and sale the shares of common stock that are reserved for issuance pursuant to outstanding options. Shares covered by such registration statements upon the exercise of stock options generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act of 1933, as amended. The issuance or sale of such shares could depress the market price of our common stock.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of the completion of 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. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may suffer or be more volatile.

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

After 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 and under certain circumstances Vivo Ventures and its affiliates may have control over key decision making.

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

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

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

Participation in this offering by certain of our existing stockholders would reduce the available public float for our shares.

Entities associated with Vivo Ventures and Ernest Mario have purchased \$5.5 million of units in this offering at the offering price. They, together with our other directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, would own approximately 77%

of our outstanding common stock after this offering, based on the number of shares outstanding as of June 30, 2014.

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Purchases of our securities in our initial public offering will reduce the available public float for our securities because such stockholders will be restricted from selling any such securities by a lock-up agreement they have entered into with our underwriters and by restrictions under applicable securities laws. As a result, purchases of units by such stockholders in this offering will reduce the liquidity of our securities relative to what it would have been had these shares been purchased by investors that were not affiliated with us.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the other rules and regulations of the Securities and Exchange Commission, or SEC, and the rules and regulations of The NASDAQ Capital Market, or NASDAQ. The expenses that will be required in order to adequately prepare for being a public company will be material, and compliance with the various reporting and other requirements applicable to public companies will require considerable time and attention of management. For example, the Sarbanes-Oxley Act and the rules of the SEC and national securities exchanges have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. These rules and regulations will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits on coverage or incur substantial costs to maintain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers.

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

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective

and to obtain an unqualified report on internal controls from our auditors as required under Section 404. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Prior to the completion of this offering, we have been a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for this offering, we determined that material adjustments to various accounts were necessary, which required us to restate the financial statements for the year ended December 31, 2012, which had been previously audited by another independent audit firm. These adjustments leading to a restatement of those financial statements led us to conclude that we had a material weakness in internal control over financial reporting as of December 31, 2012. The material weakness that we identified was that we did not maintain a sufficient complement of resources with an appropriate level of accounting knowledge, experience and training commensurate with our structure and financial reporting requirements. We also found that the weakness persisted through the year ending December 31, 2013. As of that time, our financial operations staff consisted of one part-time consultant.

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

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

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

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

Our ability to utilize our federal net operating loss, carryforwards and federal tax credit may be limited under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code. The limitations apply if an ownership

change, as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect five percent shareholders increases by more than 50% over their lowest ownership percentage at any time during the applicable testing period (typically three years). If we have experienced an ownership change at any time since our formation, we

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may already be subject to limitations on our ability to utilize our existing net operating losses and other tax attributes to offset taxable income. In addition, future changes in our stock ownership, which may be outside of our control, may trigger an ownership change and, consequently, Section 382 and 383 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

If you purchase our securities in this offering, you will incur immediate and substantial dilution in the book value of your investment.

The initial public offering price is substantially higher than the net tangible book value per share of our securities. Investors purchasing units in this offering will pay a price per unit that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing units in this offering will incur immediate dilution of \$5.68 per share, based on the initial public offering price of \$6.50 per unit. Investors purchasing units in this offering will contribute approximately 18% of the total amount invested by stockholders since our inception, and will own, as a result of such investment, approximately 24% of the shares of common stock outstanding immediately following this offering.

The exercise of any of our outstanding options would result in additional dilution. As a result of the dilution to investors purchasing units in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. Further, because we may need to raise additional capital to fund our clinical development programs, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of equity or equity-linked securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in further dilution to investors.

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

We are issuing Series A warrants and Series B warrants to purchase a total of 3,300,000 shares of common stock in this offering (or 3,795,000 shares if the over-allotment option is exercised in full). In the event that the market price of our common stock falls below \$6.50 at any time between four and fifteen months after the issuance of the Series B warrants, the Series B warrants will become exercisable on a cashless basis for a number of common shares that increases as the market price of our common stock decreases, and exercisable at a discount to the tracking price of our common stock at the time. See Description of Securities . This may result in a number of shares issued, pursuant to the cashless exercise of Series B warrants, significantly in excess of the original 1,650,000 shares (or in excess of 1,897,500 shares if the over-allotment option is exercised in full). If the price of our common stock were to fall to \$1.00 per share, the minimum share price necessary for continued listing on the NASDAQ Capital Market, at any time more than four months, and less than fifteen months, after this offering, the number of shares for which the Series B warrants may be exercised would exceed eighteen million shares. This would result in majority ownership of our common stock by Series B warrant holders. Under certain other circumstances, exercises of the Series A and Series B warrants may be on a cashless basis, resulting in dilutive issuance of common shares of the company without cash proceeds to the company.

We will also issue compensation warrants to the underwriters in this offering to purchase an additional 82,500 shares of our common stock and additional compensation warrants to the underwriters to purchase 12,375 shares of our common stock if the over-allotment option is exercised in full. In addition, as of June 30, 2014, we had outstanding options to purchase 240,906 shares of our common stock and outstanding warrants to purchase an aggregate of 918,551 shares of our common stock. We will also have outstanding other options that are expected to be granted upon the completion of this offering that, if granted, would result in the issuance of an additional 924,180 shares of common stock.

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As of June 30, 2014, we had \$14,778,534 in aggregate principal amount and accrued interest outstanding under the 2010/2012 convertible promissory notes and \$1,783,880 in aggregate principal amount and accrued interest outstanding under the April 2014 convertible promissory notes. The 2010/2012 convertible promissory notes will automatically convert into shares of our common stock upon the completion of this offering. The 2014 convertible promissory notes will automatically convert into units of common stock and warrants issued in this offering. At the initial public offering price of \$6.50 per unit, the 2010/2012 convertible promissory notes and the April 2014 convertible promissory notes will automatically convert into 3,036,131 shares of common stock and 385,425 units (which shall consist of 385,425 shares of common stock, Series A warrants to purchase 385,425 shares of common stock, and Series B warrants to purchase 385,425 shares of common stock), respectively.

As of June 30, 2014, options to purchase 240,906 shares of our common stock were issued and outstanding with a weighted average exercise price of \$3.59 per share. Options to purchase 240,906 of such shares are currently exercisable or will be exercisable and we expect that we will grant additional options to purchase 924,180 shares of common stock upon the completion of this offering within 60 days of the date of this prospectus.

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

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

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

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

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

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An active trading market may not develop for our securities, and you may not be able to sell your units, common stock or warrants at or above the initial public offering price or warrant exercise price per share.

There is no established trading market for our securities, and the market for our securities may be highly volatile or may decline regardless of our operating performance. Prior to this offering, you could not buy or sell our securities publicly. An active public market for our securities may not develop or be sustained after this offering. While we have been approved to list our common stock and Series A warrants on the NASDAQ Capital Market, our units and our Series B warrants will not be listed on any exchange. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market in our units, common stock or warrants or how liquid that market might become. If a market does not develop or is not sustained, it may be difficult for you to sell your securities at the time you wish to sell them, at a price that is attractive to you, or at all.

The initial public offering price per unit has been determined through negotiation between us and representatives of the underwriter, and may not be indicative of the market prices that prevail after this offering. You may not be able to sell your common stock or warrants at or above the initial public offering price or warrant exercise price per share.

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

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

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

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

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

The warrants being offered as part of the units do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, following issuance of the warrants, Series A warrant holders may exercise their right to acquire the common stock and pay an exercise price of \$6.50 per share prior to the expiration of the five-year term on November 12, 2019, after which date any unexercised Series A

warrants will expire and have no further value. Series B warrant holders may exercise their right to acquire the common stock and pay an exercise price of \$6.50 per share prior to the expiration of their 15-month term on February 12, 2016, after which date any unexercised Series B warrants will expire and have no further value. In certain circumstances, the Series A and Series B warrants may be exercisable on a cashless

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basis, and certain other circumstances may affect the number of shares into which the Series B warrants may be exercisable. See Description of Securities. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

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

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

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Although we currently intend to use the net proceeds from this offering in the manner described in the section entitled Use of Proceeds, our management will have broad discretion in the application of the balance of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the commercialization of CoSense or other planned products. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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

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

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our board of directors will be divided into three classes with staggered three-year terms which may delay or prevent a change of our management or a change in control;

our board of directors will have the right to elect directors to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which will prevent stockholders from being able to fill vacancies on our board of directors;

our stockholders will not be able to act by written consent or call special stockholders meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take

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certain actions other than at annual stockholders meetings or special stockholders meetings called by our board of directors, the chairman of our board, the chief executive officer or the president;

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

future amendments of our certificate of incorporation and bylaws will require the approval of 66 $\frac{2}{3}$ % of our outstanding voting securities;

our stockholders will be required to provide advance notice and additional disclosures in order to nominate individuals for election to our board of directors or to propose matters that can be acted upon at a stockholders meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and

our board of directors will be able to issue, without stockholder approval, shares of undesignated preferred stock, which makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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

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

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately \$0.6 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately \$0.5 million (as of June 30, 2014, based on the initial public offering price of \$6.50 per unit) in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any

future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled Prospectus Summary, Risk Factors, Use of Proceeds, Management's Discussion and Analysis of Financial Condition and Results of Operations, Market, Industry and Other Data, Business and Shares Eligible for Future Trading, contains forward-looking statements. In some cases you can identify these statements by forward-looking words, such as believe, may, will, estimate, continue, anticipate, intend, could, project, plan, potential, seek, expect, goal, or the negative or plural of these words or similar expressions. The forward-looking statements include, but are not limited to, statements concerning the following:

our expected uses of the net proceeds to us from this offering;

our ability to commercialize CoSense on the timetable that we project;

the timing and the success of U.S. approval of Serenz pursuant to our clinical and regulatory efforts;

whether the results of the trials will be sufficient to support domestic or global regulatory approvals for Serenz;

our ability to maintain regulatory approval of CoSense or to obtain and maintain regulatory approval of our planned products;

our expectation that our existing capital resources and the net proceeds from this offering will be sufficient to enable us to successfully commercialize CoSense;

the benefits of the use of CoSense or Serenz;

the projected dollar amounts of future sales of established and novel diagnostics for neonatal hemolysis;

our ability to successfully commercialize CoSense or any planned products;

the rate and degree of market acceptance of CoSense, Serenz, or any planned products;

our expectations regarding government and third-party payor coverage and reimbursement;

our ability to manufacture CoSense instruments and consumables in conformity with the FDA's requirements and to scale up manufacturing of CoSense instruments and consumables to commercial scale;

our ability to successfully build a sales force and commercial infrastructure;

our ability to compete with companies that may enter the market with products that compete with CoSense;

our reliance on third parties to conduct clinical studies;

our reliance on third-party contract manufacturers to manufacture and supply our planned products for us;

our reliance on our collaboration partners' performance over which we do not have control;

our ability to retain and recruit key personnel, including development of a sales and marketing function;

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our ability to obtain and maintain intellectual property protection for CoSense, Serenz or any planned products;

our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;

our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act;

our ability to identify, develop, acquire and in-license new products and planned products;

our ability to successfully establish and successfully maintain appropriate collaborations and derive significant revenue from those collaborations;

our financial performance; and

developments and projections relating to our competitors or our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Risk Factors. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

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MARKET, INDUSTRY AND OTHER DATA

We obtained the industry, market and similar data set forth in this prospectus from our own internal estimates and research, and from industry publications and research, surveys and studies conducted by third party consultants, which were commissioned by us. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information and estimates.

Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

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USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of our units in this offering will be \$8.2 million, or \$9.7 million if the underwriters exercise their over-allotment option to purchase additional units in full, at the initial public offering price of \$6.50 per unit, after deducting underwriting discounts and commissions and offering expenses payable by us.

As of June 30, 2014, we had cash and cash equivalents of approximately \$1.2 million and we received approximately an additional \$0.3 million in gross proceeds from our convertible promissory note financing in August 2014, and an additional \$0.5 million in gross proceeds from our convertible promissory note financing in October 2014. We intend to use the net proceeds from this offering as follows:

Approximately \$5.6 million of the net proceeds from this offering will fund our commercial launch of CoSense; and

Approximately \$2.6 million to fund working capital, capital expenditures, research and development of additional future products, and other general corporate purposes, which 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.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. We believe that the proceeds of this offering will be sufficient to support hiring of commercial personnel at the level that we have described herein, and will support our anticipated marketing spends related to the launch of CoSense. To the extent that warrant exercises result in additional cash proceeds to the company, we anticipate deploying these funds on expansion of marketing and medical affairs activities supporting CoSense, as well as in research, development, and launch expenses related to additional products on the Sensalyze platform. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts and the status of and results from clinical studies, as well as any collaborations that we may enter into with third parties and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds from this offering described above, and our planned use of our existing cash and cash equivalents, we expect that such funds may not be sufficient to enable us to complete our planned development of additional diagnostic products based on our Sensalyze Technology Platform. Nor do we expect that the net proceeds from this offering and our existing cash and cash equivalents will be sufficient to enable us to fund Phase 3 clinical trials for Serenz, if necessary for regulatory approval in the U.S., or other development work that might be necessary to advance Serenz toward product launch or partnership.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as money market funds, certificates of deposit, commercial paper and U.S. government securities.

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DIVIDEND POLICY

We have never declared or paid, and do not anticipate declaring or paying, any cash dividends on any of our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends in the foreseeable future. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial conditions, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Table of ContentsIndex to Financial Statements**CAPITALIZATION**

The following table sets forth our capitalization as of June 30, 2014:

on an actual basis;

on a pro forma basis to reflect: (1) the filing of an amendment to our amended and restated certificate of incorporation effectuating a 1-for-12 reverse split of our capital stock, which was filed with the Secretary of State of the State of Delaware on July 28, 2014; (2) the automatic conversion of outstanding shares of our convertible preferred stock in connection with this offering as of June 30, 2014 into an aggregate of 865,429 shares of common stock immediately prior to the closing of this offering; and (3) the automatic conversion of the 2010/2012 convertible promissory notes in connection with this offering into 3,036,131 shares of common stock as if they had converted as of June 30, 2014, and (4) 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 770,850 shares of common stock, including the acceleration of the amortization of debt discounts upon conversion.

on a pro forma as adjusted basis to further reflect (1) the sale by us of 1,650,000 units in this offering at \$6.50 per unit, after deducting underwriting discounts and commissions and offering expenses payable by us, (2) capitalization of \$681,017 of deferred offering costs into additional paid-in capital, and (3) 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 109,748 shares of common stock, as if these had converted as of June 30, 2014, (4) the issuance of \$0.5 million in convertible promissory notes in October 2014 and the automatic conversion of those notes into 105,536 units, which shall consist of 105,536 shares of common stock and warrants to purchase 211,072 shares of common stock, as if these had converted as of June 30, 2014, and (5) due to the cashless exercise feature of the Series B warrants, the value of the Series B warrants is treated as a derivative liability.

You should read this table 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.

As of June 30, 2014		
	Actual	Pro Forma As Adjusted
	(in thousands, except share data) (unaudited)	
	\$ 14,852	

Convertible promissory notes issued in 2010, 2012 and April 2014, and accrued interest, net of discounts			
Convertible preferred stock warrant liability	2,635		
Series B Warrant liability			3,689 ⁽¹⁾
Convertible preferred stock, par value \$0.001 per share: 1,860,000 shares authorized, 865,429 shares issued and outstanding, actual; 10,000,000 shares authorized and no shares issued and outstanding pro forma and pro forma as adjusted			
	23,808		
Stockholders' equity (deficit):			
Common stock, par value \$0.001 per share: 10,000,000 shares authorized, 535,685 shares issued and outstanding, actual; 100,000,000 shares authorized, 4,822,670 shares issued and outstanding pro forma; 6,633,080 shares issued and outstanding, pro forma as adjusted			
	1	5	7
Additional paid-in capital	20,599	63,600	68,151
Accumulated deficit	(60,727)	(62,437)	(62,437)
Total stockholders' equity (deficit)	(40,127)	\$ 1,168	5,720 ⁽²⁾
Total liabilities and stockholders' equity (deficit)	\$ 2,154		\$ 10,396

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- (1) We have accounted for the Series B warrants as a derivative liability. As provided under ASC 815 and the associated guidance, an instrument or embedded feature in an instrument, such as our Series B warrants, should be treated as a derivative liability if its settlement amount is not indexed to the stock price of the entity. Because the number of our shares to be issued upon exercise of the Series B warrants is variable as the stock price decreases below the offering price, the Series B warrants are treated as derivative liability.
- (2) Our shareholders' equity, on a pro-forma as-adjusted basis, reflects approximately \$3.7M of derivative liability relating to the Series B warrants, or \$1.68 for each Series B warrant share to be issued in the offering. This includes Series B warrants issued to new holders purchasing units in the offering, and those issued to holders of our 2014 Notes who are receiving units in conversion of those Notes at the offering.

We determined the liability amount by combining three components: (a) the value of the warrants without the cashless exercise provisions, (b) the probability-weighted average value of each warrant share under various scenarios in which the cashless exercise provision would apply, and (c) the probability-weighted average value of additional shares of common stock for which the warrants might be exercised in the event that our common stock traded at a value below the offering price. For (a), we engaged an independent third party valuation firm to value the warrants via the Black-Scholes method for valuing such instruments. For component (b), the same independent third party valuation firm provided a Black-Scholes valuation of the warrants under several scenarios in which the cashless exercise provisions would be in effect, which we discounted in each scenario by the probability that the common share price would reach the expected level based on a normal probability distribution. The center of the distribution was deemed to be \$6.49, the offering price, and the standard deviation was chosen based on the share price movement of a basket of comparable companies in the 15 months subsequent to the initial public offering of those companies. We then averaged the resulting probability-weighted values across the scenarios to determine the value of component (b). For component (c), we determined the number of shares, in excess of the base amount, that would be issued to Series B warrant holders, in a series of scenarios varying the market price of the common share from \$0.25 to \$6.49. We then determined an average value of these additional shares across the various scenarios, probability-weighting each scenario according to the normal distribution of possible share prices used for component (b). The Company's estimated fair value of this liability is calculated using key assumptions including the probabilities of scenarios, enterprise value, time to liquidity, risk-free interest rates, discount for lack of marketability, and volatility. The estimates are based, in part, on subjective assumptions and could differ materially in the future.

The number of shares of our common stock issued and outstanding on an actual, pro forma and pro forma as adjusted basis in the table above 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;

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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 estimated exercise price of \$4.87 per share, which is 75% of the initial public offering price of the common stock underlying the units sold in this offering;

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1,650,000 shares of our common stock issuable upon the exercise of Series A warrants that are part of the units sold in this offering, subject to adjustment as described herein;

1,650,000 shares of our common stock issuable upon the exercise of Series B warrants that are part of the units sold in this offering, subject to adjustment as described herein;

82,500 shares of our common stock issuable upon the exercise of the underwriters' compensation warrants; and

924,180 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.

Table of ContentsIndex to Financial Statements**DILUTION**

Dilution is the amount by which the offering price paid by the purchasers of the units sold in the offering exceeds the pro forma as adjusted net tangible book value per share of our common stock after this offering. Such calculation does not reflect any dilution associated with the sale and exercise of the warrants issued as part of the units. The historical net tangible book value of our common stock, assuming the conversion of all convertible preferred stock into equivalent shares of common stock, as of June 30, 2014 was \$(16.3) million, or \$(11.65) per share. The pro forma net tangible book value of our common stock as of June 30, 2014 was \$1.2 million, or \$0.24 per share. Pro forma net tangible book value per share represents our total tangible assets less our total liabilities, divided by the number of outstanding shares of our common stock, after giving effect to the pro forma adjustments referenced under Capitalization.

After giving effect to (i) the pro forma adjustments referenced under Capitalization, (ii) an increase in total assets to reflect our receipt of the net proceeds from this offering at \$6.50 per unit, and after deducting underwriting discounts and commissions and offering expenses payable by us, and (iii) the addition of the number of shares offered by this prospectus to the number of shares outstanding, our pro forma as adjusted net tangible book value as of June 30, 2014 would have been approximately \$5.7 million, or \$0.86 per share. This represents no immediate increase in pro forma as adjusted net tangible book value per share to our existing stockholders, but an immediate dilution of \$5.63 per share to investors purchasing units in this offering.

The following table illustrates this dilution on a per share basis to new investors, assuming \$0.005 of value is attributed to each Series A warrant and Series B warrant issued as a part of each unit:

Initial public offering price per share		\$ 6.49
Historical net tangible book value per share as of June 30, 2014	\$ (11.65)	
Pro forma net tangible book value per share as of June 30, 2014	\$ 0.24	
Increase (Decrease) in pro forma net tangible book value per share attributable to new investors	0.62	
Pro forma as adjusted net tangible book value per share after this offering		0.86
Dilution per share to investors participating in this offering		\$ 5.63

The table below summarizes as of June 30, 2014, on a pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration, and the average price per share (i) paid to us by our existing stockholders and convertible noteholders and (ii) to be paid by new investors purchasing our common stock in this offering at \$6.50 per unit, before deducting underwriting discounts and commissions and offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price
	Number	Percent	Number	Percent	Per Share
Existing stockholders before this offering	4,822,670	75%	\$ 56,355,277	84%	\$ 11.69

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New investors	1,650,000	25	10,725,000	16	6.50
Total	6,472,670	100.0%	\$ 67,080,277	100.0%	\$ 10.36

If the underwriters exercise their option to purchase additional units in this offering in full, the percentage of shares of our common stock held by existing stockholders will be reduced to 82% of the total number of shares of our common stock outstanding after this offering, and the number of shares held by new investors will increase to 18% of the total number of shares of our common stock outstanding after this offering.

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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, 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 initial public offering price of the common stock underlying the units sold in this offering;

1,650,000 shares of our common stock issuable upon the exercise of Series A warrants that are part of the units sold in this offering, subject to adjustment as described herein;

1,650,000 shares of our common stock issuable upon the exercise of Series B warrants that are part of the units sold in this offering, subject to adjustment as described herein;

82,500 shares of our common stock issuable upon the exercise of the underwriters' compensation warrants; and

924,180 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.

To the extent that any outstanding options or warrants, including the warrants issued as part of the units sold in this offering, are exercised, new options are issued under our stock-based compensation plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. If all of these options and warrants were exercised, then our existing stockholders, including the holders of these options and warrants, would own 59% and our new investors would own 41% of the total number of shares of our common stock outstanding upon the closing of this offering. In such event, the total consideration paid by our existing stockholders and convertible noteholders, including the holders of these options and warrants, would be approximately \$56.4 million, or 63%, the total consideration paid by our new investors would be \$32.8 million, or 37%, the average price per share paid by our existing stockholders would be \$7.88, and the average price per share paid by our new investors would be \$5.74. Moreover, in certain circumstances, the number of shares into which our Series B warrants are exercisable may increase; see Description of Securities .

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You should read the following selected financial data together with the section of this prospectus entitled

Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes included in this prospectus. The statement of operations data for the years ended December 31, 2012 and 2013 and the period from inception to December 31, 2013 and the balance sheet data as of December 31, 2012 and 2013, respectively, are derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the six months ended June 30, 2014 and the balance sheet data as of June 30, 2014, are derived from our unaudited financial statement included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

Statement of Operations Data:	Year Ended		Six Months Ended	
	December 31, 2012	2013	2013	2014
	(in thousands, except share and per share data)			
	(unaudited)			
Revenue	\$	\$ 3,000	\$ 3,000	\$
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 expenses	3,597	3,847	2,295	1,991
Operating income (loss)	(3,597)	(847)	705	(1,991)
Interest and other income (expense)				
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)
Weighted average common shares outstanding ⁽¹⁾				
Basic and diluted	520,312	535,648	535,611	535,685
Net loss per share ⁽¹⁾				
Basic and diluted	\$ (12.46)	(6.92)	\$ (2.13)	\$ (6.77)

(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.

Balance Sheet Data	December 31		June 30
	2012	2013	2014 (unaudited)
Cash and cash equivalents	\$ 2,155	\$ 1,269	\$ 1,208
Working capital (deficit)	(9,155)	(12,655)	446
Total assets	2,514	1,587	2,154
Convertible promissory notes	11,132	13,992	14,852
Total stockholders equity (deficit)	(34,196)	(37,864)	(40,127)

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

You should read the following discussion and analysis of our financial condition and results of operations together with the portion of this prospectus entitled "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, intentions, and beliefs. Our actual results may differ materially from those discussed in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and in other parts of this prospectus. The share numbers in the following discussion reflect a 1-for-12 reverse split of our common stock and convertible preferred stock that we effected on July 28, 2014.

Overview

We were incorporated in the State of Delaware on August 25, 1999. Our principal executive offices are located at 3 Twin Dolphin Drive, Suite 160, Redwood City, California, 94065. We develop 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 in the first quarter of 2014 and received CE Mark approval for sale in the E.U. in the third quarter of 2013. We are commercializing CoSense using our own sales efforts, and intend to direct a significant portion of the use of proceeds of this offering to sales and marketing of CoSense, which is scheduled to begin in the second half of 2014. In addition, we are applying our research and development efforts to additional diagnostic products based on our Sensalyze Technology Platform, a portfolio of proprietary methods and devices which enables CoSense and can be applied to detect a variety of analytes in exhaled breath.

Prior to 2010, our efforts were primarily focused on development of therapeutics rather than diagnostics. We have previously obtained CE Mark approval in the E.U. for Serenz, an as-needed treatment for AR that has shown statistically significant improvements in AR symptoms in randomized, controlled Phase 2 clinical trials completed by us. We outlicensed Serenz to GSK in 2013, realizing revenue in the form of a non-refundable up-front payment of \$3 million. In June 2014, the agreement terminated and GSK returned the licensed rights to Serenz back to us. We have no further monetary obligations to GSK related to the terminated agreement. We intend to engage in further research and development of Serenz prior to obtaining a partner for the final development and commercialization of the product.

Financial overview

Summary

We have not generated net income from operations, and, at December 31, 2013 and as of June 30, 2014, we had an accumulated deficit of \$57.1 million and \$60.7 million, respectively, primarily as a result of research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, potentially including sales of CoSense and other diagnostic products, license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships, we have, to date, generated

revenue only from the 2013 license agreement pertaining to Serenz. The GSK agreement terminated in June 2014, and we may not generate future licensing revenue. We may never be successful in commercializing our CoSense product or in developing additional products. Accordingly, we expect to incur significant losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenue or profits.

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Revenue recognition

We have thus far earned revenue primarily from a licensing agreement in connection with intellectual property created by us. We apply the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605, *Revenue Recognition*, to recognize revenue. We begin recognizing revenue when persuasive evidence of an arrangement exists, such as a contract or purchase order, delivery has occurred, no significant obligations with regard to implementation or integration exist, the fee is fixed or determinable, and collectability is reasonably assured.

Research and development expenses

Research and development costs are expensed as incurred. Research and development costs consist primarily of salaries and benefits, consultant fees, prototype expenses, certain facility costs and other costs associated with clinical trials, net of reimbursed amounts. Costs to acquire technologies to be used in research and development that have not reached technological feasibility, and have no alternative future use, are expensed to research and development costs when incurred.

Sales and marketing expenses

Sales and marketing expenses consist principally of personnel-related costs, professional fees for consulting expenses, and other expenses associated with commercial activities. We anticipate these expenses will increase significantly in future periods, reflecting the increased level of sales and marketing activity necessary for the commercial launch of CoSense.

General and administrative expenses

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, insurance, rent, and other general operating expenses not otherwise included in research and development. We anticipate general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, other administrative expenses and increased professional fees associated with being a public reporting company.

Other income (expense), net

Other income (expense), net is comprised of changes in the fair value of the convertible preferred stock warrant liabilities.

Critical accounting policies, significant judgments and use of estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily

apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

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Research and development expense

Research and development costs are expensed as incurred. Research and development expense includes payroll and personnel expenses; consulting costs; external contract research and development expenses; and allocated overhead, including rent, equipment depreciation and utilities, and relate to both company-sponsored programs as well as costs incurred pursuant to reimbursement arrangements. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized and recognized as an expense as the goods are delivered or the related services are performed.

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing contracts and purchase orders, reviewing the terms of our intellectual property agreements, communicating with our applicable personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees to:

contract manufacturers in connection with the production of clinical trial materials;

contract research organizations and other service providers in connection with clinical studies;

investigative sites in connection with clinical studies;

vendors in connection with preclinical development activities; and

professional service fees for consulting and related services.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows and expense recognition. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in our reporting changes in estimates in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred. However, due to the nature of these estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical studies

or other research activity.

Stock-based compensation expense

For the years ended December 31, 2012 and 2013 and for the six-month periods ended June 30, 2013 and 2014, stock-based compensation expense was approximately \$24,000, \$38,000, 31,000 and \$16,000, respectively. As of December 31, 2013 and as of June 30, 2014, we had approximately \$8,000 and \$39,000, respectively, of total unrecognized compensation expense, which we expect to recognize over a period of approximately 0.4 years and 0.3 years, respectively. The intrinsic value of all outstanding stock options as of June 30, 2014 was approximately \$0.7 million based on a hypothetical common stock fair value of \$6.49 per share, which is the price of the common stock underlying the units being sold in this offering. We expect to

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continue to grant equity incentive awards in the future as we continue to expand our number of employees and seek to retain our existing employees, and to the extent that we do, our actual stock-based compensation expense recognized in future periods will likely increase.

Stock-based compensation costs related to stock options granted to employees are measured at the date of grant based on the estimated fair value of the award, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option-pricing model. The grant date fair value of stock-based awards is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Stock options we grant to employees generally vest over four years.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions to estimate the fair value of stock-based awards. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different. These assumptions include:

Fair value of our common stock: Because our stock is not publicly traded, we must estimate its fair value, as discussed in *Common stock valuations* below.

Expected volatility: As we do not have a trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average historical price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the medical device and diagnostics industries that are similar in size, stage of life cycle and financial leverage. We did not rely on implied volatilities of traded options in our industry peers' common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

Expected term: We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in estimating the fair value-based measurement of our options. Therefore, we have opted to use the *simplified method* for estimating the expected term of options.

Risk-free rate: The risk-free interest rate is based on the yields of U.S. Treasury securities with maturities similar to the expected time to liquidity.

Expected dividend yield: We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

No employee options were granted in 2012 or 2013. There were 12,683 options granted in February 2014. In addition to the assumptions used in the Black-Scholes option-pricing model, we must also estimate a forfeiture rate to calculate the stock-based compensation expense for our awards. We will continue to use judgment in evaluating the expected volatility, expected terms, and forfeiture rates utilized for our stock-based compensation expense calculations on a prospective basis.

Common stock valuations

The estimated fair value of the common stock underlying our stock options was determined at each grant date by our board of directors and was supported by periodic independent third-party valuations. Our board

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of directors intended all options granted to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant. The valuations of our common stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. The methodology used by the third-party valuation specialists to determine the fair value of our common stock included estimating the fair value of the enterprise, subtracting the fair value of debt from this enterprise value, and then allocating this value to all of the equity interests using the option pricing method. The assumptions used in the valuation model to determine the estimated fair value of our common stock as of the grant date of each option are based on numerous objective and subjective factors, combined with management judgment, including the following:

independent third-party valuations as of December 31, 2013 and June 30, 2014;

progress of research and development activities;

our operating and financial performance, including our levels of available capital resources;

the valuation of publicly-traded companies in the diagnostics and biotechnology sectors;

rights and preferences of our common stock compared to the rights and preferences of our other outstanding equity securities;

equity market conditions affecting comparable public companies, as reflected in comparable companies market multiples, initial public offering valuations and other metrics;

the achievement of enterprise milestones, including our progress toward product approvals;

the likelihood of achieving a liquidity event for the shares of common stock, such as an initial public offering or an acquisition of our company given prevailing market and biotechnology sector conditions;

sales of our convertible preferred stock and convertible promissory notes in arms-length transactions;

the illiquidity of our securities by virtue of being a private company;

business risks; and

management and board experience.

Common stock valuation methodologies

Because there has been no public market for our stock, our board of directors has determined the fair value of the common stock by considering a number of objective and subjective factors including valuations performed by unrelated third-party specialists, which included valuations of comparable companies, operating and financial performance, lack of liquidity of capital stock and general and industry-specific economic outlook, among other factors. The independent third-party specialists have provided valuations of our common stock as of December 31, 2013 and June 30, 2014. Our board of directors has reviewed the valuations of common stock performed by the third party valuation expert as part of determining the fair value of the common stock to set the exercise price for granted stock options.

The valuations were performed in accordance with applicable elements of the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as*

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Compensation, or the Practice Aid. The Practice Aid prescribes several valuation approaches for estimating the value of an enterprise, such as the cost, market and income approaches, and various methodologies for allocating the value of an enterprise to its common stock.

The Practice Guide identifies various available methods for allocating enterprise value across classes and series of capital stock to determine the estimated fair value of common stock at each valuation date. In accordance with the Practice Aid, we considered the following methods:

Option Pricing Method. Under the option pricing method, or OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The estimated fair values of the preferred and common stock are inferred by analyzing these options.

Hybrid Method. The Hybrid Method blends the concepts of the Probability-Weighted Expected Return Method, or PWERM, with the concepts of the Option Pricing Method, or OPM. We considered the valuation of the common stock under the following scenarios: (a) the currently planned initial public offering; (b) a merger or sale of the business; or (c) remaining private. The first two scenarios were implemented by: (i) estimating the future equity value under each case; (ii) allocating the future value in each scenario according to the subject company's capital structure; (iii) weighting each scenario; (iv) discounting the value to a present value equivalent using a risk-adjusted discount rate; and (v) considering discounts for lack of control or marketability, as appropriate. In accordance with the Practice Aid, the third scenario, remaining private, is modeled using the OPM over a variety of timeframes until the senior securities such as our preferred stock are redeemed or repurchased.

Based on our early stage of development and other relevant factors, we determined that this combination was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock for valuations performed as of December 31, 2013 and June 30, 2014. On December 31, 2013 and June 30, 2014, we estimated the fair value of our common stock to be \$7.56 and \$7.56, respectively. Following the closing of this offering, the fair value of our common stock will be determined based on its closing price on NASDAQ.

Estimated fair value of convertible preferred stock warrant liabilities

We have issued warrants to purchase shares of our convertible preferred stock. We have classified the fair value of these warrants as liabilities on the balance sheet as they correspond to the treatment of the preferred stock as temporary equity. We account for the warrants as a derivative instrument. Changes in the fair value of the warrants are presented separately as changes in warrant liability in our statements of operations for each reporting period. We use the Monte Carlo simulation model to determine the fair value of the warrants. As a result, the valuation of this derivative instrument is subjective because the option-valuation model requires the input of highly subjective assumptions, including the expected stock price volatility and the probability of a future occurrence of an fundamental transaction. Changes in these assumptions can materially affect the fair value estimate and, such impacts can, in turn, result in material non-cash charges or credits, and related impacts on earnings or loss per share, in the statements of operations. We will continue to adjust the liability for changes in fair value until the earlier of the expiration of the warrants or their exercise, at which time the liability will be reclassified into stockholders' deficit. We records any change in fair value as a component of other income or expense.

Income taxes

We account for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the

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amounts at which assets and liabilities are recorded for financial reporting purposes and the amounts recorded for income tax purposes. Deferred income taxes are classified as current or non-current, based on the classifications of the related assets and liabilities giving rise to the temporary differences. A valuation allowance is provided against our deferred income tax assets when their realization is not reasonably assured.

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

Results of operations***Comparison of the six months ended June 30, 2013 and 2014 (Unaudited)***

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

	Six Months Ended June 30,		Increase/(Decrease)	
	2013	2014		
Revenue	\$ 3,000	\$	\$ (3,000)	(100)%
Operating expenses:				
Research and development	1,275	921	(354)	(28)%
Sales and marketing		12	12	100%
General and administrative	1,020	1,058	38	4%
Income (loss) from operations	705	(1,991)	(2,696)	(382)%
Interest income (expense), net	(1,899)	(1,058)	(841)	(44)%
Other income (expense), net	51	(578)	629	1,233
Net loss	\$ (1,143)	\$ (3,627)	\$ (2,484)	(217)%

Revenue

No revenue was recognized in the six months ended June 30, 2014. The \$3.0 million revenue recognized in the six months ended June 30, 2013 represented the revenue recognized in the form of a non-refundable up-front payment pursuant to our license agreement with GSK.

Research and development expense

Research and development expense decreased \$0.4 million, or 28%, from \$1.3 million in the six months ended June, 2013 to \$0.9 million in the six months ended June 30, 2014. The expenses are associated with clinical trials conducted with CoSense in 2013 and the decline in expenses was due to the ramp-down of regulatory costs associated with the approval of CoSense.

Sales and marketing expense

Sales and marketing expense increased \$12,000, or 100%, from zero in the six months ended June 30, 2013 to \$12,000 in the six months ended June 30, 2014. The increase was due to higher personnel-related expenses associated with the commercial launch of CoSense.

Table of Contents**Index to Financial Statements*****General and administrative expense***

General and administrative expense increased \$0.04 million, or 4%, from \$1.02 million in the six months ended June 30, 2013 to \$1.06 million in the six months ended June, 2014. The increase in general and administrative expense was primarily due to higher consulting fees, professional services and compensation expenses incurred during the 2014 period as compared to 2013.

Interest income

Interest income was not material and remained relatively consistent between the two quarters.

Interest expense

Interest expense decreased \$0.8 million, or 44% from \$1.9 million in the six months ended June 30, 2013 to \$1.1 million in the six months ended June 30, 2014. Interest expense includes the amortization of the debt discounts associated with the convertible notes, and because the discounts to the notes were fully amortized as of December 31, 2013, the six months ended June 30, 2014 was less than the comparable period in 2013. We recorded accrued interest expense on the convertible promissory notes outstanding during the six months ended June 30, 2013 and 2014. The total principal plus accrued interest on the convertible promissory notes as of June 30, 2013 and 2014 was \$13.0 million and \$16.5 million, respectively.

Other income (expense), net

The other income in the six months ended June 30, 2013 decreased by \$0.6 million or 1,233% from \$51,000 in the six months ended June 30, 2013 to (\$578,000) in the six months ended June 30, 2014. This decrease was primarily due to a change in the fair value of the preferred stock warrants.

Results of operations***Comparison of the years ended December 31, 2012 and 2013***

The following table summarizes our net loss during the periods indicated (in thousands, except percentages):

	Year Ended December 31,		Increase/(Decrease)	
	2012	2013		
Revenue	\$	\$ 3,000	\$ 3,000	NM ⁽¹⁾
Operating expenses:				
Research and development	2,470	2,380	(90)	(4)%
General and administrative	1,127	1,467	340	30%
Loss from operations	(3,597)	(847)	(2,750)	(76)%
Interest income (expense), net	(2,863)	(2,858)	(5)	NM ⁽¹⁾
Other income (expense), net	(22)	(2)	(20)	NM ⁽¹⁾

Net loss	\$	(6,482)	\$	(3,707)	\$	(2,775)	(43)%
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(1) Not meaningful.

Revenue

No revenue was recognized in the year ended December 31, 2012. The \$3.0 million revenue recognized in the year ended December 31, 2013 represented the revenue recognized pursuant to our license agreement with GSK.

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Research and development expense

Research and development expense decreased \$0.1 million, or 4%, from \$2.5 million for 2012 to \$2.4 million for 2013. This was due to expenses associated with clinical trials conducted with CoSense in 2013 and the ramp-down of regulatory costs associated with approval of CoSense. For the years ended December 31, 2012 and 2013, substantially all of our research and development expense related to our development activity for Serenz and CoSense.

General and administrative expense

General and administrative expense increased \$0.3 million, or 30%, from \$1.1 million for 2012 to \$1.5 million for 2013. The increase in general and administrative expense was primarily due to additional consulting, professional services and facilities expenses incurred during the 2013 period as compared to 2012, as we prepared for commercialization of the CoSense product and pursued license opportunities for our Serenz product.

Interest income

Interest income was not material and remained relatively consistent between the two years.

Interest expense

Interest expense remained relatively the same in each period, including \$2.9 million for both periods. We record interest expense on the convertible promissory notes outstanding during the year, and as of December 31, 2012 and 2013, the total principal and accrued but unpaid interest balance on the notes was \$11.1 and \$14.0 million, respectively. Interest expense included non-cash expense related to the amortization of the debt discount in both years.

Other income (expense), net

Other income (expense), net decreased \$20,000, from \$22,000 in expense for 2012 to \$2,000 in expense for 2013. This decrease was primarily due to a change in the fair value of the preferred stock warrant liability and the receipt in 2013 of \$0.1 million due to a payment from an insurance company that converted from a mutual company to a privately held company.

Liquidity, capital resources and plan of operations

Since our inception and through June 30, 2014, we have financed our operations primarily through private placements of our equity securities and debt financing. At June 30, 2014, we had cash and cash equivalents of \$1.2 million, a majority of which is invested in a money market fund at an AAA-rated financial institution. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of Serenz and CoSense products.

We may continue to require additional financing to develop our future products and fund operations for the foreseeable future. In April 2014, we received gross proceeds of approximately \$1.8 million from the sale of convertible promissory notes, and in August 2014 and October 2014, we received gross proceeds of approximately \$0.3 million and \$0.5 million, respectively, from the sale of additional similar notes. In addition, on September 29, 2014, we established a line of credit of up to an aggregate of \$0.1 million. We will continue to seek funds through equity or debt financings (including this offering), collaborative or other arrangements with corporate sources, or

through other sources of financing. Assuming we are successful in concluding this offering, we expect that we will have sufficient working capital to execute on our business plan through at least September 2015. If we are not successful in concluding this offering, nor able to raise any additional funds via alternative

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sources of financing, we expect that we will have to restructure our business significantly to focus resources on the commercial launch of CoSense, and without significant near-term revenue from CoSense sales, we may not continue as a going concern. Adequate additional funding may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. These uncertainties raise substantial doubt as to our ability to continue as a going concern. Our financial statements included in this prospectus do not include any adjustments that might be necessary if we are unable to continue as a going concern. We anticipate that we may need to raise substantial additional capital, the requirements of which will depend on many factors, including:

the rate of progress in the commercialization of our products and the generation of revenue from product sales;

the degree and rate of market acceptance of any products launched by us or future partners;

the cost of commercializing our products, including the costs of sales, marketing, and distribution;

the costs of developing our anticipated internal sales and marketing capabilities;

the cost of preparing to manufacture our products on a larger scale;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and

the emergence of competing technologies or other adverse market developments.

If we are unable to raise additional funds when needed, our ability to attain commercial success with CoSense, or our other potential products, may be impaired. We may also be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others technologies or future products or programs that we would prefer to develop and commercialize ourselves.

Cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31,		Six Months Ended June,	
	2012	2013	2013	2014
			(unaudited)	
Net cash used in operating activities	\$ (3,496,432)	\$ (885,218)	\$ 761,086	\$ (1,665,770)
Net cash used in investing activities	(2,490)	(1,274)		(4,074)
Net cash provided by financing activities	5,026,898		160	1,608,881
Net increase (decrease) in cash and cash equivalents	\$ 1,527,976	\$ (886,492)	\$ 761,246	\$ (60,963)

Cash provided by (used in) operating activities

During the six months ended June 30, 2014, net cash used in operating activities was \$1.7 million, which was primarily due to the use of funds in our operations related to the development of our products. Net

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cash provided by operating activities in the six months ended June 30, 2013 was due primarily to the receipt of \$3.0 million from GSK, less operating expenses incurred during the period.

Net cash used in operating activities was \$3.5 million and \$0.9 million in 2012 and 2013, respectively, which was primarily due to the use of funds in our operations related to the development of our products. Cash used in operating activities in 2013 decreased compared to 2012 primarily due to licensing revenues received in 2013, resulting in lower net loss from operations.

Cash used in investing activities

Cash used in investing activities consisted primarily of investment in equipment, and an increase in restricted cash due to requirements under lease obligations.

Cash provided by financing activities

During the six months ended June 30, 2014, cash provided by financing activities was \$1.6 million, consisting primarily of net proceeds from the issuance of convertible promissory notes.

Cash provided by financing activities was \$0 in 2013, compared to \$5.0 million in 2012. Cash provided by financing activities in 2012 consisted primarily of net proceeds from the issuance of convertible promissory notes.

As of June 30, 2014, we had cash and cash equivalents of approximately \$1.2 million. 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. The offering contemplated in this prospectus would give us cash resources for at least the next twelve months according to our current business plan. In the event that this offering does not raise a sufficient amount, we may be required to alter our business plan, which may impair the value of our business.

Contractual obligations and commitments

As of December 31, 2013, we had lease obligations totaling \$111,000 consisting of an operating lease for our operating facility that expired in May 2014. We signed a sublease in May 2014, which expires in May 2015, for a new office space in Redwood City, California. The sublease is for one year commencing June 1, 2014, with an option to renew to June 2018. We prepaid rent for the last four months of the initial lease term. Minimum payments under the agreement are \$199,000 in calendar 2014 and \$18,000 in calendar 2015.

The following table summarizes our contractual obligations as of December 31, 2013. The liability amounts attributable to the convertible notes payable and interest will convert automatically into shares of common stock immediately prior to the close of this offering.

Less than 1 year	1 to 3 years	Payments due by period		Total
		4 to 5 years	After 5 years	
(in thousands)				

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Lease obligations	\$ 111	\$	\$	\$	\$ 111
Convertible notes payable and interest ⁽¹⁾		13,992			13,992
Total	\$ 111	\$ 13,992	\$	\$	\$ 14,103

(1) Includes accrued and unpaid interest.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties, and payments that become due and payable on the achievement of certain development

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and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above. We are also obligated to make certain payments of deferred compensation to management upon completion of certain types of transactions. As the amount and timing of such payments are not probable and estimable, such commitments have not been included on our balance sheet or in the contractual obligations tables above.

Convertible Promissory Notes

In 2010, we entered into a convertible promissory note and warrant purchase agreement with various investors, pursuant to which we sold convertible promissory notes to the investors totaling approximately \$5.2 million. The notes are collateralized by substantially all of our assets and bear interest at a fixed rate of 12% per annum, which is accrued but not paid. These notes are convertible into equity securities at a 25% discount to the price per share of the next round of equity securities to be issued. In connection with the sale of additional convertible promissory notes issued by us in April 2014, as described below, we extended the maturity date of the outstanding 2010 convertible promissory notes to September 30, 2015, or upon an occurrence of demand, made after such date, by the holders of two-thirds of the total principal amount of the 2010 convertible promissory notes then outstanding.

In 2012, we entered into a convertible promissory note and warrant purchase agreement, as amended, with various investors, pursuant to which we sold convertible promissory notes totaling: (i) in January 2012, \$1.9 million; and (ii) in July 2012, \$3.1 million. The notes are collateralized by substantially all of our assets and bear interest at a fixed rate of 12% per annum, which is accrued but not paid. They are convertible into equity securities at a 25% discount to the price per share of the next round of equity securities to be issued. In connection with the sale of additional convertible promissory notes issued by us in April 2014, as described below, we extended the maturity date of the outstanding 2012 convertible promissory notes to September 30, 2015, or upon an occurrence of demand, made after such date, by the holders of two-thirds of the total principal amounts of 2012 convertible notes payable then outstanding.

We refer to the 2010 convertible promissory notes and 2012 convertible promissory notes, collectively in this prospectus as the 2010/2012 convertible promissory notes. The outstanding 2010/2012 convertible promissory notes, and warrants associated therewith, were subsequently amended in May 2014 to provide for the conversion of these notes into shares of our common stock, in connection with this offering, at a discount of 25% of the public offering price of the common stock, and exercise of the warrants for shares of our common stock with an exercise price of 75% of the public offering price of the common stock. Additionally, upon conversion of the outstanding 2010/2012 convertible promissory notes into shares of our common stock in this offering, the security interest associated with these instruments will be extinguished.

We refer to the April 2014 promissory notes, the August 2014 promissory notes, and the October 2014 promissory notes collectively in this prospectus as the 2014 convertible promissory notes. In April 2014, we entered into a convertible promissory note and warrant purchase agreement with various investors, pursuant to which we sold convertible promissory notes to the investors totaling approximately \$1.8 million. In August 2014 and October 2014, we entered into a convertible promissory note and warrant purchase agreement with various investors, pursuant to which we sold convertible promissory notes to the investors totaling approximately \$0.3 million and \$0.5 million, respectively. The 2014 convertible promissory notes have a maturity date of September 30, 2015. If these notes are outstanding, and not converted to any form of equity securities as of the maturity date, then two (2) times the unpaid principal amount, together with any then accrued but unpaid interest, and any other amounts payable under these

notes, shall be due and payable upon demand of the holders of two-thirds or more of the principal amount of all 2014 convertible promissory notes then outstanding. The 2014 convertible promissory notes are unsecured and bear interest as follows: (i) if this offering is completed, at a fixed rate of 2% per annum; or (ii) if a convertible preferred stock financing occurs before the completion of this offering, or if neither this offering nor a convertible preferred stock financing is completed before the maturity

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date of these notes, at a fixed rate of 12% per annum. The 2014 convertible promissory notes are convertible as follows: (i) if this offering is completed, these notes will automatically convert into units at a discount of 30% to the public offering price of the units; or (ii) (A) if a convertible preferred stock financing which results in gross proceeds to us of at least \$1.5 million (excluding the conversion of all of our outstanding convertible promissory notes) occurs prior to this offering being completed, the 2014 convertible promissory notes will automatically convert into the series of convertible preferred stock sold in that financing at a price per share equal to 75% of the price per share paid by other investors in that financing, or (B) if no such preferred stock financing which results in gross proceeds to us of at least \$1.5 million (excluding conversion of these notes) occurs prior the maturity date of these notes, these notes may be converted, at the election of each note holder, into either (1) shares of the series of convertible preferred stock sold in our next preferred stock financing at a price per share equal to 75% of the price per share paid by other investors in such financing, or (2) shares of our Series C convertible preferred stock, at a price per share of \$16.20 per share, in each case following the maturity date of these notes.

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

Line of Credit

On September 29, 2014, we established a line of credit in the amount of up to an aggregate of \$0.1 million. The line of credit bears a fixed interest rate of 6% per annum simple interest. The line of credit has a two-year repayment term, with prepayment at our option with no penalty. The line of credit is unsecured and shall be payable out of cash received in our accounts receivable following commencement of our commercial sales, or upon the second anniversary of the loan date.

Off-balance sheet arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as these are defined in the rules and regulations of the SEC.

JOBS Act accounting election

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to take advantage of this provision and, as a result, we will adopt the extended transition period available under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided under the JOBS Act.

Quantitative and qualitative disclosures about market risk

The primary objective of our investment activities is to preserve our capital to fund our operations. We also seek to maximize income from our cash and cash equivalents without assuming significant risk. To achieve our objectives, we invest our cash and cash equivalents in money market funds. As of June 30, 2014, we had cash and cash equivalents of \$1.2 million consisting of cash and investments in a highly liquid U.S. money market fund. A portion of our investments may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our

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exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio. We actively monitor changes in interest rates and invest in accordance with an investment policy ratified by the Audit Committee of our board of directors.

Controls and procedures

A company's internal control over financial reporting is a process designed by, or under the supervision of, that company's principal executive and principal financial officers, or persons performing similar functions, and effected by that company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

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

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

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

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

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

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

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

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BUSINESS

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 excessive hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, hemolysis is a dangerous condition which can lead to long-term developmental disability. CoSense received initial 510(k) clearance for sale in the U.S. in the fourth quarter of 2012, with a more specific Indication for Use related to hemolysis 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.

With respect to therapeutics, we have previously obtained CE Mark approval in the E.U. for Serenz, an as-needed treatment for allergic rhinitis, or AR, that has shown statistically significant improvements in AR symptoms in randomized, controlled Phase 2 clinical trials. Our research and development efforts are focused on additional diagnostic products based on our Sensalyze Technology Platform, a portfolio of proprietary methods and devices which enables CoSense, and can be applied to detect a variety of analytes in exhaled breath.

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. Currently, hemolysis is detected via a variety of blood tests, which are limited in their diagnostic accuracy and suffer from other drawbacks, including the need for painful blood draws and a waiting period for results. CoSense detects hemolysis by measuring carbon monoxide, or CO, in the portion of the exhaled breath that originates from the deepest portion of the lung. This is referred to as the end-tidal component of the breath, and the measurement we perform with CoSense is referred to as end-tidal carbon monoxide, or ETCO. This measurement is typically reported after being corrected for ambient CO levels, and is referred to as ETCOc. Throughout this document, ETCO refers to ETCOc levels. 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 transfusion levels. Because CO is a direct byproduct of hemolysis, ETCO can measure the rate of bilirubin production from hemolysis. However, 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. 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.

We are currently focused on launching CoSense commercially, which we commenced in October 2014 and intend to accelerate in the fourth quarter of 2014 with the proceeds of this offering. CoSense combines a portable detection device with a single-use disposable nasal cannula to measure ETCO. While our launch efforts will initially focus on establishing an installed base of devices and building physician support for the device, we expect sales of the disposable cannula to be the largest component of our revenue over time. An electronic interface between the device and the consumable cannula requires one-time use of our cannula, which also promotes good hygiene and is necessary to preserve the accuracy of the device.

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Sales and marketing activities associated with the launch of CoSense comprise a significant portion of our planned 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. We also intend to use our research and development expertise to develop additional diagnostic devices based on our Sensalyze Technology Platform that can also be sold by our sales force. 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, 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 completed in which Serenz showed statistically significant improvements in total nasal symptom scores, or TNSS, in symptomatic patients when compared to controls. 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.

We currently plan to commercialize Serenz in the E.U. via distributorship arrangements. In the U.S., we intend to determine the regulatory approval pathway with the U.S. Food and Drug Administration, or FDA, for Serenz and subsequently to seek a partner or distributorship arrangements for commercialization.

CoSense

CoSense is the first device using our Sensalyze Technology Platform to achieve regulatory approval. CoSense detects ETCO, which can be elevated due to endogenous causes such as excessive breakdown of red blood cells, or hemolysis, or exogenous causes such as CO poisoning and smoke inhalation. Our first target market is for the detection of hemolysis in neonates, a disorder in which CO and bilirubin are produced in excess as byproducts of the breakdown of red blood cells. Hemolysis can place neonates at high risk for hyperbilirubinemia and resulting neurodevelopmental disability. The AAP recommends the use of ETCO monitoring to evaluate neonates for hemolysis, but there is no device currently on the market for physicians to effectively monitor ETCO in clinical practice.

Hemolysis and Bilirubin

We estimate that 34% of the 9.2 million newborns in the U.S. and E.U. each year should be tested for hemolysis under current treatment practice, representing approximately 3.1 million newborns. We believe that many of these infants are tested, but using relatively inaccurate and invasive diagnostic methods. Retrospective analysis of data, including data from over 54,000 infants compiled by the Collaborative Perinatal Project sponsored by the National Institutes of Health, or NIH, suggests that the only factor that predisposes infants with jaundice to adverse neurodevelopmental outcomes is the concurrent presence of hemolysis. Hemolysis can be caused by a number of factors, including physical trauma and bruising, blood group incompatibility, autoimmune disorders, and genetic causes such as sickle cell disease and G6PD enzyme deficiency. Because bilirubin is the chemical byproduct of the destruction of hemoglobin within red blood cells, hemolysis causes bilirubin production to spike. Bilirubin is yellow in color, and if present in excessive amounts in the body, known as hyperbilirubinemia, it can be deposited in tissues such as the skin

and conjunctiva. The condition manifests as a yellowing of skin and conjunctiva and is called jaundice. Elevated levels of bilirubin are particularly dangerous to neonates, who have immature livers and therefore lack the adult ability to excrete bilirubin. Neonates also lack a well-formed blood-brain barrier to prevent bilirubin from entering the central nervous system, or CNS, where bilirubin is known to be toxic to neuronal tissue.

Table of Contents**Index to Financial Statements*****Adverse Effects of Jaundice and Hyperbilirubinemia***

Every year approximately 143 million babies are born world-wide, of which 4.0 million are in the U.S. and 5.2 million in the E.U. It is estimated that up to 60% of term neonates and 80% of preterm neonates may have jaundice. Most neonates have non-pathologic jaundice, which is related to a decreased capacity of the neonate to excrete bilirubin into the intestinal tract for elimination from the body. These neonates will often normalize their bilirubin levels without a need for treatment. When treatment is required, it is typically via phototherapy, which typically involves isolating the baby in a chamber that directs blue-wavelength light to the baby's skin. The light penetrates the skin and breaks down bilirubin via a photochemical reaction over a period of several hours. When treatment is performed in a timely fashion, adverse outcomes can be avoided. Some neonates with jaundice, however, will develop adverse neurodevelopmental outcomes related to hyperbilirubinemia.

According to the Agency for Healthcare Research and Quality, part of the U.S. Department of Health and Human Services, neonatal jaundice is the single largest cause for hospital readmission of neonates in the U.S. This results in inefficient care and can also be highly stressful and disruptive for the parents and neonate.

Exposure to excess bilirubin in the CNS as a result of hyperbilirubinemia is toxic and may cause long-term developmental disabilities. These abnormalities may be subtle, and include hearing problems and low IQ. Subtle forms of disability are known as Bilirubin-Induced Neurological Dysfunction, or BIND. More severe bilirubin-induced disabilities, including respiratory failure and resulting death, can be referred to as Acute Bilirubin Encephalopathy, or ABE. Bilirubin toxicity can ultimately result in a chronic, severe, and disabling condition called kernicterus. Kernicterus is a cerebral palsy-like condition in which the patient lacks muscle tone and motor control, cannot operate self-sufficiently, and can require long-term care. The National Quality Forum has in the past described kernicterus as a "never event," one which physicians should ensure never occurs in their practice.

Limitations of Current Diagnostic Methods

It has been reported in peer-reviewed publications that the presence of hemolysis in a neonate with jaundice is a predictor of adverse neurodevelopmental outcomes. If neonates with high rates of hemolysis could be identified before they are discharged from the hospital, treatment could begin earlier, exposure to excessive bilirubin would be minimized and readmissions for jaundice would be reduced. Currently, accurate tools for diagnosing hemolysis in neonates are not available in the market. Tests that are commonly done to assess hemolysis such as serial hematocrit levels, reticulocyte counts and peripheral smear, are all invasive blood tests and are less useful in neonates due to physiologic changes resulting from childbirth. Hematocrit levels and reticulocyte counts may be elevated in neonates unrelated to pathological conditions, and confound the diagnosis of hemolysis, which typically involves low hematocrit and high reticulocyte counts. The Coombs test, a blood test that detects antibodies that can cause hemolysis, is used extensively as a measure of hemolysis; however, it often requires a painful heel stick to draw a blood sample, and other conditions besides hemolysis may trigger a false positive or false negative Coombs test. In spite of these limitations, we believe that the Coombs test remains the most frequently used diagnostic for hemolysis by physicians.

Today, the AAP recommends that all neonates be routinely tested for bilirubin levels at some point prior to being discharged from the hospital, although other organizations such as the United States Preventive Services Task Force or USPSTF, have not made similar recommendations. In many hospitals this is done via a blood test, although transcutaneous bilirubin meters are now available to test bilirubin levels non-invasively through the skin. Inaccurate results with use of these devices have been reported based on serum bilirubin level, measurement site, race, and

ethnicity. In addition, bilirubin levels reflect only a point in time rather than the rate of increase, and therefore, may not address the risk of subsequent adverse outcomes. These tests do 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. Since many babies have bilirubin levels in a zone described as intermediate risk by current treatment guidelines, it is difficult for physicians to decide whether to treat aggressively or more conservatively.

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Phototherapy is widely used to treat jaundice, and applied to approximately 8% of all births in the U.S. However, phototherapy treatment disrupts the opportunity for parent-newborn bonding, and is often highly stressful for infants and new parents. In some cases, particularly among low-risk newborns who are jaundiced, but not hemolyzing, phototherapy may not be necessary. In other cases, observation of jaundice and early testing for hemolysis may accelerate diagnosis and treatment with phototherapy. In all cases, understanding the rate of hemolysis is a critical part of providing timely and effective care. There is a significant need for a test to aid in the diagnosis of hemolysis that is rapid, accurate, and easy to use across all acuity levels within neonatal care.

Also, neonates are typically discharged from the hospital at approximately 48 hours of normal birth in the U.S. Hospitals are under pressure to discharge even earlier, in order to reduce costs and manage inpatient capacity. Bilirubin levels, however, typically peak more than 72 hours post birth, as shown in Figure 1 below. We believe that neonates with hemolysis can experience bilirubin levels in the intermediate risk range at time of discharge, but can spike rapidly to neurotoxic levels in the post-discharge period, out of the range expected based on the Bhutani nomogram.

Figure 1: Survey-based Bhutani nomogram of bilirubin levels over time, based on data from 2,840 neonates

Curved lines represent 40th, 75th and 95th percentile levels of bilirubin at specific age in hours

Physicians need to identify the cause of the jaundice and, based upon these findings, determine whether the infant is at serious risk for BIND, ABE, or kernicterus. However, physicians often have a diagnostic dilemma as to what is causing the jaundice. It is often not possible, with current diagnostic techniques and clinical workflow, to test whether it is merely a physiologic jaundice that poses little risk, or some other process that

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presents a serious risk to the neonate. Risk arises primarily from the presence of hemolysis, which leads to hyperbilirubinemia that persists rather than resolving spontaneously. As a result of the serious consequences of hyperbilirubinemia, the AAP recommends that all neonates be closely monitored for jaundice, and has called for physicians to determine the presence or absence of hemolysis in order to make appropriate treatment decisions. As a result, there are both clinical need and physician interest in the development of accurate and non-invasive methods for detecting hemolysis. CoSense addresses this need to measure a baby's exhaled CO to assess the rate of hemolysis accurately, and does so via a non-invasive measurement at the point-of-care. It delivers results within minutes, enabling more timely treatment than the current standard of care.

CoSense: FDA 510(k) Clearance and CE Mark Approval

CoSense, our first Sensalyze Technology Platform product to receive 510(k) clearance from the FDA and CE mark approved, is a monitor of ETCO. CO is a direct byproduct of hemolysis, and based on extensive published data such as that from Stanford University, the rate of bilirubin production can be measured by analyzing the concentration of CO in a neonate's exhaled breath.

CoSense is a point-of-care device that consists of a light-weight, compact monitoring device and a single-use nasal cannula, both shown in Figure 2 below. The cannula is placed just inside the nostril of the neonate and is connected to the monitor. The CoSense device is turned on and acquires the breath signal while the neonate breathes. Appropriate sample acquisition takes an average of 30 seconds. The cannula can then be removed from the baby and the device takes another four minutes to report the test result.

Figure 2: CoSense**CoSense**

Dimensions: 9.7 x 7.8 x 2.7 inches

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The AAP recommends the use of ETCO monitoring for the detection of hemolysis. We believe ETCO monitoring will enable more rapid and appropriate treatment decisions and reduce overall costs of patient care. However, there is currently no device on the market that effectively measures ETCO in neonates.

With CoSense data, physicians may be able to quickly identify neonates with jaundice who are at risk of adverse neurological outcomes or other disability because of hemolysis. The physician can then initiate earlier treatments for jaundice, such as phototherapy, when necessary. As shown in Figure 3 below, we believe the potential impact of CoSense should result in reduced development of hyperbilirubinemia in neonates. In addition, CoSense may also help identify neonates who do not have excessive hemolysis, and therefore may not require phototherapy or serial bilirubin measurements. As a result, these infants may be discharged from the hospital earlier, or with less intensive clinical follow-up. We believe this will reduce the total number of blood draws that are necessary. We also believe this will reduce the rate of readmissions, resulting in significant cost savings for the hospital.

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 is priced at a level that falls below the typical capital equipment purchasing threshold for a hospital or other medical institution in the U.S.

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Figure 3: Guidelines for phototherapy from the AAP based on bilirubin levels (solid lines) at a specified age for infants at low, medium or high risk. The potential trajectory of bilirubin with early intervention based on CoSense testing, as estimated by us, is represented by dashed lines. This suggests that exposure to bilirubin in medium and high risk patients could be substantially reduced by testing with CoSense.

Clinical Trials

Three investigator-sponsored clinical trials have been performed to validate the ability of CoSense to detect the presence of hemolysis. Two of these were performed in neonates. A third trial was performed in children with sickle cell anemia, or SCA, a disease which results in chronic hemolysis.

In a pilot clinical trial at Stanford University, a bench to bedside evaluation of CoSense was undertaken to identify hemolysis in neonates, and to correlate ETCO levels with bilirubin production as defined by levels of carboxyhemoglobin, or COHb, in the blood. When red blood cells are broken down, the pigment heme is released from the red blood cells. In turn, when heme is broken down, CO and biliverdin are produced in equimolar amounts. That is, the same number of moles – a measure of molecule mass – of both CO and biliverdin are produced from the same chemical reaction. Biliverdin is a precursor of bilirubin, and is converted into bilirubin. CO combines with hemoglobin in the blood with high affinity to form carboxyhemoglobin, or COHb. Therefore, the level of COHb provides an accurate measurement of bilirubin production, or hemolysis. CO from COHb is released when the blood circulates through the lungs and as a result, levels of ETCO correlates to levels of COHb, bilirubin production and hemolysis. For accurate measurements of low levels of CO, gas chromatography is the method of choice.

In bench studies, inter-device accuracy and intra-device imprecision were evaluated in three different CoSense devices. In the clinical setting, 73 neonates who all had a gestational age, or GA, more than 30 weeks were tested. ETCO measurements, in triplicate, were compared to COHb levels measured by gas chromatography in the subset of 20 of the 73 neonates who consented to testing for COHb and were suspected of having hemolysis. Gas chromatography is a technique better suited to the laboratory than to high-volume clinical use, particularly in the point-of-care neonatal diagnostic setting. It requires a large, complicated chromatography instrument and highly trained staff.

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In the bench studies, overall mean inter-device accuracy was high ($98.3\pm 3\%$ (range 93.2–99.4%) and $98.7\pm 2.1\%$ (range 93.3–101.2%) at 2.4 and 5.1 ppm, respectively. Mean intra-device imprecision was low (3.3% (range 2.8–3.7%) and 2.5% (range 1.9–2.6%) at 2.4 and 5.1 ppm, respectively), indicating that CoSense provides consistent results across multiple devices as well as repeatedly within a device. Figure 4 represents the distribution of 102 ETCO measurements from 73 neonates. We believe that values over the 50th percentile (or 1.5 ppm) represent a risk for hemolysis, and the risk increases with values at the higher percentile levels. Figure 5 shows the relationship between ETCO measurements from CoSense and COHb levels measured via gas chromatography (23 samples from 20 patients). A close correlation between the two is seen ($r^2 = 0.97$), confirming that ETCO values with CoSense accurately measure bilirubin production and therefore hemolysis.

Figure 4: *Distribution of ETCO Values.* A total of 102 ETCOc measurements were collected from 73 newborns. We believe that infants with ETCO values above the 50th percentile are at risk for hemolysis, with the risk increasing at higher percentiles.

Figure 5: *Correlation of ETCO as measured via CoSense with COHb measured via gas chromatography.* The correlation coefficient is 0.97.

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The ability of CoSense to identify hemolysis in neonates with significant hyperbilirubinemia was evaluated at The Children's Hospital of Zhejiang University School of Medicine in Hangzhou, China. Significant hyperbilirubinemia was defined as total serum bilirubin, TSB, levels that require phototherapy according to AAP guidelines. Investigators compared ETCO, as measured with CoSense, with current blood tests for hemolysis, such as hematocrit, or Hct, which measures the number of red blood cells, reticulocyte count, or Retic, which measures new red cell production levels, serum bilirubin test, and the Coombs Test. While these tests are often performed to detect hemolysis in neonates, they are not considered to be reliable in the neonatal setting. The information that is gained from a combination of all these tests is therefore used to inform a determination of the presence or absence of hemolysis. Certain tests may be better than others for a given type of hemolysis, whereas ETCO levels are elevated due to hemolysis regardless of the cause.

Fifty-six neonates with significant hyperbilirubinemia participated in this non-randomized open-label trial.

The groups with positive and negative Coombs test were well-matched for GA and birth weight. Mean results are shown in Figure 6 below. The group with positive Coombs had lower hematocrit and higher reticulocyte counts, supporting the presence of hemolysis. Total serum bilirubin was similar across the two groups, suggesting that bilirubin by itself is not a specific marker for hemolysis. ETCO levels were statistically significantly higher in the positive Coombs group. These data show that ETCO measurement with CoSense can provide the physician with similar information to that currently provided by invasive blood tests regarding the patient's hemolytic status, but with a simple, non-invasive breath test.

Figure 6: The Children's Hospital of Zhejiang University School of Medicine Clinical Trial Results

Patients (N = 56)	Positive Coombs	Negative Coombs	P value
Hematocrit (%)	47.1 ± 8.4	57.3 ± 9.8	0.348
Reticulocyte Count (%)	5.6 ± 3.9	2.8 ± 1.3	< 0.01
Total Serum Bilirubin (umol/L)	320.3 ± 88.8	329.4 ± 83.8	0.969
ETCOc (ppm) via CoSense	2.8 ± 2.1	1.7 ± 1.0	0.028

In a third clinical trial, ETCO concentration was measured in children with SCA, who are known to have chronic hemolysis, using CoSense at Children's Hospital & Research Center in Oakland, California. Children between five and fourteen years old with SCA, who were not on regular transfusions, were eligible to participate in the trial. Children with exposure to second-hand smoke, acute respiratory infection or symptomatic asthma were excluded. Healthy children between five and fourteen years old served as matched controls. Up to three measurements were taken for each subject using CoSense, and the highest ETCO value was used. One control subject had a high ETCO value and was excluded from the analysis since he was found to have asthma and was on anti-epileptic medication.

The mean ages of 16 children with SCA and 17 healthy children controls were 9.7 years and 9.9 years, respectively. The mean ± standard deviation ETCO for SCA was 4.85 ± 2.24 ppm versus 0.96 ± 0.54 ppm for controls (p<0.001).

The mean ETCO in the children with SCA was five-fold higher than the control group, with little overlap seen between the groups. ETCO levels were measured during tidal breathing in the tested children using CoSense. The data shows that CoSense may be useful to monitor the rate of hemolysis in children with SCA.

Table of Contents**Index to Financial Statements****Figure 7: Significantly higher ETCO in sickle cell patients compared with normals**

Highest ETCOc Value for Each Subject		
Patients	Sickle Cell	Control
(N=33)	(N=16)	(N=17)
Mean	4.85	0.96
Standard Deviation	2.24	0.54
p < 0.001		

Market Opportunity

Independent market research that we conducted has identified a large market opportunity for the CoSense device in the well-baby nursery and labor and delivery units in term neonates (less than 37 weeks), as well as in the neonatal intensive care unit, or NICU, in preterm births (less than 34 weeks) and late preterm births (between 34 and 37 weeks).

In the U.S. and E.U., there are approximately 8.1 million term births and 1.1 million preterm and late preterm births each year. Approximately 60% of term births, or approximately 4.9 million births, and 80% of preterm and late preterm births, or approximately 900,000 births, are jaundiced and are at greatest risk for adverse outcomes. We believe that these neonates are at risk for hemolysis and are candidates to receive one or more CoSense tests during their hospital stay if our product was available for commercial sale.

Today, the presence of jaundice triggers either a transcutaneous or serum bilirubin test. With the availability of CoSense, physicians may complement bilirubin testing with hemolysis testing in order to perform a more complete clinical assessment. Neonates who are jaundiced but not hemolyzing may receive conservative management or phototherapy. Neonates with jaundice found to be hemolyzing will likely receive early phototherapy and also additional testing such as the Coombs test, Hct or Retic to diagnose the underlying cause of hemolysis. We believe that CoSense will allow physicians to reduce the number of neonates that receive these more invasive and more costly tests for hemolysis.

Sales and Marketing

We intend to market CoSense for evaluating neonates for the presence, or the rate, of hemolysis. In the U.S., we will sell via a direct sales force, with potential augmentation of our reach via distributors. In the E.U., we expect to partner

with distributors in each country, with oversight and marketing assistance from our personnel that we intend to base in the E.U.

Our U.S. direct sales efforts will initially focus on large hospital systems with high volumes of births. Approximately 100 centers in the U.S. are responsible for over 5,000 births per center per annum, and collectively make up approximately 16% of all births in the U.S., according to public information from Billian's HealthDATA. A second tier of approximately 300 hospitals, those with approximately 2,500 or more births per year, accounts for an additional one million births, approximately 25% of the U.S. total. With a field sales force of 12-16 representatives, deployed primarily in large metropolitan areas, including the New York Tri-State area,

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Los Angeles, Chicago and Atlanta, we believe we will have the sales force capacity to develop appropriate relationships with various stakeholders at these centers.

We expect the majority of our revenues to be sales of consumables. Because customers will order these repeatedly once they have adopted CoSense as part of their standard procedures, we expect that our sales force can drive higher revenue per salesperson than might otherwise be the case.

Dr. Robert Christensen, the Director of Neonatal Research at Intermountain Healthcare, and Director of the Intermountain Healthcare Clinical Neonatology Program for the Northern region, has signed a letter of intent, or LOI, with us, on behalf of Intermountain Healthcare System, or IHS to purchase CoSense devices. IHS has used CoSense as part of various ongoing and completed clinical trials. In conjunction with Dr. Christensen, we have conducted a usage analysis to forecast the potential volume of CoSense use within the IHS.

IHS consists of 21 hospitals, of which 18 have labor and delivery services. IHS has approximately 30,000 total births annually, of which approximately 20,000 are in the largest eight hospitals. Per IHS letter of intent with us, pending appropriate approvals within the hospital system, IHS intends to purchase 16 CoSense devices, with two to be deployed in each of these eight largest hospitals initially. We believe roll-out of CoSense to the smaller hospitals within IHS could then happen over time.

The IHS has indicated they will use CoSense to inform treatment decisions for infants whose serum bilirubin levels are at or above the 75th percentile, which includes 25% of the births at these centers. The premise of this case study provides that half of those tested with CoSense will require a second CoSense test (average of 1.5 tests per infant). We therefore estimate that approximately 7,500 tests would be performed annually at the initial-adopter hospitals within this system, with usage rising to approximately 11,250 tests annually if CoSense devices are deployed across the entire IHS system.

In addition, Dr. David Stevenson, the Director of Pregnancy and Newborn Services for the Lucille Packard Children's Hospital at Stanford University, or LPCH-Stanford, has signed an LOI with us on behalf of LPCH-Stanford. This LOI indicates intent, subject to institutional approvals, to purchase six CoSense devices for placement at the Lucille Packard Children's Hospital and four other joint venture neonatology centers operated by LPCH-Stanford. LPCH-Stanford faculty have used the CoSense device in the context of clinical trials.

LPCH-Stanford and its joint venture centers together host approximately 11,500 births per year. Dr. Stevenson has indicated that they intend for all babies with a bilirubin level in the 40th percentile or higher to be tested with CoSense, equating to 60% of the babies delivered in the LPCH-Stanford system and approximately 6,900 newborns/year. Again assuming an average of 1.5 tests per infant, potential usage of CoSense in this system is over 10,000 CoSense tests i.e. consumables per year.

In addition to the aforementioned, key elements of our sales and marketing strategy include:

Subsequent efforts will focus on growing the volume of tests performed and associated consumables used. We plan to focus specifically on sales to the NICU, well-baby nursery, and labor/delivery units within each hospital. Because CoSense is a point-of-care device, each of these units of the hospital is a separate opportunity for CoSense placement.

Establish and engage a network of distributors in the E.U. We may establish continuing operations at a location in the E.U. to ensure close coordination and effective execution of the CoSense sales and marketing plan in the E.U.

Price the CoSense device at a list price of \$4,995, a level that allows hospitals to purchase it without protracted review via a capital purchase committee or analogous body. We believe that the cost of goods of CoSense devices allows us flexibility in setting this price, and we also believe we can

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offer customer hospitals attractive financing options to smooth out costs associated with the device purchase.

Price the CoSense consumable cannula at a list price of \$50-100, a price that is competitive with the current costs of performing the Coombs Test and other associated invasive assays. We believe that this cost offset, complemented by potential improvements in readmission rates and clinical outcomes, will provide hospital decision-makers with a compelling economic case for adoption of CoSense.

Build awareness of the AAP treatment guidelines, and of the benefits of CoSense, via medical education efforts to key clinical audiences, including neonatologists, pediatricians, obstetricians, and pediatric nurses.

Collaborate with key specialty societies, including the Pediatric Academic Societies, American Academy of Family Physicians, or AAFP, and patient advocacy groups such as Parents of Infants and Children with Kernicterus, to ensure ongoing support for ETCO testing in clinical guidelines and to identify opportunities for expanding awareness of ETCO among their respective constituencies.

Support clinical trials and publications that expand the base of evidence supporting broad adoption and use of CoSense. We expect these efforts will build support for the clinical benefits to patients as well as economic benefits to various stakeholders in the healthcare system.

We expect that we will expand our direct sales efforts to encompass lower-volume birthing centers in the U.S., once a sufficient proportion of the larger hospitals have begun to use CoSense. We may also selectively initiate direct sales to certain countries in the E.U. Furthermore, we see potential to use CoSense to make more rapid assessments of jaundiced babies in the outpatient pediatric setting, where new parents are frequently directed for followup care after hospital discharge. We will continue to evaluate expansion opportunities and pursue those where the potential to accelerate our business is deemed sufficient for the investment we put at risk.

Figure 8: Intended deployment of field sales personnel by hospital tier

SOURCE: Billian s HealthData 2013 and Capnia analysis

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We expect to sell the CoSense device at a price below the typical capital expenditure approval threshold levels of most hospitals and other medical institutions in the U.S. The decision to buy, therefore, would likely be driven at the departmental rather than at the institutional level. The primary decision makers are expected to be the neonatologists and nurse managers in the pediatrics and neonatology departments. Our initial efforts will be to expand the installed base of devices, and will be followed by efforts to increase use of the disposable cannula. The business model anticipates a significant proportion of the revenues coming from the disposable sales, even more so in later years as the number of total CoSense devices in use in the field increases. With manufacturing scale up, we expect to drive our cost of goods below fifty percent for devices and below ten percent for disposables. We believe this will lead to scaleable future growth.

Since the use of CoSense is almost entirely in the inpatient setting around the time of birth, reimbursement would be in the form of a Diagnosis-Related Group, or DRG. Frequently referred to as a bundled payment, the DRG is a specific flat-fee payment amount for all services performed by a medical institution pursuant to a single diagnosis. We can, therefore, be reimbursed for the cost of a test directly from an institution without the need to approach payors such as insurance companies, or to obtain a separate reimbursement cost code. Hospital decisions to adopt new technologies for inpatient care are usually driven by improved outcomes and reduced costs of patient care. We expect that the use of CoSense will both improve outcomes related to hyperbilirubinemia and reduce the need for certain diagnostic tests in a subset of neonates with jaundice, which, as a result, will reduce overall testing costs. We also believe that positive identification of infants with hemolysis will lead to a reduced rate of readmissions for jaundice, and this array of benefits may support adoption of CoSense by clinicians and their institutions. We also plan to undertake a comprehensive effort to partner with key physician specialty societies, physician opinion leaders and patient advocacy groups to educate and inform payer stakeholders. The AAP guidelines recommend ETCO detection to confirm the presence of hemolysis in neonates requiring phototherapy, neonates unresponsive to phototherapy or readmitted for phototherapy, and neonates with bilirubin levels approaching transfusion levels. In general, payer policies related to the care of neonates with jaundice reflect third-party treatment guidelines, and in this case the AAP guidelines favor use of ETCO testing, which CoSense is able to perform.

Clinical Advisors

We have a number of clinical advisors to our company, made up of key opinion leaders in the field of neonatology. The principal clinical advisors that we use are the following individuals:

Vinod (Vinny) K. Bhutani, M.D. Dr. Bhutani, a pro bono advisor, is a Professor of Pediatrics at the Stanford University School of Medicine's Division of Neonatal and Developmental Medicine and is also a Faculty member in the Stanford-India Biodesign Program. He serves as an elected member of the American Academy of Pediatrics Executive Committee, Section on Perinatal Pediatrics, and is an appointed member to the AAP Committee of Fetus and Newborn and the Subcommittee on Hyperbilirubinemia. An elected member of the American Pediatrics Society, Dr. Bhutani Co-Chairs the Audrey K. Brown Kernicterus Symposium and coordinates the Bilirubin Club at the Pediatric Academic Society annual meetings. He serves on the Board of California Association of Neonatologists and chairs the California Committee of Fetus and Newborn. Through the Program for Global Paediatric Research, Dr. Bhutani launched the Global Prevention of Kernicterus Network, serving as its Medical Director. His global health-societal research and community service interests include prevention of jaundice-related newborn brain damage and ventilation-induced respiratory injury through systems-approach, biotechnologies, biodesign of affordable medical devices, and chemoprevention, as well as development, of affordable, sustainable, high quality strategies and

policies to reduce infant mortality and morbidities.

David K. Stevenson, M.D. Dr. Stevenson, a pro bono advisor, is the Harold K. Faber Professor of Pediatrics, Director of the Charles B. and Ann L. Johnson Center for Pregnancy and Newborn Services, and the

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Former Vice Dean and Senior Associate Dean for Academic Affairs at Stanford University School of Medicine. He serves as Director of an NIH-Funded Training Program in Developmental and Neonatal Biology, Co-Director of Stanford's CTSA (Spectrum) and Leader of Child Health (Spectrum Child Health), and Principal Investigator of the March of Dimes Center for Prematurity Research, a transdisciplinary research effort with the objective of reducing the preterm birth rate. Dr. Stevenson was the recipient of the Virginia Apgar Award, the highest award in Perinatal Pediatrics in 2006. He served as President of the American Pediatric Society for 2005-06. More recently, he received the Maureen Andrew Mentor Award from the Society of Pediatric Research, and the Jonas Salk Award for Leadership in Prematurity Prevention from the March of Dimes Foundation. Dr. Stevenson was elected to the Institute of Medicine of the National Academy of Sciences.

Robert D. Christensen, M.D. Dr. Christensen, a pro bono advisor, is the Director of Neonatal Research at Intermountain Healthcare and Director of the Intermountain Healthcare Clinical Neonatology Program for the northern region where the majority of his research work is focused on observational and interventional clinical studies of neonatal clinical hematology and transfusion medicine. He has authored over 300 publications. Dr. Christensen held positions including Professor of Pediatrics at the University of Utah School of Medicine, the University of Florida College of Medicine, and the University of South Florida College of Medicine, and was Physician-in-Chief at All Children's Hospital in St. Petersburg, Florida. He has been a member of the NIH National Heart, Lung and Blood Institute, NIH National Institute of Child Health and Human Development, and National Foundation March of Dimes, was on the executive committee of Thrasher Research Fund, and was sub-committee chair of the American Academy of Pediatrics.

These clinical advisors are not subject to contractual relationships with us, but generally make themselves available to us for various clinical, scientific and other needs on an ad-hoc basis.

Competition for CoSense

Currently CoSense is the only device commercially available with the sensitivity and accuracy necessary to detect ETCO levels that are meaningful for monitoring the rate of hemolysis in neonates, and we do not know of any such device that is under development by any party. From 2001 to 2004, Natus Medical marketed the Co-Stat device for detection of ETCO in neonates. The Natus product was withdrawn from the market due to poor sales. We believe Natus' Co-Stat did not achieve commercial success due to several disadvantages that we have overcome with our product, including a lack of consistent accuracy, limited ability to compensate for environmental factors such as humidity and heat, high price, and poor ease of use, including a requirement for frequent calibration.

In addition, devices are commercially available to measure CO poisoning from external sources, but these are less-sensitive devices that are not appropriate for detecting ETCO in the low concentrations (less than 10 ppm), small volumes and high breath rates that are clinically relevant in neonates. CoSense has the ability to overcome these problems using our Sensalyze technology. Several companies and academic groups have capabilities sufficient to develop such devices, and these parties may have significant resources to devote to research, development, and commercialization of devices that may compete with CoSense as well as technologies that compete with our Sensalyze Technology Platform generally. Competition within our target market will depend on several factors, including:

quality and strength of clinical and analytical validation data;

confidence of health care providers in diagnostic results;

reimbursement and payment factors;

inclusion in practice guidelines;

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cost-effectiveness;

ease of use; and

the strength of our intellectual property

Today, physicians primarily diagnose hemolysis via Coombs and other blood tests, and these will represent the primary competition to CoSense initially. These tests do 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. We believe that we can demonstrate compelling advantages over such tests, including faster results, the ability to avoid painful blood draws and greater diagnostic clarity and accuracy. We also believe we will be able to demonstrate economic and workflow advantages over the existing diagnostic practice.

Our Sensalyze Technology Platform

A variety of medical diagnostic testing is performed via measurement of gas concentrations, either from blood samples or from exhaled breath. Examples include capnometry and pulse oximetry, both routinely used in patient monitoring. Devices used for detecting the presence of various analytes in exhaled breath typically rely on the patient performing a specified breath maneuver. Examples of such maneuvers include breath holding, forced expiration, or breathing at a specified rate. The use of these devices is limited to those who can perform such maneuvers, such as adults and older children.

The limitations of existing breath-based technologies are particularly problematic in neonates. Neonates typically have very rapid and irregular breathing patterns as shown in Figure 9 below. They also inhale and exhale relatively small volumes, which limits the accuracy of devices that require the larger-volume sample sizes exhaled by older patients. In addition, they are not able to perform specified breath maneuvers. Our Sensalyze Technology Platform allows the measurement of analytes in all patients, from neonates to adults, regardless of their ability to actively perform a breath maneuver.

Figure 9: Breath Patterns in Newborns

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. Our platform can identify physiologic breaths even if the patient is breathing very rapidly, a capability that is particularly relevant in infants.

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

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

When combined, these capabilities provide a novel platform for non-invasive detection of various analytes.

Sensalyze Technology Platform - Research and Development of Additional Diagnostic Products

The commercialization of CoSense will be our primary focus with the use of proceeds from this offering. Once the CoSense business is generating adequate revenue, we intend to utilize our research and development expertise to develop other diagnostic devices that leverage the capabilities of our Sensalyze Technology Platform. We expect to introduce additional products of our own over time and intend to develop additional diagnostic tests for analytes that might be found in the exhaled breath. These include the following diagnostic opportunities:

nitric oxide (NO) for assessment and management of asthma in children younger than seven years of age;

end-tidal CO₂ for neonates; and

hydrogen breath testing for infants with colic.

We may also license elements of our Sensalyze Technology Platform to other companies that have complementary development or commercial capabilities.

Nitric Oxide for Assessment and Management of Asthma in Children Younger than Seven Years of Age

Asthma is a highly prevalent pediatric disease, occurring in 9% of children in the U.S. There are an estimated five million children under the age of seven with asthma in the U.S. and the E.U. Diagnosis and management of asthma in children under seven years of age is clinically challenging. The use of NO to assess and manage asthma in older children and adults at the point-of-care has been well established in the clinical literature and in clinical practice, and is recommended by the American Thoracic Society. However, the use of current diagnostic technologies, such as the NIOX MINO marketed by Aerocrine AB, requires the patient to follow specific instructions, including controlled exhalation in a specific manner, in order to collect a valid breath sample. These instructions are typically too complex for children under the age of seven. As a result, there are no reliable point-of-care tests for the assessment and management of asthma in infants and children under the age of seven. The lack of a diagnostic and management tool may contribute to delayed diagnosis or inappropriate treatment of these younger patients.

We believe we can develop an additional diagnostic using our Sensalyze Technology Platform for assessing and managing children with asthma under the age of seven with NO. Our Sensalyze Technology Platform is uniquely suited to address the need of pediatricians and pediatric pulmonologists. Our proprietary sampling technology can capture a breath sample during a child's natural breathing cycle and as a result, no controlled exhalation is required, which enables use in younger children.

End-Tidal Carbon Dioxide for Neonates

End-tidal CO₂, or ETCO₂, monitoring is often necessary for neonates in the NICU, in order to ensure adequate ventilation. The measurement of arterial CO₂ tension, PaCO₂, is the current standard of care for

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evaluating the adequacy of oxygenation. However, due to the risks of arterial blood sampling, including the requirement for central or peripheral arterial catheters, increased risk of infection, and blood loss requiring transfusion, there is an unmet need for alternative methods of monitoring CO₂ in the blood. Monitoring neonates using ETCO₂ may be beneficial because it is non-invasive, portable, and provides a rapid assessment of the trend in CO₂. ETCO₂ is used in estimating PaCO₂ in adult and pediatric intensive care settings; however, the devices available for neonatal use lack accuracy.

We believe our Sensalyze Technology Platform can be used to facilitate more precise ETCO₂ monitoring in neonates. Of the nine million babies born in the U.S. and the E.U. each year, 12% may be admitted to the NICU. We expect that neonatologists and NICU nurses would perform ETCO₂ testing on neonates in the NICU frequently in order to track CO₂ levels.

Hydrogen Breath Testing for Infants with Colic

Each year, up to 2.5 million infants in the U.S. and the E.U. are diagnosed with colic, a non-specific condition that is often blamed on gastrointestinal intestinal, or GI, distress. Parents of infants with colic must often support extensive dietary modifications, including trials of different types of baby formula, in order to reduce the colic. Despite these efforts, the source of the colic often remains unknown and may not even be GI related. Identifying malabsorption as a cause of the colic, or ruling out malabsorption, may help clinicians better diagnose and treat these patients. Although hydrogen breath testing is frequently used to identify patients with dietary intolerances or bacterial overgrowth in the GI tract, it is not routinely used to identify malabsorption in infants with colic. Similar to NO breath testing, most devices currently available for hydrogen breath testing require a forced exhalation and are not appropriate for an infant patient population.

We believe our Sensalyze Technology Platform can be leveraged for hydrogen breath testing in infants. This would most likely be performed in the outpatient clinic setting, where pediatricians and pediatric gastroenterologists are the key institutional decision makers. Our proprietary sampling technology can capture a breath sample during an infant's natural breathing cycle, again with no forced exhalation required, a significant innovation which enables its use in with infants.

Serenz***Allergic Rhinitis***

Allergic rhinitis, which is commonly and colloquially referred to as allergies, is characterized by symptoms are often episodic and include nasal congestion, itching, sneezing and runny nose. It is one of the most common ailments in the western world and is growing rapidly, making AR one of the largest potential pharmaceutical markets. There are approximately 39 million sufferers in the U.S. and 48 million in France, Germany, Italy, Spain and the United Kingdom, and an additional 36 million in Japan, according to research firm GlobalData. Prevalence of AR is growing rapidly in the developed world. The most common AR drug therapies include antihistamines, and intranasal steroids. Leukotriene inhibitors and other drugs are also currently prescribed to AR patients. Several of these drugs have generated sales in excess of \$1 billion per year as branded products. However, these products have significant limitations and AR sufferers remain dissatisfied with the available treatments. Thus, there is a need for a more effective treatment with a faster onset of action and improved safety profile.

AR is a cause of significant morbidity in spite of available treatments. According to the Allergies In America Survey conducted in 2006, most AR sufferers reported themselves to be less than very satisfied with the products they were taking for allergy relief. Fifty-two percent reported they had suffered from impaired work performance or missed work due to their AR symptoms even though 69% had used medication at some point in the prior four weeks. Current treatments provide incomplete relief from symptoms, and have significant side effects such as drowsiness.

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Serenz Technology

Our Serenz technology is based upon the observation that non-inhaled CO₂ delivered at a low-flow rate into the nasal cavity, alleviates the symptoms of AR. Serenz is a convenient, hand-held device that delivers low-flow CO₂ to the nasal mucosa. It contains a pressurized canister of gas, with approximately enough gas to dose as-needed for one to two weeks. The device is disposable and engineered for ease of use. Our proprietary technology ensures very precise control of aspects such as flow rate and volume, which we believe are both critical to achieve the desired clinical performance.

In our clinical trials to date, Serenz has shown a large effect size, an onset of effect within 30 minutes 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.

Figure 10: Serenz Device

Serenz

Dimensions: 4-7/8 x 1-3/8 inches

One Serenz device, as shown in Figure 10, contains enough gas for approximately 22 doses, which we believe will treat AR for an average of one to two weeks, depending on frequency of use. We have not determined pricing for Serenz, but expect to price it at a premium to existing over-the-counter therapies for AR due to the benefits we believe the product provides to patients over such therapies.

Based on clinical trials to date, we believe Serenz exhibits the ideal characteristics of an AR therapeutic, including:

Rapid relief

Locally acting

Relief from all nasal symptoms

Non-sedating

Mild side effect profile

Non-steroidal

No long-lasting side effects

Usable on an as-needed basis

The As-Needed Only Treatment Paradigm

The traditional therapeutics used for the symptomatic treatment of AR have left a significant unmet need in this population. These therapeutics, mostly antihistamines and nasal steroids, are typically used on a scheduled basis, for example daily or twice a day. This is counter-intuitive given that the symptoms of AR are typically episodic, such as when a subject is exposed to a pollen when they step outdoors in allergy season. The reason for chronic treatment of this episodic disorder is that the available treatments for AR take too long to act. Even when used as-needed, these products are unlikely to have a meaningful effect on efficacy in a very short time frame.

Antihistamines typically take one or more hours to have an effect. Their efficacy may decrease further over time for patients and as exposure to allergens continues, whether seasonal or perennial. In addition, antihistamines in general do not have any effect on congestion.

Nasal steroids can take days before peak effect. While they are more efficacious than antihistamines, they must be taken regularly during the allergy season or indefinitely for perennial allergies. In addition, they have bothersome side effects and are associated with the perception issues that relate to steroid use in general.

We believe that a treatment that can act rapidly such that it can be taken only when needed is ideal for the AR patient population. In addition, it should not have any lasting or significant side effects. Serenz has the characteristics of such a treatment.

Table of Contents**Index to Financial Statements*****Clinical Trials of Serenz in Allergic Rhinitis***

We have conducted six randomized, controlled clinical trials involving 975 patients, testing the safety and efficacy of nasal CO₂ in treating the symptoms of AR. Four of these clinical trials were in patients with seasonal AR, or SAR, and two of these clinical trials was in patients with perennial AR, or PAR. In addition, GSK conducted a trial in 147 patients to assess the consumer appeal of Serenz for patients with nasal congestion. The trials using the as-needed approach showed statistically significant and clinically meaningful effects in both SAR and PAR. The effect is seen on each of the individual nasal and non-nasal symptoms, with as little as a 10 second per nostril application of Serenz. Given the rapid onset and generally mild side effect profile, we believe Serenz is ideally suited for marketing to patients for use on an as-needed basis. Effectiveness of treatments for AR is typically assessed in trials by measuring change in TNSS from before to after treatment. Each nasal symptom (congestion, runny nose, itchy nose and sneezing) is assigned a value of 0 to 5 (such as in SAR-2005) or 0 to 3 (such as in C216). Lower values denote less severe symptoms. The TNSS is then calculated by adding values for each of the four symptoms. Therefore, the worst TNSS corresponding to the worst symptoms could be 12 or 20.

Figure 11: Serenz Allergic Rhinitis Clinical Trial Summary

Trial	N=	Dosing
SAR-2005	89	As Needed Single dose: 60s @ 10 ml/s
C211 (PAR-2006)	348	As Needed Single dose: 10s or 30s @ 5 or 10 ml/s
C213	20	Dose A: 5s / nostril @ 0.5 SLPM Dose B: 10s / nostril @ 0.5 SLPM Dose C: 30s / nostril @ 0.5 SLPM Dose D: 30s / nostril @ 0 SLPM, no gas 14 day Tx BID
C215	453	10s @ 0.5 SLPM
C216	32	As-Needed 14 day Tx PRN 10s @ 0.5 SLPM 14 day Tx QID
C218	33	10s @ 0.5 SLPM 7 day Tx:
RH01910	147	d1 single-dose + d2-7 as-needed up to QID

Clinical Trials of Serenz Using As-Needed Dosing

The as-needed use of Serenz is supported by single as well as multiple dose studies.

The first single dose study was conducted by us in 2005 (SAR-2005). It was a randomized, placebo-controlled clinical trial in patients with SAR. Symptomatic patients were treated with a single one-time application of active nasal CO₂ or placebo dose for 60 seconds per nostril. Symptoms were measured just before and at several time points after the treatment. Statistically significant improvements in symptoms were noted as early as 10 minutes and lasting for as long as 24 hours following treatment. Figure 12 shows the mean change from baseline in TNSS as well as individual nasal symptoms at 30 minutes, which was the pre-specified primary endpoint (p=0.0002).

Table of Contents**Index to Financial Statements****Figure 12: SAR 2005 Change in TNSS and Individual Symptoms from Baseline at 30 minutes**

Our second study in AR was a randomized, placebo-controlled clinical trial in patients with PAR called C211 (PAR-2006), conducted in 2006. Symptomatic patients were treated with a single application of active nasal CO₂ or placebo dose. Patients were assigned to one of six treatment groups in order to determine the optimal dose for future studies based on duration and flow rate. Symptoms were measured just before and at several time points after the treatment. Statistically significant improvements in symptoms ($p < 0.05$) were noted at 30 minutes in the CO₂ at 10 mL per second for 10 seconds per nostril cohort. This improvement was sustained for between four to six hours of relief of AR symptoms in this cohort, supporting the efficacy of nasal CO₂ in symptomatic patients with PAR and confirming the dose of 10 seconds per nostril as appropriate for future clinical trials.

In 2009, we completed C216, our first multi-application, randomized, placebo-controlled trial in which the nasal CO₂ device was used as needed in patients with SAR. Patients applied active or placebo 10 seconds per nostril, only as needed, up to a maximum of six times per day for 14 days. Symptoms were measured just before, and again at 30 minutes after, each treatment during the 14-day treatment period. Statistically significant improvements ($p < 0.0001$) in symptoms were noted at 30 minutes after treatment during the 14-day treatment period (Figure 13). The magnitude of the treatment effect became larger (from -0.51 to -1.61) as the severity of baseline symptoms increased, which was denoted by higher pre-use TNSS (greater than or equal to 10). These results show that the nasal CO₂ device is effective for the as-needed treatment of SAR symptoms. The treatment effectiveness was rapid (within 30 minutes), the effect on symptoms was clinically meaningful, and highly statistically significant ($p < 0.0001$).

Table of Contents**Index to Financial Statements****Figure 13: C216 Change from Pre-Use TNSS at 30 Minutes****(individual symptoms scored 0 (none) to 3 (severe), maximum worst TNSS 12)**

Study RH01910 was a multi-center, open-label, two-part study conducted by GSK, and completed in 2014, with the primary objective of estimating the consumer appeal of Serenz in subjects with nasal congestion. 147 subjects were enrolled into Part 1 of the study and administered a single dose of nasal CO₂ in the clinic. At the end of Part 1, subjects were given the option to continue in the study in which they could take a Serenz device home for an additional six days of use. 143 subjects (100% of subjects who completed Part 1) chose to continue into Part 2 of the study, took a Serenz device home to treat their nasal congestion as needed but no more than four times per day.

The primary analysis in this study was performed on the Per Protocol (PP) Population (N=133). The subjects, n=10, not included in the PP population were due to incomplete diaries, use for more days than specified and faulty devices. After initial product use in clinic, 90% of subjects thought that Serenz was as good or better than they expected and 59% would probably or definitely buy the product. After in-home use for six additional days, the proportion that would probably or definitely buy it remained unchanged. 46% would buy Serenz every two weeks or more frequently and 32% would like to buy the product more than once a week. Twelve percent (12%) or less disagreed with the statement that the product helped relieve congestion through all seven days of treatment. 75% of subjects stated that the Serenz worked as well or better than their usual product for treating congestion, with over 30% stating that it was much better than their usual product. Serenz was well-tolerated with adverse events consistent with previous studies and no serious adverse events.

These data show that Serenz has an attractive profile for the treatment of congestion sufferers.

Clinical Trials of Serenz Using Other Dosing Methods

One trial in PAR patients was designed to quantify an effect on nasal congestion with an acoustic rhinometer but the data was not evaluable due to malfunctioning of the rhinometer. Other clinical trials that have been conducted with nasal CO₂ for AR have evaluated the more traditional paradigm of scheduled dosing. Efficacy measurements in these clinical trials, based on a guidance document published by the FDA, are recorded in the morning and evening, regardless of the time of the treatment or pre-treatment symptoms. These measurements reflect the overall symptomatic relief during the day and do not measure the specific effect of a treatment on an episode of symptoms. Two of these clinical trials evaluated scheduled dosing – one was twice a day and the other four times a day in patients with SAR.

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In 2008, we completed our first multi-application, randomized, placebo-controlled clinical trial in patients with SAR, called C215. Approximately 450 patients were randomized in the trial and treated with active or placebo 10 seconds per nostril two times a day for 14 days. There were no statistically significant improvements in TNSS, during the 14-day treatment period with scheduled dosing ($p>0.05$).

In 2009, we completed a multi-application, randomized, placebo-controlled clinical trial called C218 in which the nasal CO₂ device was used four times a day in patients with SAR for 14 days, regardless of symptoms at the time of administration. There were no statistically significant improvements in TNSS during the 14-day treatment period ($p>0.05$).

Measurement of TNSS in this scheduled dosing paradigm, or reflective and instantaneous TNSS, show the efficacy to be predictably lacking since these measurements reflect the overall symptomatic relief during the day, and do not measure the specific effect of a treatment on an episode of symptoms.

Safety of Serenz

There were no application-related or device-related serious adverse events in any of the clinical trials conducted. Adverse events were generally mild and application-related, and resolved immediately upon cessation of application. The most common adverse events were transient nasal sensation and tearing of the eyes, or lacrimation, that lasted for the duration of the application only.

The nasal sensation commonly encountered during these clinical trials was described by patients differently, and ranges from tingling to burning to pain. We also observed that these sensations were generally not severe enough for patients to discontinue use of nasal CO₂, and for more than 1,000 patients treated in all of the AR clinical trials, only six patients discontinued use of nasal CO₂ due to an adverse event. We believe that these clinical trials provide evidence that gentle cleansing of the nasal mucosa with Serenz is safe, acts locally and provides rapid relief of allergy symptoms.

Serenz Regulatory Status

A CE Mark was granted to us for marketing of Serenz in the E.U. in December 2011. Following out-licensing of Serenz to GSK in 2013, we withdrew our CE mark, since CE marks are site-specific and not transferable. In June 2014, the agreement terminated and the licensed rights to Serenz was returned to us. We believe a partner could file the documentation to reinstate our CE Mark without any additional clinical data.

The approval route for Serenz in the U.S. may be through a device approval or a drug-device combination approval. In the case of a drug-device combination, a new drug application, or NDA, filing with the FDA will be required. If it is a device approval pathway, it may be either via the PMA process, a *de novo* 510(k) pathway, or traditional 510(k). Additional randomized, controlled clinical trials may be necessary to obtain approval.

We expect to clarify the pathway for approval in dialogue with the FDA. If pivotal clinical trials are required by the FDA particularly in the case of an NDA or a PMA filing, we currently believe that each of these trials will be 400 to 600 patients in size, and take approximately a year to complete once started. We may partner the program in advance of such clinical trials, if we can do so on terms that maximize the value of the program, and as a result, we may not conduct these clinical trials but instead rely on collaboration partners.

Our Partnership for Serenz

In 2013 we entered into a partnership with GSK, in which GSK was solely responsible for the development and commercialization of Serenz world-wide. In April 2014, GSK notified us that they were terminating our license agreement with them, following which, pursuant to a 30-business-day prior notice

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provision contained in the license agreement allowing GSK to terminate upon such notice before commercialization, the license agreement formally terminated and the licensed rights to Serenz were returned to us in June 2014. GSK informed us that this decision to terminate the relationship was made due to GSK's belief that the product would be classified as a drug-device combination by the FDA, which would increase development costs and timelines to the point that their strategic objectives would no longer be met. We believe that their decision to terminate the relationship was unrelated to any clinical data from, or technical aspects of, the program. GSK's decision to terminate our license agreement for Serenz may negatively impact the perception of Serenz held by other potential partners for the program. This may impair our efforts to partner the program on terms that are favorable to us, or at all.

We intend to pursue certain capital-efficient strategies to advance the program until such point as we can again identify a partner with appropriate clinical and commercial capabilities.

Other Serenz Clinical Trials

Prior to the nasal CO₂ Phase 2 clinical trials in AR, we had conducted a safety and feasibility study involving 54 patients in migraine patients. We have also explored the use of nasal CO₂ for treatment of migraine headaches and temporomandibular disorders. A total of 928 patients were enrolled across six separate safety and efficacy trials in these non-AR indications. The product showed signs of efficacy, statistically significant in some, but not all, trials, and rapid onset of effect. For strategic reasons we have focused further development on AR. Importantly, in the non-AR trials, the product showed a mild and well-tolerated safety profile that is similar to that seen in trials of Serenz for AR.

Manufacturing

We currently manufacture CoSense instruments at our facility in Redwood City, California. We assemble components from a variety of original equipment manufacturer, or OEM, sources. Our manufacturing facility is registered with the FDA and certified to the ISO 13485 standard, the internationally harmonized regulatory requirement for quality management systems of medical device companies. We may, depending on sales volume and ongoing requirements in specific sales geographies, outsource manufacturing of components, or finished goods, to various OEMs in the future.

We have manufactured the Serenz device in partnership with an OEM supplier based in Shenzhen, China and intend to manufacture future supply with this same OEM supplier.

Intellectual Property***Our Sensalyze Technology Platform Patent Portfolio***

Our patent portfolio surrounding our Sensalyze Technology Platform, including CoSense, consists of one issued U.S. patent, four pending U.S. non-provisional patent applications, and eight pending U.S. provisional patent applications. Three of the non-provisional filings have corresponding Patent Cooperation Treaty, or PCT, filings and are still eligible for expansion into other geographies. It is our intent to file these, and future cases, in other major commercial geographies over time. Our issued U.S. patent (no. 8,021,308) expires in August 2027. The pending patent applications, if issued, would likely expire on dates ranging from 2023 through 2034.

The issued patent and patent pending applications include:

detection and storage of discrete portions of a breath;

methods of diversion and isolation of gases to enable measurement within a breath pattern;

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specific compositions of valving and pumps to route airflow in a tightly controlled manner;

collection methods for increasing the precision of measurement of small volumes of gas;

identifying a physiologically representative breath, including both algorithm and physical capture; and

various methods for arrangement and specification of components to enhance precision and compensate for factors that cause inaccurate measurements.

Our issued U.S. patent was acquired from BDDI and is subject to an asset purchase agreement with BDDI that contains ongoing contingent payment obligations, including the following royalty range on aggregate net sales of CoSense in the U.S.:

Net sales at or below \$10 million	2%
Net sales at between \$10 million and \$25 million	3%
Net sales at between \$25 million and \$50 million	4%
Net sales above \$50 million	5%

Serenz Patent Portfolio

Successful application of therapeutic gases to the nasal mucosa is generally dependent on specific dosing, concentration, and rate of gas outflow. The CO₂ gas used in the Serenz product is packaged in small sealed cylinders with relatively high internal pressure; regulating the flow of gas from this high pressure cylinder to the relatively low flow rates required for Serenz presents significant technical challenges. Our Serenz patent portfolio addresses these challenges.

Our Serenz patent portfolio consists of over 30 issued patents and over 40 pending patent applications. In the U.S., twelve issued patents, one allowed non-provisional patent application, and 7 pending non-provisional patent applications cover the Serenz technology. The U.S. patents and patent applications have corresponding issued patents and pending patent applications in developed nations. The expiration dates for the issued patents vary, with the latest being in 2022. Patent term extension due to regulatory review may be requested in the U.S. based upon one or more of the issued U.S. patents under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.

Our pending applications, when issued, would likely expire between 2020 and 2033.

Our issued patents and pending patent applications include claims directed to:

gas dispensing devices, including various nosepiece configurations, pressure regulators, and cylinder configurations;

methods for delivering therapeutic gases to patients;

the treatment of various medical conditions via delivery of therapeutic gases to the nasal cavity; and

combined delivery of gases with other therapeutic agents.

Table of Contents**Index to Financial Statements****Government Regulation*****Federal Food, Drug, and Cosmetic Act***

In the U.S., diagnostic assays are regulated by the FDA as medical devices under the Federal Food, Drug, and Cosmetic Act, or FFDC. We received initial FDA 510(k) clearance for CoSense in the fourth quarter of 2012 for the monitoring of CO from endogenous and exogenous sources in exhaled breath, particularly in smoking cessation programs for the screening of CO poisoning and smoke inhalation. In the first quarter of 2014, CoSense received 510(k) clearance for the monitoring of CO from endogenous sources, including hemolysis, and exogenous sources, including CO poisoning and smoke inhalation, in exhaled breath. Serenz has not yet commenced any process for regulatory approval in the U.S. We also plan to seek FDA clearance or approval for other diagnostic products currently under development. There are two regulatory pathways to receive authorization to market diagnostics: a 510(k) premarket notification and a premarket approval application, or PMA. The FDA makes a risk-based determination as to the pathway for which a particular diagnostic is eligible. CoSense was cleared via the 501(k) premarket notification pathway as a Class II medical device.

The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling, registration and listing and adherence to FDA's quality system regulation, which are device-specific good manufacturing practices. Class II devices are subject to general controls and special controls, including performance standards and postmarket surveillance. Class III devices are subject to most of these requirements, as well as to premarket approval. Most Class I devices are exempt from premarket submissions to the FDA; most Class II devices require the submission of a 510(k) premarket notification to the FDA; and Class III devices require submission of a PMA. Most diagnostic kits are regulated as Class I or II devices and are either exempt from premarket notification or require a 510(k) submission.

510(k) premarket notification. A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a predicate device, that is legally marketed in the U.S. and for which a PMA was not required. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate; or has the same intended use but different technological characteristics, where the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device. Under current FDA policy, if a predicate device does not exist, the FDA may make a risk-based determination based on the complexity and clinical utility of the device that the device is eligible for *de novo* 510(k) review instead of requiring a PMA. The *de novo* 510(k) review process is similar to clearance of the 510(k) premarket notification, despite the lack of a suitable predicate device.

The FDA's performance goal review time for a 510(k) notification is 90 days from the date of receipt, however, in practice, the review often takes longer. In addition, the FDA may require information regarding clinical data in order to make a decision regarding the claims of substantial equivalence. Clinical studies of diagnostic products are typically designed with the primary objective of obtaining analytical or clinical performance data. If the FDA believes that the device is not substantially equivalent to a predicate device, it will issue a "Not Substantially Equivalent" letter and designate the device as a Class III device, which will require the submission and approval of a PMA before the new device may be marketed. Under certain circumstances, the sponsor may petition the FDA to make a risk-based determination of the new device and reclassify the new device as a Class I or Class II device. Any modifications made

to a device, its labeling or its intended use after clearance may require a new 510(k) notification to be submitted and cleared by FDA. Some modifications may only require documentation to be kept by the manufacturer, but the manufacturer's determination of the absence of need for a new 510(k) notification remains subject to subsequent FDA disagreement and enforcement to cease marketing of the modified device.

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The FDA has undertaken a systematic review of the 510(k) clearance process that includes both internal and independent recommendations for reform of the 510(k) system. The internal review, issued in August 2010, included a recommendation for development of a guidance document defining a subset of moderate risk (Class II) devices to include implantable, life-supporting or life-sustaining devices, called Class IIb, for which additional clinical or manufacturing data typically would be necessary to support a substantial equivalence determination. In the event that such new Class IIb sub-classification is adopted, we believe that most of the tests that we may pursue would be classified as Class IIa devices having the same requirements of the current Class II designation. In July 2011, the Institute of Medicine, or IOM, issued its independent recommendations for 510(k) reform. As the FDA receives public comment on the IOM recommendations and reconciles its plan of action to respond to both the internal and IOM recommendations, the availability of the 510(k) pathway for our diagnostic tests, and the timing and data burden required to obtain 510(k) clearance, could be adversely impacted. We cannot predict the impact of the 510(k) reform efforts on the development and clearance of our future diagnostic tests.

De Novo 510(k). If a previously unclassified new medical device does not qualify for the 510(k) pre-market notification process because there is no predicate device to which it is substantially equivalent, and if the device may be adequately regulated through general controls or special controls, the device may be eligible for *de novo* classification through what is called the *de novo* review process. In order to use the *de novo* review process, a company must receive a letter from the FDA stating that, because the device has been found not substantially equivalent to a legally marketed Class I or II medical device or to a Class III device marketed prior to May 28, 1976 for which the FDA has not required the submission of a PMA application, it has been placed into Class III. After receiving this letter, we, within 30 days, must submit to the FDA a request for a risk based down classification of the device from Class III to Class I or II based on the device's moderate or low risk profile which meets the definition of a Class I or Class II medical device. The FDA then has 60 days in which to decide whether to down classify the device. If the FDA agrees that a lower classification is warranted, it will issue a new regulation describing the device type and, for a Class II device, publish a Special Controls guidance document. The Special Controls guidance document specifies the scope of the device type and the recommendations for submission of subsequent devices for the same intended use. If a product is classified as Class II through the *de novo* review process, then that device may serve as a predicate device for subsequent 510(k) pre-market notifications.

Premarket approval. The PMA process is more complex, costly and time consuming than the 510(k) process. A PMA must be supported by more detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a significant risk, the sponsor may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial.

After the PMA is submitted, the FDA has 45 days to make a threshold determination that the PMA is sufficiently complete to permit a substantive review. If the PMA is complete, the FDA will file the PMA. The FDA is subject to a performance goal review time for a PMA of 180 days from the date of filing, although in practice this review time is longer. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably. Indeed, the total process may take several years and there is no guarantee that the PMA will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. The FDA may also request additional clinical data as a condition of approval or after the PMA is approved. Any changes to the medical device may require a supplemental PMA to be submitted and approved.

Regulation of Pharmaceuticals or Combination Products. In the U.S., the FDA may determine that Serenz should be regulated as a combination product or as a drug. The sales and marketing of pharmaceutical products in the U.S. are

subject to extensive regulation by the FDA. The FDCA and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA

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or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the U.S. The process required by the FDA before a drug may be marketed in the U.S. generally involves:

completion of pre-clinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice regulation;

submission to the FDA of an investigational new drug, or IND, application for human clinical testing which must become effective before human clinical trials may begin in the U.S.;

approval by an IRB at each clinical trial site before a trial may be initiated at the site;

performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or GCP regulations, to establish the safety and efficacy of the proposed drug product for each intended use;

satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations, and for devices and device components, the FDA's Quality Systems Regulation, or QSR, and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

submission to the FDA of an NDA;

satisfactory review by an FDA advisory committee, if applicable; and

FDA review and approval of the NDA.

The pre-clinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our future products will be granted on a timely basis, if at all. Pre-clinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The results of pre-clinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. Some pre-clinical testing may continue even after the IND is submitted. The

IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places a trial on clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, our submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

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

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Clinical trials involve the administration of an investigational drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into healthy human subjects or patients and tested for safety, dose tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.

Phase 3: These are commonly referred to as pivotal studies. When Phase 2 evaluations demonstrate that a dose range of the product appears to be effective and has an acceptable safety profile, Phase 3 trials are undertaken in large patient populations to further evaluate dosage, to obtain additional evidence of clinical efficacy and safety in an expanded patient population at multiple, geographically-dispersed clinical trial sites, to establish the overall risk-benefit relationship of the drug and to provide adequate information for the labeling of the drug.

Phase 4: In some cases, the FDA may condition approval of an NDA for a future product on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 studies.

The results of product development, pre-clinical studies and clinical trials are submitted to the FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, CMC and proposed labeling, among other things.

For combination products, the FDA's review may include the participation of both the FDA's Center for Drug Evaluation and Research and the FDA's Center for Devices and Radiological Health, which may complicate or prolong the review.

Before approving an NDA, the FDA may inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP, and if applicable, QSR, requirements and are adequate to assure consistent production of the product within required specifications. Additionally, the FDA will typically inspect one or more clinical sites to assure compliance with GCP before approving an NDA.

After the FDA evaluates the NDA and, in some cases, the related manufacturing facilities, it may issue an approval letter, or it may issue a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific

prescribing information for specific indications.

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

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

Continuing FDA Regulation

Devices. Under the medical device regulations, the FDA regulates quality control and manufacturing procedures by requiring us to demonstrate and maintain compliance with the quality system regulation, which sets forth the FDA's current good manufacturing practices requirements for medical devices. The FDA monitors compliance with the quality system regulation and current good manufacturing practices requirements by conducting periodic inspections of manufacturing facilities. We could be subject to unannounced inspections by the FDA. Violations of applicable regulations noted by the FDA during inspections of our manufacturing facilities, or the manufacturing facilities of these third parties, could adversely affect the continued marketing of our tests.

The FDA also enforces post-marketing controls that include the requirement to submit medical device reports to the agency when a manufacturer becomes aware of information suggesting that any of its marketed products may have caused or contributed to a death, serious injury or serious illness or any of its products has malfunctioned and that a recurrence of a malfunction would likely cause or contribute to a death or serious injury or illness. The FDA relies on medical device reports to identify product problems and utilizes these reports to determine, among other things, whether it should exercise its enforcement powers. The FDA may also require postmarket surveillance studies for specified devices.

FDA regulations also govern, among other things, the preclinical and clinical testing, manufacture, distribution, labeling and promotion of medical devices. In addition to compliance with good manufacturing practices and medical device reporting requirements, we will be required to comply with the FDCA's general controls, including establishment registration, device listing and labeling requirements. If we fail to comply with any requirements under the FDCA, we could be subject to, among other things, fines, injunctions, civil penalties, recalls or product corrections, total or partial suspension of production, denial of premarket notification clearance or approval of products, rescission or withdrawal of clearances and approvals, and criminal prosecution. We cannot assure you that any final FDA policy, once issued, or future laws and regulations concerning the manufacture or marketing of medical devices will not increase the cost and time to market of new or existing tests. Furthermore, any current or future federal and state regulations also will apply to future tests developed by us.

If our promotional activities fail to comply with these FDA regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw a product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution.

Pharmaceuticals. Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug-device listing, recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to

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

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

restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

fines, warning letters or holds on post-approval clinical trials;

refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;

product seizure or detention, or refusal to permit the import or export of products; and

injunctions or the imposition of civil or criminal penalties.

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

Advertising

Advertising of our tests is subject to regulation by the Federal Trade Commission, or FTC, under the FTC Act. The FTC Act prohibits unfair or deceptive acts or practices in or affecting commerce. Violations of the FTC Act, such as failure to have substantiation for product claims, would subject us to a variety of enforcement actions, including compulsory process, cease and desist orders and injunctions, which can require, among other things, limits on advertising, corrective advertising, consumer redress and restitution, as well as substantial fines or other penalties. Any enforcement actions by the FTC could have a material adverse effect our business.

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established for the first time comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or Covered Entities : health plans, healthcare clearing houses, and healthcare providers which conduct certain healthcare transactions electronically. Covered Entities and their Business Associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. Because we are a healthcare provider and we conduct certain healthcare transactions electronically, we are presently a Covered Entity, and we must have in place the administrative, physical, and technical safeguards required by HIPAA, HITECH and their implementing regulations. Additionally, some state laws impose privacy protections more stringent than HIPAA. Most of the

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institutions and physicians from which we obtain biological specimens that we use in our research and validation work are Covered Entities and must obtain proper authorization from their patients for the subsequent use of those samples and associated clinical information. We may perform future activities that may implicate HIPAA, such as providing clinical laboratory testing services or entering into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Our activities must also comply with other applicable privacy laws. For example, there are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain tissue samples and associated patient information could significantly impact our business and our future business plans.

Federal and State Billing and Fraud and Abuse Laws

Antifraud Laws/Overpayments. As participants in federal and state healthcare programs, we are subject to numerous federal and state antifraud and abuse laws. Many of these antifraud laws are broad in scope, and neither the courts nor government agencies have extensively interpreted these laws. Prohibitions under some of these laws include:

the submission of false claims or false information to government programs;

deceptive or fraudulent conduct;

excessive or unnecessary services or services at excessive prices; and

prohibitions in defrauding private sector health insurers.

We could be subject to substantial penalties for violations of these laws, including denial of payment and refunds, suspension of payments from Medicare, Medicaid or other federal healthcare programs and exclusion from participation in the federal healthcare programs, as well as civil monetary and criminal penalties and imprisonment. One of these statutes, the False Claims Act, is a key enforcement tool used by the government to combat healthcare fraud. The False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, violations of the federal physician self-referral laws, such as the Stark laws discussed below, may also violate false claims laws. Liability under the False Claims Act can result in treble damages and imposition of penalties. For example, we could be subject to penalties of \$5,500 to \$11,000 per false claim, and each use of our product could potentially be part of a

different claim submitted to the government. Separately, the HHS office of the Office of Inspector General, or OIG, can exclude providers found liable under the False Claims Act from participating in federally funded healthcare programs, including Medicare. The steep penalties that may be imposed on laboratories and other providers under this statute may be disproportionate to the relatively small dollar amounts of the claims made by these providers for reimbursement. In addition, even the threat of being excluded from participation in federal healthcare programs can have significant financial consequences on a provider.

Numerous federal and state agencies enforce the antifraud and abuse laws. In addition, private insurers may also bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

Table of Contents**Index to Financial Statements*****Federal and State Self-Referral and Anti-Kickback Restrictions***

Self-Referral law. We are subject to a federal self-referral law, commonly referred to as the Stark law, which provides that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. The Stark law contains a number of specific exceptions which, if met, permit physicians who have ownership or compensation arrangements with a testing laboratory to make referrals to that laboratory and permit the laboratory to submit claims for Medicare payments for laboratory tests performed pursuant to such referrals.

We are subject to comparable state laws, some of which apply to all payors regardless of source of payment, and do not contain identical exceptions to the Stark law. For example, we are subject to a North Carolina self-referral law that prohibits a physician investor from referring to us any patients covered by private, employer-funded or state and federal employee health plans. The North Carolina self-referral law contains few exceptions for physician investors in securities that have not been acquired through public trading, but will generally permit us to accept referrals from physician investors who buy their shares in the public market.

We have several stockholders who are physicians in a position to make referrals to us. We have included within our compliance plan procedures to identify requests for testing services from physician investors and we do not bill Medicare, or any other federal program, or seek reimbursement from other third-party payors, for these tests. The self-referral laws may cause some physicians who would otherwise use our laboratory to use other laboratories for their testing.

Providers are subject to sanctions for claims submitted for each service that is furnished based on a referral prohibited under the federal self-referral laws. These sanctions include denial of payment and refunds, civil monetary payments and exclusion from participation in federal healthcare programs and civil monetary penalties, and they may also include penalties for applicable violations of the False Claims Act, which may require payment of up to three times the actual damages sustained by the government, plus civil penalties of \$5,500 to \$11,000 for each separate false claim. Similarly, sanctions for violations under the North Carolina self-referral laws include refunds and monetary penalties.

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term remuneration is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, or PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes, effective March 23, 2010. Pursuant to the statutory amendment, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act or the civil monetary penalties

statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Sanctions for violations of the federal Anti-Kickback Statute may include imprisonment and other criminal penalties, civil monetary penalties and exclusion from participation in federal healthcare programs.

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The OIG has criticized a number of the business practices in the clinical laboratory industry as potentially implicating the Anti-Kickback Statute, including compensation arrangements intended to induce referrals between laboratories and entities from which they receive, or to which they make, referrals. In addition, the OIG has indicated that dual charge billing practices that are intended to induce the referral of patients reimbursed by federal healthcare programs may violate the Anti-Kickback Statute.

Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. For example, North Carolina has an anti-kickback statute that prohibits healthcare providers from paying any financial compensation for recommending or securing patient referrals. Penalties for violations of this statute include license suspension or revocation or other disciplinary action. Other states have similar anti-kickback prohibitions.

Both the federal Anti-Kickback Statute and the North Carolina anti-kickback law are broad in scope. The anti-kickback laws clearly prohibit payments for patient referrals. Under a broad interpretation, these laws could also prohibit a broad array of practices involving remuneration where one party is a potential source of referrals for the other.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. To the extent that any product we make is sold in a foreign country in the future, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. To reduce the risks associated with these various laws and governmental regulations, we have implemented a compliance plan. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

International Medical Device Regulations

International marketing of medical devices is subject to foreign government regulations, which vary substantially from country to country. The European Commission is the legislative body responsible for directives with which manufacturers selling medical products in the E.U. and the European Economic Area, or EEA, must comply. The E.U. includes most of the major countries in Europe, while other countries, such as Switzerland, are part of the EEA and have voluntarily adopted laws and regulations that mirror those of the E.U. with respect to medical devices. The E.U. has adopted directives that address regulation of the design, manufacture, labeling, clinical studies and post-market vigilance for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be marketed throughout the E.U. and EEA.

Outside of the E.U., regulatory pathways for the marketing of medical devices vary greatly from country to country. In many countries, local regulatory agencies conduct an independent review of medical devices prior to granting

marketing approval. For example, in China, approval by the SFDA, must be obtained prior to marketing an medical device. In Japan, approval by the MHLW following review by the Pharmaceuticals and Medical Devices Agency, or the PMDA is required prior to marketing an medical device. The process in such countries may be lengthy and require the expenditure of significant resources, including the conduct of clinical trials. In other countries, the regulatory pathway may be shorter or less costly. The timeline for the introduction

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of new medical devices is heavily impacted by these various regulations on a country-by-country basis, which may become more lengthy and costly over time.

U.S. Healthcare Reform

In March 2010, the PPACA was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. Beginning in August 2013, the Physician Payment Sunshine Act, enacted as part of PPACA, and its implementing regulations requires medical device manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any transfer of value made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to report this information to Centers for Medicare & Medicaid Services, or CMS, beginning in 2014. Various states have also implemented regulations prohibiting certain financial interactions with healthcare professionals or mandating public disclosure of such financial interactions. We may incur significant costs to comply with such laws and regulations now or in the future.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Employees

As of October 30, 2014, we had nine full-time employees. We also have six full-time or part-time consultants providing services to us. None of our employees is represented by a labor union or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our principal facilities consist of office space in Redwood City, California, which also contains our final assembly and calibration facility for CoSense. We currently occupy approximately 6,000 square feet of office space under a sublease that expires in May 2015.

Legal proceedings

We are not currently subject to any legal proceedings.

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The following table sets forth information regarding our executive officers and directors as of June 30, 2014:

Name	Age	Position
Executive Officers:		
Anish Bhatnagar, M.D.	46	President, Chief Executive Officer and Director
David D. O Toole	55	Chief Financial Officer
Anthony Wondka	53	Vice President of Research and Development
Antoun Nabhan, J.D.	39	Vice President of Corporate Development
Gina Phelps	58	Vice President of Sales
Non-Employee Directors:		
Ernest Mario, Ph.D.	76	Chairman
Edgar G. Engleman, M.D.	69	Director
Steinar J. Engelsen, M.D., M.Sc. ⁽¹⁾⁽²⁾⁽³⁾	64	Director
William G. Harris ⁽¹⁾⁽²⁾	56	Director
Stephen Kirnon, Ed.D. ⁽²⁾⁽³⁾	52	Director
William James Alexander, M.D. ⁽¹⁾⁽³⁾	65	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Anish Bhatnagar, M.D. Dr. Bhatnagar was appointed as our Chief Executive Officer in February 2014. Prior to that, he served as our President and Chief Operating Officer. Dr. Bhatnagar joined us in 2006, and has held positions of increasing responsibility since then. Dr. Bhatnagar is a physician with over 15 years of experience in the medical device and biopharmaceutical industries. His experience spans development of biologics, drugs, drug-device combinations and diagnostic as well as therapeutic medical devices. His prior experience includes working at Coulter Pharmaceuticals, Inc. from 1998 to 2000 and Titan Pharmaceuticals, Inc. from 2000 to 2006. He is the author of several peer-reviewed publications, abstracts and book chapters. He obtained his medical degree at SMS Medical College in Jaipur, India and completed his Residency and Fellowship training in the U.S. at various institutions, including Georgetown University Hospital and the University of Pennsylvania.

We believe Dr. Bhatnagar is able to make valuable contributions to our board of directors due to his service as an executive officer of our company, including as Chief Executive Officer, extensive knowledge of medical device and pharmaceutical company operations, and extensive experience working with companies, regulators and other stakeholders in the medical device and pharmaceutical industries.

David D. O Toole was appointed as our Chief Financial Officer in July 2014. He has more than 30 years of experience in the accounting and finance sectors, and for the past 14 years has focused on the medical device, tools, and

diagnostics industry. From September 2012 to June 2014 Mr. O Toole was Senior Vice President and Chief Financial Officer at Codexis, Inc., a public company focused on developing biocatalysts. From May 2010 to August 2012 Mr. O Toole was Vice President and Chief Financial Officer at Response Genetics, Inc., and served from May 2008 to August 2010 as Executive Vice President and Chief Financial Officer of Abraxis Bioscience, Inc. From 1992 to 2008, Mr. O Toole worked at Deloitte & Touche LLP, where he served for 12 of those years as a partner. He worked at Arthur Anderson & Co., from 1984 to 1992, as an international tax manager. Mr. O Toole received his Bachelor of Science, Accounting from the University of Arizona and is a certified public accountant.

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Anthony Wondka. Mr. Wondka was appointed as our Vice President of Research and Development in June 2013. Prior to that, he was a consultant for us since May 2011. He has held management and executive positions in the medical device industry for over 20 years, in large and small companies. From April 2006 to March 2011, Mr. Wondka served as VP of R&D and then VP of Technology and Clinical Affairs for Breathe Technologies, where he invented and co-invented ventilation products that address large unmet needs in chronic obstructive pulmonary disease, or COPD, and obstructive sleep apnea. From July 1997 to April 2006, Mr. Wondka was Director of R&D and VP of Manufacturing at Pulmonx, where he co-invented and led the early development of the Chartist diagnostic system and procedure that is used to guide endobronchial lung volume reduction for the treatment of COPD, and is currently being sold in the E.U. Prior to Pulmonx, Mr. Wondka worked at Pfizer subsidiary Shiley (acquired by Covidien) and Bear Medical (acquired by Carefusion), where he held lead roles in engineering and quality assurance, supporting commercialization activities for market leading ENT and respiratory products. He holds over 40 issued or pending patents and has a B.S. in Bioengineering from University of California San Diego.

Antoun Nabhan, J.D. Mr. Nabhan joined us in April 2014 as an employee, and before that was a consultant to Capnia since October of 2013. He is a specialist in finance and corporate development for healthcare-related businesses. From 2012 to 2013, he was the Vice President of Corporate Development at Tobira Therapeutics, a drug development company. From 2008 to 2012, he was part of the corporate development and strategy team at Onyx Pharmaceuticals, Inc., an oncology drug company acquired by Amgen for \$10.6 billion in 2013. He played a significant role in that company's acquisition of Proteolix, Inc. and subsequent out-license of Japanese-territory rights to its product, Kyprolis® (carfilzomib). Mr. Nabhan is a Principal of Sagamore Bioventures, a biotechnology-focused investment fund that he joined in 2002. From 2006 to 2008, he was a founder and Chief Financial Officer at Presidio Pharmaceuticals, Inc., a drug discovery company focused on hepatitis C, HIV, and other viral diseases. He co-founded Incellico Inc. (acquired by Sylventa Inc.) and served as its VP of Finance & Business Development. He started his career as an analyst for Deloitte & Touche Consulting Group. Mr. Nabhan received his J.D. from Harvard Law School, where he was an Affiliate of the Berkman Center for Law and Technology, and his A.B. from the University of Chicago.

Gina Phelps. Ms. Phelps joined Capnia in June 2014 and has over 25 years of experience in sales of medical devices and point-of-care diagnostics. Prior to joining Capnia, Ms. Phelps served as Director of Sales (West) for Accumetrics, leading the company's sales efforts for the VerifyNo® line of hospital-based diagnostics. She held this position from 2011 until the acquisition of Accumetrics by ITC Corporation in 2013. Prior to that, Ms. Phelps was the National Sales Director for Metrika, Inc., where she had a leadership role in the launch of Metrika's point-of-care diagnostic devices for diabetes management. Metrika was acquired by Bayer Healthcare LLC in 2006. Ms. Phelps continued her sales leadership role for the Metrika products post-acquisition, serving in various positions of increasing responsibility with Bayer Healthcare from 2006 through 2011. She started her career in medical device and diagnostics sales with Roche Diagnostics. Ms. Phelps was a licensed practical nurse and received her B.S. from Utah College of Applied Technology.

Non-Employee Directors

Ernest Mario, Ph.D. Dr. Mario joined our board of directors in August 2007 and served as Chairman and Chief Executive Officer until February 2014 when he was named Chairman. From April 2003 to August 2007, Dr. Mario served as Chief Executive Officer and Chairman of Reliant Pharmaceuticals, Inc., a privately held pharmaceutical company that was acquired by GSK for approximately \$1.6 billion in 2007. Dr. Mario served as Chief Executive Officer and Chairman of ALZA Corporation, a research-based pharmaceutical company, from November 1997 to December 2001, when ALZA was acquired by Johnson & Johnson for approximately \$12 billion. Previously he

served as Chief Executive Officer and Co-Chairman of ALZA from August 1993 to November 1997. From January 1992 until March 1993, Dr. Mario served as Deputy Chairman of Glaxo Holdings plc., a pharmaceutical company, and as Chief Executive from May 1989 to March 1993. Dr. Mario has current and past service on a number of corporate boards including Boston Scientific Corporation, Celgene Inc., Chimerix, Inc., Kindred Biosciences Inc., Tonix Pharmaceuticals Holding Corp. and XenPort Inc. Dr. Mario is active in numerous

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educational and healthcare organizations. He is Chairman of the American Foundation for Pharmaceutical Education, a Director of the Gladstone Foundation, and past Chairman of the Duke University Health System. Dr. Mario earned his M.S. and Ph.D. in physical sciences at the University of Rhode Island and a B.S. in pharmacy at Rutgers. He holds honorary doctorates from the University of Rhode Island and Rutgers University. In 2007 he was awarded the Remington Medal by the American Pharmacists Association, pharmacy's highest honor.

We believe Dr. Mario is able to make valuable contributions to our board of directors due to his extensive knowledge of our company, the industry, and our competitors, his extensive experience in risk oversight, quality and business strategy as a result of serving in leadership roles at multiple companies, his status as a significant stockholder and his prior service as our Chief Executive Officer.

Edgar G. Engleman, M.D. Dr. Engleman has been a member of our board of directors since June 2001. He is a founding member of Vivo Ventures, LLC (formerly BioAsia Investments) and since 1990 has served as Professor of Pathology and Medicine at Stanford University School of Medicine, where he oversees the Stanford Blood Center as well as his own immunology research group. An editor of numerous scientific journals and the inventor of multiple patented technologies, Dr. Engleman has authored more than 250 publications in medical and scientific journals and has trained more than 200 graduate students and postdoctoral fellows. Dr. Engleman has co-founded a number of biopharmaceutical companies including Cetus Immune Corporation (acquired by Chiron Corporation), Genelabs Technologies, Inc., (acquired by GlaxoSmithKline plc), National Medical Audit, and Dendreon Corporation. He is the lead inventor of the technology underlying Provenge, Dendreon's cancer vaccine, which was approved in 2010 to treat asymptomatic or minimally symptomatic metastatic hormone-refractory prostate cancer. Dr. Engleman currently serves on the boards of several private biotechnology companies, including Gryphon Therapeutics, Inc., Naryx Pharma, Inc., Eiger BioPharma, Inc., Nuveta, Inc. and Semnur Pharmaceuticals, Inc. He received his M.D. from Columbia University School of Medicine and his B.A. from Harvard University.

We believe Dr. Engleman is able to make valuable contributions to our board of directors due to his extensive knowledge of the healthcare industry, his medical expertise, his service on other company boards of directors, and his understanding of our company.

Steinar J. Engelsen, M.D., M.Sc., CEFA. Dr. Engelsen has been a member of our board of directors since April 2004. Since November 1996, Dr. Engelsen has been a partner of Teknoinvest AS, a venture capital firm based in Norway. From June 1989 until October 1996, Dr. Engelsen held various management positions within Hafslund Nycomed AS, a pharmaceutical company based in Europe, and affiliated companies. He was responsible for therapeutic research and development, most recently serving as Senior Vice President, Research and Development of Nycomed Pharma AS from January 1994 until October 1996. He currently serves on the board of directors of Insmmed, Inc. In addition, from January to November 2000, Dr. Engelsen was acting Chief Executive Officer of Centaur Pharmaceuticals, Inc., a biopharmaceutical company. Dr. Engelsen also served as Chairman of the board of directors of Centaur. Dr. Engelsen received his M.Sc. in Nuclear Chemistry and his M.D. from the University of Oslo, and is a Certified European Financial Analyst from The Norwegian School of Economics.

We believe Dr. Engelsen is able to make valuable contributions to our board of directors due to his extensive healthcare management experience, his financial and business leadership and expertise resulting from serving as a director or executive officer of multiple companies, and his understanding of our company.

William G. Harris. Mr. Harris has been a member of our board of directors since June 2014. Since 2001, he has been the Senior Vice President of Finance and Chief Financial Officer of Xenoport, Inc. From 1996 to 2001, he held

several positions with Coulter Pharmaceutical, Inc., a biotechnology company engaged in the development of novel therapies for the treatment of cancer and autoimmune diseases, the most recent of which was Senior Vice President and Chief Financial Officer. Corixa Corp., a developer of immunotherapeutic products, acquired Coulter Pharmaceutical in 2000. Prior to Coulter Pharmaceutical, from 1990 to 1996, Mr. Harris held several positions at Gilead Sciences, Inc., the most recent of which was director of finance. Mr. Harris received a B.A. from the University of California, San Diego and an M.B.A. from Santa Clara University, Leavey School of Business and Administration.

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We believe Mr. Harris is able to make valuable contributions to our board of directors due to his vast experience as a finance professional in the biomedical and pharmaceutical industries.

Stephen Kirnon, Ed.D. Dr. Kirnon has been a member of our board of directors since July 2002. He has over 20 years of operational experience in biomedical organizations. Since January 2009, he has served as the Co-founder and CEO of PharmaPlan LLC. From January 2012 until July 2013 he served as Vice President, Co-Lead Life Science Practice at Witt/Kieffer, Ford, Hadelman, Lloyd Corp. Prior to that, Dr Kirnon was the President and Chief Executive Officer of Pepgen Corporation, a biopharmaceutical company based in Alameda, California, specializing in autoimmune diseases. He was formerly the President and CEO of Target Protein Technologies, Inc., a pharmaceutical company based in San Diego and specializing in the development of pharmaceutical compounds targeted to specific tissues and organs of the human body. Prior to TPT, he was the President and COO and a member of the Board of Yamanouchi Pharma Technologies, Inc., which is responsible for developing and commercializing Yamanouchi's proprietary drug delivery technologies as well as the U.S. development and manufacture of Yamanouchi's pharmaceuticals. Previously, Dr. Kirnon was the President of the Drug Delivery Division of Cygnus, Inc., successfully leading that Division into profitability and subsequently through sale of its business. Dr. Kirnon has also held various business development, sales, and marketing positions at Cygnus, Biogenex Laboratories, Inc., and GlaxoSmithKline plc. Dr. Kirnon received his doctorate in organization change and transformational leadership from as well as his M.B.A. from Pepperdine University, where he is an Adjunct Professor. He received a B.A. degree in Biochemistry from Harvard University. He is also a trustee of the New England College of Optometry.

We believe Dr. Kirnon is able to make valuable contributions to our board of directors due to his extensive operational experience in the biomedical and pharmaceutical industries, and his knowledge of our company.

William James Alexander, M.D., M.P.H., FACP. Dr. Alexander has been a member of our board of directors since June 2008. Since June 2008, he has worked as an independent consultant to the pharmaceutical industry. He also serves as Senior Director of Medical Affairs at Chiesi USA, Inc. He has held senior clinical development and regulatory positions at a number of companies, including Beecham, SmithKline The Beecham Group plc, GlaxoSmithKline plc, and Glaxo Wellcome plc. He has contributed to successful NDAs for products in multiple therapeutic areas, including antibacterials, antivirals (herpes, hepatitis, and HIV), asthma and COPD, as well as migraine. Dr. Alexander was a public health medical officer and clinical investigator in Birmingham, Alabama, and collaborated with the CDC in investigating the epidemiology of hepatitis C and HIV. He is certified by the American Board of Internal Medicine and has been a member of the Infectious Diseases Society of America since 2010. Dr. Alexander received his M.D. from the University of Missouri and his M.P.H. from the University of Alabama, Birmingham. He received his B.S. in science from Mississippi State University.

We believe Dr. Alexander is able to make valuable contributions to our board of directors due to his years of public health and pharmaceutical industry experience, his business and regulatory expertise resulting from his service in leadership positions at multiple companies, and his knowledge of our company.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of seven members. The members of our board of directors were elected in compliance with the provisions of our amended and restated certificate of incorporation, as amended, and a voting agreement among certain of our stockholders, as amended. The voting agreement will terminate upon the closing of this offering and none of our stockholders will have any special rights regarding the election or designation of members of our board of directors.

In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

The Class I directors will be Drs. Engleman and Alexander, and their terms will expire at our annual meeting of stockholders to be held in 2017;

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The Class II directors will be Drs. Kirnon and Engelsen, and their terms will expire at our annual meeting of stockholders to be held in 2018; and

The Class III directors will be Drs. Bhatnagar and Mario and Mr. Harris, and their terms will expire at our annual meeting of stockholders to be held in 2019.

We expect that additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms could potentially delay or prevent a change of our management or a change in control of our company.

Director Independence

Under the listing requirements and rules of The NASDAQ Capital Market, or NASDAQ, independent directors must comprise a majority of a listed company's board of directors within a specified period of time after this offering.

Our board of directors has undertaken a review of its composition, the composition of its committees, and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that Mr. Harris and Drs. Engelsen, Kirnon, and Alexander have no relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is independent, as that term is defined under the applicable rules and regulations of the Securities and Exchange Commission, or the SEC, and the listing requirements and rules of NASDAQ. In making this determination, our board of directors considered the current and prior relationships that each non-employee director has with our company, any other transactional relationships a non-employee director may have with our company, and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock held by each non-employee director and any of his and our respective affiliates.

Board Leadership Structure

Our board of directors has a Chairman, Dr. Mario, who has authority, among other things, to preside over board of directors meetings, and to call special meetings of the board. Accordingly, the Chairman has substantial ability to shape the work of our board of directors. We currently believe that separation of the roles of Chairman and Chief Executive Officer reinforces the leadership role of our board of directors in its oversight of the business and affairs of our Company. In addition, we currently believe that having a separate Chairman creates an environment that is more conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of our board of directors to monitor whether management's actions are in the best interests of the company and its stockholders. However, no single leadership model is right for all companies and at all times. Our board of directors recognizes that depending on the circumstances, other leadership models, such as combining the role of Chairman with the role of Chief Executive Officer, might be appropriate. As a result, our board of directors may periodically review its leadership structure.

Board committees

Our board of directors has the authority to appoint committees to perform certain management and administration functions. Our board of directors has an audit committee, a compensation committee and a nominating and corporate

governance committee. The composition and responsibilities of each committee are described below. Members will serve on these committees until their resignation or until otherwise determined by our board of directors. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus.

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Audit committee

Our audit committee consists of Steinar J. Engelsen, William G. Harris, and William James Alexander, each of whom satisfies the independence requirements under NASDAQ listing standards and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The chairperson of our audit committee is Mr. Harris. Each member of our audit committee can read and understand fundamental financial statements in accordance with audit committee requirements. In arriving at this determination, our board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in oversight of the integrity of our financial statements, our compliance with legal and regulatory requirements, our independent auditor's qualifications, independence and performance and our internal accounting and financial controls. Our audit committee is responsible for the appointment, compensation, retention and oversight of our independent auditors. Our board of directors has determined that Dr. Engelsen and Mr. Harris are audit committee financial experts, as defined by the rules promulgated by the SEC.

Following the closing of this offering, the charter of the audit committee will be available on our website at www.capnia.com. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Compensation committee

Our compensation committee consists of Steinar J. Engelsen, William G. Harris and Stephen Kirnon each of whom our board of directors has determined to be independent under NASDAQ listing standards, a non-employee director as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director as that term is defined in Section 162(m) of the Code. The chairperson of our compensation committee is Dr. Engelsen.

Our compensation committee oversees our compensation policies, plans and benefits programs and assists our board of directors in meeting its responsibilities with regard to oversight and determination of executive compensation. In addition, our compensation committee reviews and makes recommendations to our board of directors with respect to our major compensation plans, policies and programs and assesses whether our compensation structure establishes appropriate incentives for officers and employees.

Following the closing of this offering, the charter of the compensation committee will be available on our website at www.capnia.com. The inclusion of our website address in this prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Nominating and corporate governance committee

Our nominating and corporate governance committee consists of Steinar J. Engelsen, Stephen Kirnon and William James Alexander, each of whom our board of directors has determined to be independent under NASDAQ listing standards. The chairperson of our nominating and corporate governance committee is Dr. Kirnon.

Our nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of the board of directors and its committees. In addition, our nominating and corporate governance committee is responsible for reviewing and making

recommendations to our board of directors on matters concerning corporate governance and conflicts of interest.

Following the closing of this offering, the charter of the nominating and corporate governance committee will be available on our website at www.capnia.com. The inclusion of our website address in this

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prospectus does not include or incorporate by reference into this prospectus the information on or accessible through our website.

Role in Risk Oversight

Our board of directors oversees an enterprise-wide approach to risk management, designed to support the achievement of business objectives, including organizational and strategic objectives, to improve long-term organizational performance and enhance stockholder value. The involvement of our board of directors in setting our business strategy is a key part of its assessment of management's plans for risk management and its determination of what constitutes an appropriate level of risk for our company. The participation of our board of directors in our risk oversight process includes receiving regular reports from members of senior management on areas of material risk to our company, including operational, financial, legal and regulatory, and strategic and reputational risks.

While our board of directors has the ultimate responsibility for the risk management process, senior management and various committees of our board of directors will also have responsibility for certain areas of risk management.

Our senior management team is responsible for day-to-day risk management and regularly reports on risks to our full board of directors or a relevant committee. Our finance and regulatory personnel serve as the primary monitoring and evaluation function for company-wide policies and procedures, and manage the day-to-day oversight of the risk management strategy for our ongoing business. This oversight includes identifying, evaluating, and addressing potential risks that may exist at the enterprise, strategic, financial, operational, compliance and reporting levels.

Our audit committee will focus on monitoring and discussing our major financial risk exposures and the steps management has taken to monitor and control such exposures, including our risk assessment and risk management policies. As appropriate, the audit committee will provide reports to and receive direction from the full board of directors regarding our risk management policies and guidelines, as well as the audit committee's risk oversight activities.

In addition, our compensation committee will assess our compensation policies to confirm that the compensation policies and practices do not encourage unnecessary risk taking. The compensation committee will review and discuss the relationship between risk management policies and practices, corporate strategy and senior executive compensation and, when appropriate, report on the findings from the discussions to our board of directors. Our compensation committee intends to set performance metrics that will create incentives for our senior executives that encourage an appropriate level of risk-taking that is commensurate with our short-term and long-term strategies.

Code of Business Conduct and Ethics

Upon the closing of this offering, we will adopt a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Following the closing of this offering, the code of business conduct and ethics will be available on our website at www.capnia.com. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this prospectus does not incorporate by reference the information on or accessible through our website into this prospectus.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been an officer or employee of the company. None of our executive officers serve, or have served during the last fiscal year, as a member of a board

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of directors, compensation committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving on our board directors or on our compensation committee.

Non-Employee Director Compensation

Directors who are employees do not receive any additional compensation for their service on our board of directors. We reimburse our non-employee directors for their reasonable out-of-pocket costs and travel expenses in connection with their attendance at board of directors and committee meetings. In 2013, certain of our non-employee directors received cash compensation as set forth below.

The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2013.

Name	Cash Compensation	Option Awards ⁽¹⁾	Other Compensation	Total
Edgar G. Engleman				
Steinar J. Engelsen				
Stephen Kirnon				
William James Alexander				
William G. Harris				

(1) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal year, computed in accordance with FASB ASC Topic 718. The valuation assumptions used in determining such amounts are described in Note 6 and Note 9 to our financial statements included in this prospectus. The table below lists the aggregate number of shares and additional information with respect to the outstanding option awards held by each of our non-employee directors.

Name	Equity Award Grant Date	Number of Shares Subject to Outstanding Options as of December 31, 2013	Option Exercise Price ⁽⁵⁾	Option Expiration Date
Edgar G. Engleman ⁽¹⁾				
Steinar J. Engelsen ⁽²⁾				
Stephen Kirnon ⁽³⁾	6/21/2005	1,822	\$ 5.76	6/21/2015
Stephen Kirnon ⁽³⁾	6/27/2008	1,666	\$ 3.48	9/25/2018
Stephen Kirnon ⁽³⁾	10/15/2008	833	\$ 3.48	10/15/2018
William James Alexander ⁽⁴⁾	9/25/2008	1,666	\$ 3.48	9/25/2018
William James Alexander ⁽⁴⁾	10/15/2008	833	\$ 3.48	10/15/2018

(1) Dr. Engleman joined our board of directors in June 2001.

(2) Dr. Engelsen joined our board of directors in April 2004.

(3) Dr. Kirnon joined our board of directors in July 2002.

- (4) Dr. Alexander joined our board of directors in June 2008.
- (5) The grant date fair market value of the common stock underlying these option awards is equal to the option exercise price on the date of grant.

Our board of directors has adopted a non-employee director compensation policy, which will be effective for all of our non-employee directors upon the closing of this offering, pursuant to which we will compensate our non-employee directors with a combination of cash and equity. Each such director will receive an annual base cash retainer of \$35,000 for such service, to be paid quarterly. The policy also provides that we compensate certain members of our board of directors for service on our committees as follows:

The chair or executive chair of our board of directors will receive an annual cash retainer of \$25,000 for such service, paid quarterly;

The chairperson of our audit committee will receive an annual cash retainer of \$10,000 for such service, paid quarterly;

The chairperson of our compensation committee will receive an annual cash retainer of \$10,000 for such service, paid quarterly; and

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The chairperson of our nominating and corporate governance committee will receive an annual cash retainer of \$10,000 for such service, paid quarterly.

The policy further provides for the grant of equity awards for each new director that joins our board of directors after the closing of this offering and all of our current directors upon completion of this offering, an initial stock option grant to purchase 7,000 shares of our common stock, vesting annually over four years and with an exercise price per share equal to at least 110% of the fair market value of the common stock on the date of grant.

We intend to retain an outside consulting firm to evaluate compensation parameters for our non-executive directors after the completion of this offering.

Each of these options will be granted with an exercise price equal to the fair market value of our common stock on the date of such grant.

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As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to smaller reporting companies, as such term is defined in the rules promulgated under the Securities Act of 1933, as amended, or the Securities Act, which require compensation disclosure for our principal executive officer and the two most highly compensated executive officers other than our principal executive officer. Our named executive officers for the year ended December 31, 2013 are:

Ernest Mario, Ph.D., our Chairman and Former Chief Executive Officer;

Anish Bhatnagar, M.D., our Chief Executive Officer, President and Chief Operating Officer;

David D. O Toole, our Chief Financial Officer;

Anthony Wondka, our Vice President, Research & Development; and

Antoun Nabhan, J.D., our Vice President of Corporate Development.

Throughout this section, we refer to these four officers as our named executive officers.

The Summary Compensation Table below sets forth information regarding the compensation awarded to or earned by our named executive officers during the year ended December 31, 2013.

2013 Summary compensation table

Name and principal position	Year	Salary	Non-equity Incentive plan		All Other Compensation	Total
			award ⁽¹⁾	compensation		
Ernest Mario ⁽²⁾ Chairman (was Chief Executive Officer as of December 31, 2013)	2013	\$	\$	\$	\$	\$
Anish Bhatnagar ⁽³⁾ Chief Executive Officer, President and Chief Operating Officer (was President and Chief Operating Officer as of December 31, 2013)	2013	\$ 374,063	\$	\$	\$	\$ 374,063
David D. O Toole ⁽⁴⁾ Chief Financial Officer (as of July 7, 2014)	2013	\$	\$	\$	\$	\$

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Anthony Wondka Vice President, Research &	2013	\$ 125,333	\$	\$	\$	\$ 125,333
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Development

Antoun Nabhan ⁽⁵⁾ Vice President of Corporate	2013	\$	\$	\$ 4,000	\$ 4,000
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Development

- (1) The amounts in this column reflect the aggregate grant date fair value of each option award granted during the fiscal year ended December 31, 2013, computed in accordance with FASB ASC Topic 718. The valuation assumptions used in determining such amounts are described in Note 6 and Note 9 to our financial statements included in this prospectus.
- (2) Dr. Mario was our Chief Executive Officer as of December 31, 2013. On February 6, 2014, Dr. Mario was appointed as our Executive Chairman, and subsequently our Chairman, and Dr. Bhatnagar succeeded him as our Chief Executive Officer.
- (3) Dr. Bhatnagar was our President and Chief Operating Officer as of December 31, 2013. On February 6, 2014, Dr. Bhatnagar was appointed as our Chief Executive Officer following Dr. Mario's appointment as our Executive Chairman.

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- (4) Mr. O Toole joined the company as our Chief Financial Officer on July 7, 2014.
- (5) Mr. Nabhan served as a consultant upon joining our company in 2013. Accordingly, Mr. Nabhan did not receive any base salary for 2013, but received payment of consulting fees for services rendered to our company during 2013.

Employment offer letters

We have entered into employment offer letters with each of our named executive officers. The offer letters provide for at-will employment and set forth the terms and conditions of employment, including annual base salary, target bonus opportunity, equity compensation, severance benefits and eligibility to participate in our employee benefit plans and programs. In connection with their employment, our named executive officers were each also required to execute our standard proprietary information and inventions agreement. The material terms of these offer letters are summarized below. These summaries are qualified in their entirety by reference to the actual text of the offer letters, which are filed as exhibits to the registration statement of which this prospectus is a part.

Agreement with Ernest Mario

We entered into an offer letter with Dr. Mario, dated June 22, 2007, pursuant to which Dr. Mario served as our Chief Executive Officer. The agreement provided for at-will employment and sets forth certain agreed upon terms and conditions of employment.

Agreement with Anish Bhatnagar

We entered into an employment agreement with Dr. Bhatnagar, dated April 26, 2010, pursuant to which Dr. Bhatnagar serves as our President and Chief Executive Officer. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Dr. Bhatnagar's current annual base salary is \$393,750.

Agreement with David D. O Toole

We entered into an employment agreement with Mr. O Toole, dated June 25, 2014, pursuant to which Mr. O Toole serves as our Chief Financial Officer. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Mr. O Toole's current annual base salary is \$250,000.

Agreement with Anthony Wondka

We entered into an offer letter with Mr. Wondka, dated May 29, 2013, pursuant to which Mr. Wondka serves as our Vice President of Research and Development. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Mr. Wondka's current annual base salary is \$235,000.

Agreement with Antoun Nabhan

We entered into an offer letter with Mr. Nabhan, dated April 17, 2014, pursuant to which Mr. Nabhan serves as our Vice President of Corporate Development. The agreement provides for at-will employment and sets forth certain agreed upon terms and conditions of employment. Mr. Nabhan's current annual base salary is \$225,000.

Potential payments and benefits upon termination or change of control

Dr. Bhatnagar. Pursuant to Dr. Bhatnagar's employment agreement, if Dr. Bhatnagar's employment is terminated without Cause by us (or our successor company) apart from a Change of Control (as defined in

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Dr. Bhatnagar's employment agreement) within two months prior to a Change of Control or within twelve months following a Change of Control, and if he executes and does not revoke a release of claims within 60 days following the date of his termination, Dr. Bhatnagar will be entitled to: (a) a lump sum severance payment equal to twelve months' of Dr. Bhatnagar's then current base salary; and (b) reimbursement for the cost of Dr. Bhatnagar's continued coverage under our employee benefit plans for a period ending on the earlier of twelve months following the date of the termination of his employment or the date on which he becomes eligible for coverage under similar employee benefit plans. In addition, pursuant to Dr. Bhatnagar's employment agreement, if, in the event of a Change of Control, Dr. Bhatnagar's employment is terminated without cause by us (or our successor company) or Dr. Bhatnagar resigns for Good Reason (as defined in Dr. Bhatnagar's employment agreement), and if he executes and does not revoke a release of claims within 60 days following the date of his termination, Dr. Bhatnagar will be entitled to: (i) a lump sum severance payment equal to eighteen months' of Dr. Bhatnagar's then current base salary; (ii) a lump sum payment equal to the pro-rated portion of Dr. Bhatnagar's target bonus for the year of his termination; and (c) reimbursement for the cost of Dr. Bhatnagar's continued coverage under our employee benefit plans for a period ending on the earlier of eighteen months following the date of the termination of his employment or the date on which he becomes eligible for coverage under similar employee benefit plans.

Outstanding equity awards at December 31, 2013

The following table provides information regarding outstanding equity awards held by our named executive officers as of December 31, 2013.

Name	Grant date	Number of Securities Underlying		Option	Option
		Exercisable	Unexercisable	Exercise Price	Expiration Date
Anish Bhatnagar	6/8/2006	5,208 ⁽¹⁾⁽³⁾		\$ 10.56	6/8/2016
Anish Bhatnagar	3/14/2007	4,166 ⁽¹⁾⁽²⁾		\$ 10.56	3/14/2017
Anish Bhatnagar	9/25/2007	1,041 ⁽¹⁾⁽³⁾		\$ 10.56	9/25/2017
Anish Bhatnagar	6/27/2008	11,666 ⁽¹⁾⁽³⁾		\$ 3.48	9/25/2018
Anish Bhatnagar	10/15/2008	8,333 ⁽¹⁾⁽³⁾		\$ 3.48	10/15/2018
Anish Bhatnagar	6/3/2010	58,419 ⁽¹⁾⁽³⁾		\$ 1.20	6/3/2020
Anthony Wondka				\$	
Antoun Nabhan				\$	
David D. O Toole				\$	

(1) The options listed are fully vested or are subject to an early exercise right and may be exercised in full prior to vesting of the shares underlying such options. Vesting of all options is subject to continued service on each vesting date.

(2) The shares subject to the stock option vest over a four-year period as follows: 25% of the shares underlying the options vest on the one-year anniversary of the vesting commencement date and thereafter 1/48th of the shares vest each month, subject to the continued service with us through each vesting date.

(3)

The shares subject to the stock option vest over a four-year period as follows: 1/48th of the shares vest each month, subject to the continued service with us through each vesting date.

Employee Benefits and Stock Plans

2014 Equity Incentive Plan

Our board of directors and stockholders have adopted our 2014 Equity Incentive Plan, or the 2014 Plan. The 2014 Plan has become effective and is not expected to be utilized until after the completion of this offering. Our 2014 Plan provides for the grant of incentive stock options (within the meaning of Section 422 of the Code) to our employees and any of our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, or NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to our employees, directors and consultants, and our parent and subsidiary corporations' employees and consultants.

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Authorized Shares. A total of 1,437,165 shares of our common stock are reserved for issuance pursuant to the 2014 Plan, of which no awards are issued and outstanding. In addition, the shares reserved for issuance under our 2014 Plan also includes: (a) those shares reserved but unissued under our 2010 Plan (as defined below) as of the effective date described above; and (b) shares returned to our 1999 Plan and 2010 Plan as the result of expiration or termination of options (provided that the maximum number of shares that may be added to the 2014 Plan pursuant to (a) and (b) is 240,906 shares). The number of shares available for issuance under the 2014 Plan also includes an annual increase on the first day of each year beginning in 2015, equal to the least of:

1,118,714 shares;

4.0% of the outstanding shares of common stock as of the last day of our immediately preceding year; or

such other amount as our board of directors may determine.

Our compensation committee will administer our 2014 Plan after the completion of this offering. In the case of options intended to qualify as performance-based compensation within the meaning of Section 162(m) of the Code, the committee will consist of two or more outside directors within the meaning of Section 162(m) of the Code.

Plan Administration. Subject to the provisions of our 2014 Plan, the administrator has the power to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards, and the form of consideration, if any, payable upon exercise. The administrator also has the authority to amend existing awards to reduce their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator and to institute an exchange program by which outstanding awards may be surrendered in exchange for awards with a higher or lower exercise price.

Stock Options. The exercise price of options granted under our 2014 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed ten years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. Subject to the provisions of our 2014 Plan, the administrator determines the term of all other options.

After the termination of service of an employee, director or consultant, he or she may exercise his or her option or stock appreciation right for the period of time stated in his or her award agreement. Generally, if termination is due to death or disability, the option or stock appreciation right will remain exercisable for twelve months. In all other cases, the option or stock appreciation right will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term.

Stock Appreciation Rights. Stock appreciation rights may be granted under our 2014 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Subject to the provisions of our 2014 Plan, the administrator will determine the terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in

cash or with shares of our common stock, or a combination thereof, except that

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the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock may be granted under our 2014 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator will determine the number of shares of restricted stock granted and may impose whatever conditions to vesting it determines to be appropriate (for example, the administrator may set restrictions based on the achievement of specific performance goals or continued service to us). The administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units may be granted under our 2014 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. The administrator will determine the terms and conditions of restricted stock units, including the number of units granted, the vesting criteria (which may include accomplishing specified performance criteria or continued service to us), and the form and timing of payment. The administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

Performance Units and Performance Shares. Performance units and performance shares may be granted under our 2014 Plan. Performance units and performance shares are awards that will result in a payment to a participant only if performance goals established by the administrator are achieved or the awards otherwise vest. The administrator will establish organizational or individual performance goals in its discretion, which, depending on the extent to which they are met, will determine the number or the value of performance units and performance shares to be paid out to participants. After the grant of a performance unit or performance share, the administrator, in its sole discretion, may reduce or waive any performance objectives or other vesting provisions for such performance units or performance shares. The administrator, in its sole discretion, may pay earned performance units or performance shares in the form of cash, in shares, or in some combination thereof.

Non-Employee Directors. Our 2014 Plan provides that all non-employee directors are eligible to receive all types of awards (except for ISOs) under the 2014 Plan. Please see the description of our non-employee director compensation above under Management Non-Employee Director Compensation.

Non-Transferability of Awards. Unless the administrator provides otherwise, our 2014 Plan generally will not allow for the transfer of awards, and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2014 Plan, the administrator will adjust the number and class of shares that may be delivered under the 2014 Plan or the number, class and price of shares covered by each outstanding award, and the numerical share limits set forth in the 2014 Plan.

Merger or Change in Control. Our 2014 Plan provides that in the event of a merger or change in control, as defined in the 2014 Plan, each outstanding award will be treated as the administrator determines, including that the successor corporation or its parent or subsidiary will assume or substitute an equivalent award for each outstanding award. The administrator is required to treat all awards similarly. If there is no assumption or substitution of outstanding awards, the awards will fully vest, all restrictions will lapse, all performance goals or other vesting criteria will be deemed achieved at 100% of target levels and the awards will become fully exercisable.

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In May 2014 and July 2014, our board of directors approved granting stock options to certain of our executive officers and our chairman, pursuant to our 2014 Plan, contingent and effective upon the closing of this offering. Each recipient will receive an option to purchase that number of shares of the our common stock sufficient to constitute that percentage of the Company's total fully-diluted equity capitalization then outstanding, including previously granted equity, as shown alongside the name of each individual as follows:

Ernest Mario	1.00%
Anish Bhatnagar	4.00%
Anthony Wondka	0.60%
Antoun Nabhan	0.50%
David D. O Toole	1.00%
Gina Phelps	0.25%

Each of these options shall vest over a four-year period. The exercise price for these option grants shall be equal to at least 110% of the fair market value of the common stock on the date of grant.

2014 Employee Stock Purchase Plan

Our board of directors and stockholders have adopted the 2014 Employee Stock Purchase Plan, or the ESPP. The ESPP has become effective, and with our board of directors will implement commencement of offers thereunder in its discretion after the completion of this offering.

Authorized Shares. A total of 139,839 shares of our common stock has been made available for sale under the ESPP. In addition, our ESPP provides for annual increases in the number of shares available for issuance under the plan on the first day of each year beginning in the year following the initial date that our board of directors authorizes commencement, equal to the least of:

1.0% of the outstanding shares of our common stock on the first day of such year;

279,680 shares; or

such amount as determined by our board of directors.

Plan Administration. Our compensation committee administers the ESPP and has full and exclusive authority to interpret the terms of the plan and determine eligibility to participate, subject to the conditions of the plan as described below.

Eligibility. Generally, all of our employees are eligible to participate if they are employed by us, or any participating subsidiary, for at least 20 hours per week and more than five months in any calendar year. However, an employee may not be granted rights to purchase stock under the ESPP if such employee:

immediately after the grant would own stock possessing 5% or more of the total combined voting power or value of all classes of our capital stock; or

hold rights to purchase stock under all of our employee stock purchase plans that accrue at a rate that exceeds \$25,000 worth of stock for each calendar year.

Offering Periods. Our ESPP is intended to qualify under Section 423 of the Code. Each offering period includes purchase periods, which will be the approximately six months commencing with one exercise date and

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ending with the next exercise date. The offering periods are scheduled to start on the first trading day on or after and of each year, except for the first offering period, which will commence on such future date as our board of directors may determine.

Our ESPP permits participants to purchase shares of common stock through payroll deductions of up to 15.0% of their eligible compensation. A participant may purchase a maximum of shares during a six-month period.

Exercise of Purchase Right. Amounts deducted and accumulated by the participant will be used to purchase shares of our common stock at the end of each six-month purchase period. The purchase price of the shares will be 85.0% of the lower of the fair market value of our common stock on the first trading day of each offering period or on the exercise date. If the fair market value of our common stock on the exercise date is less than the fair market value on the first trading day of the offering period, participants will be withdrawn from the current offering period following their purchase of shares on the purchase date and will be automatically re-enrolled in a new offering period. Participants may end their participation at any time during an offering period and will be paid their accrued contributions that have not yet been used to purchase shares of common stock. Participation ends automatically upon termination of employment with us.

Non-Transferability. A participant may not transfer rights granted under the ESPP. If the compensation committee permits the transfer of rights, it may only be done by will, the laws of descent and distribution, or as otherwise provided under the ESPP.

Merger or Change in Control. In the event of our merger or change in control, as defined under the ESPP, a successor corporation may assume or substitute each outstanding purchase right. If the successor corporation refuses to assume or substitute for the outstanding purchase right, the offering period then in progress will be shortened, and a new exercise date will be set. The administrator will notify each participant that the exercise date has been changed and that the participant's option will be exercised automatically on the new exercise date unless prior to such date the participant has withdrawn from the offering period.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent dilution or enlargement of the benefits or potential benefits available under the ESPP, the administrator will adjust the number and class of shares that may be delivered under the ESPP, the purchase price per share and the number of shares covered by each option and the numerical share limits set forth in the ESPP.

Amendment; Termination. Our ESPP will automatically terminate in 2034, unless we terminate it sooner. Our board of directors has the authority to amend, suspend, or terminate our ESPP, except that, subject to certain exceptions described in the ESPP, no such action may adversely affect any outstanding rights to purchase stock under our ESPP.

Employee benefit plans

Our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, and accidental death and dismemberment insurance plans, in each case, on the same basis as all of our other employees. We maintain a 401(k) plan for the benefit of our eligible employees, including our named executive officers, as discussed in the section below entitled "Employee benefit plans 401(k) Plan."

1999 Stock Plan

Our board of directors and stockholders adopted our 1999 Incentive Stock Plan, or the 1999 Plan, in October 1999. Our 1999 Plan provided for the grant of nonstatutory stock options, or NSOs, and stock purchase rights to employees and consultants of ours or any parent or subsidiary of ours and to our directors. Our 1999 Plan

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also provided for the grant of incentive stock options, or ISOs (within the meaning of Section 422 of the Code), to employees of ours or any parent or subsidiary of ours. Our 1999 Stock Plan expired by its terms on October 5, 2009 and, accordingly, no further grants will be made under our 1999 Stock Plan. However, any outstanding awards granted under our 1999 Plan will remain outstanding, subject to the terms of our 1999 Plan and the applicable award agreements, until such awards are exercised or otherwise terminate or expire by their terms.

Authorized shares. Prior to the expiration of the 1999 Plan, the maximum number of shares of our common stock reserved for issuance under our 1999 Plan was 154,154 shares. As of June 30, 2014, options to purchase 154,154 shares of our common stock remained outstanding under the 1999 Plan.

Shares issued under our 1999 Plan included any authorized but unissued or reacquired shares of our common stock.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, may administer our 1999 Plan. Subject to the terms of our 1999 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise or purchase price of the awards (if any), the number of shares subject to awards, the vesting schedule applicable to the awards, and any transfer restrictions or rights of repurchase. Additionally, the administrator has the authority to determine the fair market value of our common stock, to determine whether and under what circumstances an option may be settled in cash instead of common stock, to reduce the exercise price of an option to the then-current fair market value of our common stock, to initiate an option exchange program whereby outstanding options are exchanged for options with a lower exercise price, and to allow optionees to satisfy withholding tax obligations by electing to have us withhold otherwise deliverable shares. The administrator also has the authority to prescribe, amend, and rescind rules and regulations relating to the 1999 Plan and to construe and interpret the terms of the 1999 Plan and awards granted pursuant to the 1999 Plan. All decisions, interpretations and other actions of our board of directors will be final and binding.

Stock Options. Stock options could be granted under the 1999 Plan. The exercise price of nonstatutory stock options granted under our 1999 Plan must at least be equal to 85% of the fair market value of our common stock on the date of grant, and the exercise price of incentive stock options granted under our 1999 Plan must at least be equal to the fair market value of our common stock on the date of grant, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the exercise price of any option must equal at least 110% of the fair market value on the grant date. The term of a stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term of an incentive stock option must not exceed 5 years. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for the period of time stated in his or her option agreement. Generally, if termination is due to death or disability, the option will remain exercisable for 12 months. In all other cases, the option will generally remain exercisable for three months following the termination of service. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 1999 Plan, the administrator determined the other terms of options.

Stock Purchase Rights. Restricted stock could be issued pursuant to the exercise or stock purchase rights granted under our 1999 Plan. Restricted stock consists of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator determined the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 1999 Plan, determined the terms and conditions of such awards. The administrator could impose whatever conditions to vesting it determined to be

appropriate (for example, the administrator may have set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

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Holders of restricted stock generally have voting and dividend rights with respect to such shares upon issuance without regard to vesting, unless the administrator provided otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Non-Transferability of Awards. Our 1999 Plan does not allow for the transfer of awards, and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 1999 Plan, the administrator will adjust the number and class of shares that may be delivered under the 1999 Plan or the number, class and price of shares covered by each outstanding award.

Dissolution or Liquidation. In the event of our proposed dissolution or liquidation, the administrator will notify participants as soon as practicable. The administrator may allow for awards to be exercised until 15 days prior to such transaction as to all of the shares subject to such awards, including shares which would not otherwise be exercisable. In addition, the administrator may provide that any repurchase option of ours will lapse, so long as the proposed dissolution or liquidation takes place at the time and in the manner contemplated. All awards will terminate immediately prior to the consummation of such proposed transaction.

Merger or Asset Sale. Our 1999 Plan provides that in the event of a merger or sale of substantially all of the assets of our company, each outstanding award will be assumed or an equivalent award will be substituted by the successor corporation or its parent or subsidiary. If the successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, and the administrator will notify the holder of the award that such award will be fully exercisable for a period of 15 days from the date of such notice. The award will then terminate upon the expiration of the specified period of time.

Plan amendment or termination. Our board of directors has the authority to amend our 1999 Plan, provided that such action does not impair the existing rights of any participant without such participant's written consent.

2010 Stock Plan

Our board of directors and stockholders adopted our 2010 Plan in May 2010. Our 2010 Plan provides for the grant of NSOs, stock appreciation rights, restricted stock, and restricted stock units to employees and consultants of ours or any parent or subsidiary of ours and to our directors. Our 2010 Plan also provides for the grant of ISOs (within the meaning of Section 422 of the Code) to employees of ours or any parent or subsidiary of ours. Our 2010 Stock Plan will be terminated in connection with our initial public offering, and accordingly, no further grants will be made under our 2010 Plan. However, any outstanding awards granted under our 2010 Plan will remain outstanding, subject to the terms of our 2010 Plan and the applicable award agreements, until such awards are exercised or otherwise terminate or expire by their terms.

Authorized shares. Prior to the termination of the 2010 Plan, the maximum number of shares of our common stock reserved for issuance under our 2010 Plan is 210,314 shares. As of June 30, 2014, options to purchase 82,433 shares of our common stock remain outstanding.

Shares issued under our 2010 Plan include any authorized but unissued or reacquired shares of our common stock.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors, may administer our 2010 Plan. Subject to the terms of our 2010 Plan, the administrator will have the power to administer the 2010 Plan, including but not limited to the power to interpret the terms of the 2010 Plan and awards granted under it; to create, amend, and revoke rules relating to the 2010 Plan, including creating sub-

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plans; and to determine the terms of the awards, including the exercise price, the number of shares subject to each such award, the exercisability of the awards, and the form of consideration, if any, payable upon exercise. The administrator will also have the authority to amend existing awards to reduce or increase their exercise price, to allow participants the opportunity to transfer outstanding awards to a financial institution or other person or entity selected by the administrator, and to institute an exchange program by which outstanding awards may be surrendered in exchange for awards of the same type which may have a higher or lower exercise price or different terms, awards of a different type, or cash.

Stock Options. Stock options could be granted under the 2010 Plan. The exercise price of options granted under our 2010 Plan must at least be equal to the fair market value of our common stock on the date of grant. The term of a stock option may not exceed 10 years, except that with respect to an ISO granted to a participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed 5 years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator determined the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. After the termination of service of an employee, director or consultant, he or she may exercise his or her option for 30 days (or 6 months in the case of a termination due to death or disability) or such longer period of time stated in his or her option agreement. However, in no event may an option be exercised later than the expiration of its term. Subject to the provisions of our 2010 Plan, the administrator determines the other terms of options.

Stock Appreciation Rights. Stock appreciation rights could be granted under our 2010 Plan. Stock appreciation rights allow the recipient to receive the appreciation in the fair market value of our common stock between the exercise date and the date of grant. Stock appreciation rights may not have a term exceeding 10 years. After the termination of service of an employee, director or consultant, he or she may exercise his or her stock appreciation right for the period of time stated in his or her option agreement. However, in no event may a stock appreciation right be exercised later than the expiration of its term. Subject to the provisions of our 2010 Plan, the administrator determined the other terms of stock appreciation rights, including when such rights become exercisable and whether to pay any increased appreciation in cash or with shares of our common stock, or a combination thereof, except that the per share exercise price for the shares to be issued pursuant to the exercise of a stock appreciation right will be no less than 100% of the fair market value per share on the date of grant.

Restricted Stock. Restricted stock could be granted under our 2010 Plan. Restricted stock awards are grants of shares of our common stock that vest in accordance with terms and conditions established by the administrator. The administrator determines the number of shares of restricted stock granted to any employee, director or consultant and, subject to the provisions of our 2010 Plan, determined the terms and conditions of such awards. The administrator could impose whatever conditions to vesting it determined to be appropriate (for example, the administrator may have set restrictions based on the achievement of specific performance goals or continued service to us); provided, however, that the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed. Recipients of restricted stock awards generally have voting and dividend rights with respect to such shares upon grant without regard to vesting, unless the administrator provided otherwise. Shares of restricted stock that do not vest are subject to our right of repurchase or forfeiture.

Restricted Stock Units. Restricted stock units could be granted under our 2010 Plan. Restricted stock units are bookkeeping entries representing an amount equal to the fair market value of one share of our common stock. Subject to the provisions of our 2010 Plan, the administrator determined the terms and conditions of restricted stock units, including the vesting criteria (which may include accomplishing specified performance criteria or continued service to

us) and the form and timing of payment. Notwithstanding the foregoing, the administrator, in its sole discretion, may accelerate the time at which any restrictions will lapse or be removed.

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Non-Transferability of Awards. Unless the administrator provided otherwise, our 2010 Plan generally does not allow for the transfer of awards and only the recipient of an award may exercise an award during his or her lifetime.

Certain Adjustments. In the event of certain changes in our capitalization, to prevent diminution or enlargement of the benefits or potential benefits available under the 2010 Plan, the administrator will adjust the number and class of shares that may be delivered under the Plan or the number, class, and price of shares covered by each outstanding award, and the numerical share limits set forth in the 2010 Plan. In the event of our proposed liquidation or dissolution, the administrator will notify participants as soon as practicable and all awards will terminate immediately prior to the consummation of such proposed transaction.

Dissolution or Liquidation. In the event of our proposed dissolution or liquidation, the administrator will notify participants as soon as practicable, and all awards will terminate immediately prior to the consummation of such proposed transaction.

Change in control. Our 2010 Plan provides that in the event of a change in control, as defined under our 2010 Plan, each outstanding award will be treated as the administrator determines, except that if a successor corporation or its parent or subsidiary does not assume or substitute an equivalent award for any outstanding award, then such award will fully vest, all restrictions on such award will lapse, all performance goals or other vesting criteria applicable to such award will be deemed achieved at 100% of target levels and such award will become fully exercisable, if applicable, for a specified period prior to the transaction. The award will then terminate upon the expiration of the specified period of time.

Plan amendment or termination. Our board of directors has the authority to amend our 2010 Plan, provided that such action does not impair the existing rights of any participant without such participant's written consent.

401(k) plan

We maintain a retirement savings plan, or 401(k) plan, that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Under our 401(k) plan, eligible employees may defer eligible compensation subject to applicable annual contribution limits imposed by the Code. Employees' pre-tax contributions are allocated to each participant's individual account. Participants are immediately and fully vested in their contributions. We do not currently provide an employer match on employee contributions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Limitation on Liability and Indemnification Matters

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective upon the completion of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law, which prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

any breach of the director's duty of loyalty to the corporation or its stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

unlawful payments of dividends or unlawful stock repurchases or redemptions; or

any transaction from which the director derived an improper personal benefit.

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If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director's duty of care and in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director's responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered into indemnification agreements with each of our current directors and officers. These agreements provide indemnification for certain expenses and liabilities incurred in connection with any action, suit, proceeding, or alternative dispute resolution mechanism, or hearing, inquiry, or investigation that may lead to the foregoing, to which they are a party, or are threatened to be made a party, by reason of the fact that they are or were a director, officer, employee, agent, or fiduciary of our company, or any of our subsidiaries, by reason of any action or inaction by them while serving as an officer, director, agent, or fiduciary, or by reason of the fact that they were serving at our request as a director, officer, employee, agent, or fiduciary of another entity. In the case of an action or proceeding by, or in the right of, our company or any of our subsidiaries, no indemnification will be provided for any claim where a court determines that the indemnified party is prohibited from receiving indemnification. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as we may provide indemnification for liabilities arising under the Securities Act to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

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