Capnia, Inc.
Form 10-K
March 13, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2014

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

For the transition period from _____ to _____.

Commission File No.: 001-36593

Capnia, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	77-0523891
(State or other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

3 Twin Dolphin Drive, Suite 160

Redwood City, California	94065
(Address of Principal Executive Offices)	(Zip Code)

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

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class:	Name of Each Exchange on which Registered:
Common Stock, par value $0.001 per share	The NASDAQ Capital Market
Series A warrants to purchase Common Stock	The NASDAQ Capital Market

Securities Registered Pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

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

The aggregate market value of voting stock held by non-affiliates of the registrant on November 13, 2014, based on the closing price of $3.88 for shares of the registrant s common stock as reported by the NASDAQ Capital Market, was approximately $6.2 million. The registrant has elected to use November 13, 2014 as the calculation date, which was the initial trading date of the registrant s common stock on the Nasdaq Capital Market, because on June 30, 2014 (the last business day of the registrant s most recently completed second fiscal quarter), the registrant was a privately-held company.

As of February 15, 2015, there were 6,769,106 shares of the registrant s Common Stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Definitive Proxy Statement to be filed with the Commission pursuant to Regulation 14A in connection with the registrant s 2014 Annual Meeting of Stockholders, to be filed subsequent to the date hereof, are incorporated by reference into Part III of this Report. Such Definitive Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days after the conclusion of the registrant s fiscal year ended December 31, 2014. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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Capnia, Inc.

Annual Report on Form 10-K

For The Year Ended December 31, 2014

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, particularly in Part I, Item 1: Business, Part I, Item 1A: Risk Factors and Part 2, Item 7: Management s Discussion and Analysis of Financial Condition and Results of Operations. These statements are often identified by the use of words such as may, will, expect, believe, anticipate, intend, could, shou plan or continue, and similar expressions or variations. All statements other than statements of historical fact could be deemed forward-looking, including, but not limited to: any projections of financial information; any statements about historical results that may suggest trends for our business; any statements of the plans, strategies, and objectives of management for future operations; any statements of expectation or belief regarding future events, technology developments, our products, product sales, expenses, liquidity, cash flow, market growth rates or enforceability of our intellectual property rights and related litigation expenses; and any statements of assumptions underlying any of the foregoing. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Accordingly, we caution you not to place undue reliance on these statements. Particular uncertainties that could affect future results include: our ability to achieve or maintain profitability; our ability to obtain substantial additional capital that may be necessary to expand our business; our ability to maintain internal control over financial reporting; our dependence on, and need to attract and retain, key management and other personnel; our ability to obtain, protect and enforce our intellectual property rights; potential advantages that our competitors and potential competitors may have in securing funding or developing products; business interruptions such as earthquakes and other natural disasters; our ability to comply with laws and regulations; potential product liability claims; and our ability to use our net operating loss carryforwards to offset future taxable income. For a discussion of some of the factors that could cause actual results to differ materially from our forward-looking statements, see the discussion on risk factors that appear in Part I, Item 1A: Risk Factors of this Annual Report on Form 10-K and other risks and uncertainties detailed in this and our other reports and filings with the Securities and Exchange Commission, or SEC. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

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PART I

ITEM 1. BUSINESS

Company Overview

We develop novel products based on our proprietary technology for precision metering of gas flow. Our first product, CoSense®, aids in the detection 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 is 510(k) cleared for sale in the U.S. and received CE Mark certification for sale in the European Union, or E.U.

Our therapeutic technology involves the use of precisely metered nasal carbon dioxide for the potential treatment of various diseases. Several randomized placebo controlled trials have shown its efficacy in the symptomatic treatment of allergic rhinitis and we continue to evaluate our options to further develop this product. In addition, we have recently announced new initiatives for the development of this technology for the treatment of trigeminally mediated pain disorders such as cluster headache and trigeminal neuralgia. We have also applied for orphan designation for the latter indication in the US.

Our research and development efforts are primarily 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 widely used tool, by aiding in the detection 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 may 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 detection 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 detection of 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 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. 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.

Commercial activities for CoSense have been initiated and we announced the first commercial sales in early 2015. CoSense combines a portable detection device with a single-use disposable nasal cannula to measure

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ETCO. While our launch efforts will continue to 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.

We have begun 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 products 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 CO_2, 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.

Our therapeutic technology consists of the use of nasal, non-inhaled CO_2 for the treatment of the symptoms of allergy, as well as pain associated with migraine, cluster headache and trigeminal neuralgia, or TN. Serenz, our allergy 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 intend to determine the regulatory approval pathway with the U.S. Food and Drug Administration, or FDA, for Serenz and subsequently to seek partnership or distributorship arrangements for commercialization globally.

We currently plan to enter into a collaboration agreement Clinvest, with a research organization dedicated to the advancement of medicine and health through clinical research in order to develop a therapeutic product for the treatment of cluster headache. Cluster headaches are characterized by recurring bouts of excruciating pain in one side of the head.

We have submitted an application to the FDA, requesting Orphan Drug Designation for our nasal, non-inhaled CO_2 technology for the treatment of TN. TN is a clinical condition characterized by debilitating pain in regions of the face innervated by one or more divisions of the trigeminal nerve.

CoSense

CoSense is the first device using our Sensalyze Technology Platform to achieve regulatory approval. CoSense measures 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, other than CoSense, 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 are at risk for hemolysis under current practice, representing approximately 3.1 million newborns. We believe that many of these infants

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are tested for hemolysis, but using relatively inaccurate and/or 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.

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 central nervous system 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, Coombs test and peripheral smear, are all invasive blood tests and are less useful in neonates due to physiologic changes resulting from childbirth. For example, hematocrit levels and reticulocyte counts may be elevated in neonates unrelated to pathological conditions and may therefore 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

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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.

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 detection 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.

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 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. CoSense delivers results within minutes, which may enable more timely treatment than the current standard of care.

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

CoSense, our first Sensalyze Technology Platform product to receive 510(k) clearance from the FDA and CE Mark certification, 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. The cannula is placed just inside the nostril of the patient and is connected to the monitor. The CoSense device is turned on and acquires the breath signal while the patient breathes. Appropriate sample

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acquisition takes an average of 30 seconds. The cannula can then be removed from the patient and the device takes another four minutes to report the test result.

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 other than CoSense 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 may then initiate earlier treatments for jaundice, such as phototherapy, when necessary. 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 detect the rate 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.

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. 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, 83 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

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in the subset of 24 of the 83 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.

In the bench studies, a close correlation between the two was seen (r = 0.93), confirming that ETCO values with CoSense accurately measure bilirubin production and therefore hemolysis.

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. These data from the study showed 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.

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 the subject was found to have asthma and was on anti-epileptic medication. The data from this trial showed that CoSense may be useful to monitor the rate of hemolysis in children with SCA.

We have initiated a multi-center investigator-sponsored trial to define the normative data (mean, median, range and interquartile ranges) for all term and late-preterm newborns for CoSense. The investigating institutions include Lucile Packard Children s Hospital at Stanford University School of Medicine, Albert Einstein Medical Center, Beaumont Children s Hospital and McKay-Dee Hospital/Intermountain Healthcare. This is a collaborative, voluntary, multi-center, open-label, single-arm study. Up to 2,000 newborns will be enrolled into this study.

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 babies, and 80% of preterm and late

preterm babies, or approximately 900,000 babies, are jaundiced and are at greatest risk for

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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.

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 initially market CoSense for use in 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 deployed primarily in large metropolitan areas, including the New York Tri-State area, Los Angeles, Chicago and Atlanta, we believe we will have the sales force capacity to develop appropriate relationships with various stakeholders at the large centers within these areas.

We expect the majority of our revenues to result from 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.

Key elements of our sales and marketing strategy include:

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

Price the CoSense consumable cannula at 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.

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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 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.

Pricing and Reimbursement

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, will likely be driven at the departmental rather than at the institutional level. The primary decision makers are expected be the neonatologists and nurse managers in the pediatrics and neonatology departments. Our initial efforts are focused on expanding 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 achieve reduced cost of goods that will lead to scaleable future growth.

Since the use of CoSense is almost entirely in the inpatient setting around the time of birth, reimbursement may 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, payor 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.

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

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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;

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. 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.

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 patent protected platform for non-invasive detection of various analytes.

Sensalyze Technology Platform Research and Development of Additional Diagnostic Products

Our primary focus is currently on the commercialization of CoSense. Once the CoSense business is generating adequate revenue, we intend to utilize our research and development expertise to develop 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 or NO, for assessment and management of asthma in children younger than seven years of age;

End-tidal CO_2 for neonates;

Hydrogen breath testing for infants with colic;

Carbon monoxide levels for hemolysis, CO poisoning;

Acetone, nitrites for diabetes;

Volatile Organic Compounds (VOC) for cancer, heart failure and multiple sclerosis; and

Alkanes, transplant rejection.

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

Nasal CO_2 Technology

Cluster Headache

Cluster headaches affect approximately 0.2% of the population, and are characterized by recurring bouts of excruciating pain in one side of the head. Episodes of pain typically last from 15 minutes to three hours. They can occur several times a day over several months before remitting. The same pattern often recurs multiple times over a

patient s lifetime. Approximately 10 to 15% of cluster patients have chronic cluster headache, with continuing pain with no remission. The pain of cluster headache may be significantly greater than other conditions, such as severe migraine.

In January of 2015, we executed a memorandum of understanding with Clinvest, a division of Banyan Group, Inc., to conduct an investigator-sponsored clinical trial evaluating our nasal, non-inhaled carbon dioxide on up to 50 patients with episodic cluster headaches.

Trigeminal Neuralgia

TN is a clinical condition characterized by debilitating pain in regions innervated by one or more divisions of the trigeminal nerve. The pain is typically described as intense, sharp and stabbing, and is often described as one of the most painful conditions known to humans. It may develop without apparent cause or be a result of another diagnosed disorder. Peripheral TN is caused by a variety of diseases, including multiple sclerosis and herpes zoster.

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The International Headache Society describes TN as a disorder characterized by recurrent unilateral brief electric shock-like pains, abrupt in onset and termination, limited to the distribution of one or more divisions of the trigeminal nerve and triggered by innocuous stimuli. There may be persistent background facial pain of moderate intensity. Based on the J. Penman 1968 publication in the Handbook of Clinical Neurology, we currently estimate that approximately 100,000 people are afflicted with TN.

On December 3, 2014, we submitted an application to the FDA requesting Orphan Drug Designation for our nasal, non-inhaled CO_2 technology for the treatment of TN.

Allergic Rhinitis

Allergic rhinitis, which is commonly and colloquially referred to as allergies, is characterized by symptoms that 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.

Serenz is based upon the observation that non-inhaled CO_2 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 CO_2 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 is well tolerated. 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.

One Serenz device 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 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

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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. Given that the symptoms of AR are typically episodic, such as when an AR sufferer is exposed to a pollen when they step outdoors in allergy season, we believe an as-needed treatment paradigm is more optimal. 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.

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 CO_2 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.

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 CO_2, and for more than 1,000 patients treated in all of the AR clinical trials, only six patients discontinued use of nasal CO_2 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.

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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 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 CO_2 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 CO_2 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.

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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;
- 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 CO_2 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.

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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.

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 FFDCA. 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 a 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

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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.

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.

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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 FFDCA 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 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-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

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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 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

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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 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.

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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.

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

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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.

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.

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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 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

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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 December 31, 2014, we had 12 full-time employees and 7 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. Under the terms of our sublease, we have the option to renew our lease for the remainder of the master lease term, which expires June 20, 2018 (see Note 16).

Corporate and Available Information

Our principal corporate offices are located at 3 Twin Dolphin Drive, Suite 160, Redwood City, California 94065 and our telephone number is (650) 213-8444. We were incorporated in Delaware on August 25, 1999. Our internet address is www.Capnia.com. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such materials with, or furnish it to, the Securities Exchange Commission, or the SEC. Our SEC reports can be accessed through the Investor Relations section of our internet website. The information found on our internet website is not part of this or any other report we file with or furnish to the SEC.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below together with the other information set forth in this Annual Report on Form 10-K, which could materially affect our business, financial condition or future results. The risks described below are not the only risks facing our company. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

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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 certification 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 an indefinite period of time. As of December 31, 2014, we had an accumulated deficit of $71.0 million.

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

We currently have no source of product revenue and may never become profitable.

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

- develop a commercial organization capable of sales, marketing and distribution of any products for which we obtain marketing approval in markets where we intend to commercialize independently;
- achieve market acceptance of our products, if any;
- set a commercially viable price for our products;
- establish and maintain supply and manufacturing relationships with reliable third parties, and ensure adequate and legally compliant manufacturing to maintain that supply;

obtain coverage and adequate reimbursement from third-party payors, including government and private payors;

find suitable distribution partners for CoSense or Serenz to help us market, sell and distribute our approved products in other markets;

demonstrate the safety and efficacy of Serenz to the satisfaction of FDA and obtain regulatory approval for Serenz and planned products, if any, for which there is a commercial market;

complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;

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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 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 our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

the cost and risk of initiating sales and marketing activities, including substantial hiring of sales and marketing personnel;

the timing and cost of, and level of investment in, research and development activities relating to our planned products, which will change from time to time;

our ability to enroll patients in clinical trials and the timing of enrollment;

the cost of manufacturing CoSense and any planned products, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;

expenditures that we will or may incur to acquire or develop additional planned products and technologies;

the design, timing and outcomes of clinical studies for Serenz and any planned products or competing planned products;

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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.

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 December 31, 2014, we had approximately $8 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;

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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;

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.

Risks related to the development and commercialization of our products

Our success depends heavily on the successful commercialization of our CoSense device to aid in diagnosis of neonatal hemolysis. If we are unable to sell sufficient numbers of our CoSense instruments and disposables, our revenues may be insufficient to achieve profitability.

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

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

We have no history of successful product launches. Our efforts to launch CoSense into the neonatology marketplace are subject to a variety of risks, any of which may prevent or limit sales of the CoSense instruments and consumables. Furthermore, commercialization of products into the medical marketplace is subject to a variety of regulations regarding the manner in which potential customers may be engaged, the manner in which products may be lawfully advertised, and the claims that can be made for the benefits of the product, among other things. Our lack of experience with product launches may expose us to a higher than usual level of risk of non-compliance with these regulations, with consequences that may include fines or the removal of CoSense from the marketplace by regulatory authorities.

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

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

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

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

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

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

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

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

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

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

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

If our sole final-assembly manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to sell CoSense and to and 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.

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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 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, 2014, our research and development expenses were $2.2 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 CE Mark certification, 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 certification 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

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launch. Also, any regulatory approval of Serenz, once obtained, may be withdrawn. Even if we obtain regulatory approval for Serenz in additional countries, the commercial success of the product will depend on a number of factors, including the following:

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

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

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.

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

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

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

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

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;

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the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate or patients may drop out of these clinical studies at a higher rate than we anticipate;

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

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

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

regulators may not approve our proposed clinical development plans;

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

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

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

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

be delayed in obtaining marketing approval for our planned products;

not obtain marketing approval at all;

obtain approval for indications that are not as broad as intended;

have the product removed from the market after obtaining marketing approval;

be subject to additional post-marketing testing requirements; or

be subject to restrictions on how the product is distributed or used.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any clinical studies will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Significant clinical study delays also could shorten any periods during which we may have the exclusive right to commercialize our planned products or allow our competitors to bring products to market before we do, which would impair our ability to commercialize our planned products and harm our business and results of operations.

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

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

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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.

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.

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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;

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;

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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. 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

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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 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;

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

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

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

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

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

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

To succeed in selling CoSense and any other products that we are able to develop, we must develop a sales force in the U.S. and internationally by recruiting sales representatives with extensive experience in neonatology

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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 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.

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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;
- 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

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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 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

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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;
- 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

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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 December 31, 2014, we had 12 employees and 7 full-time or part-time consultants. Over the next several years, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of engineering, product development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Future growth would impose significant added responsibilities on members of management, including:

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

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

Because we intend to commercialize 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

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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.

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,

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

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

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

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

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commercial value of the patent rights we rely on are highly uncertain. Pending and future patent applications may not result in patents being issued which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of the patents we rely on or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we or were the first to file for patent protection of such inventions.

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

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

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

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

involved in disputes with others regarding the ownership of intellectual property rights. If we are unable to resolve these disputes, we could lose valuable intellectual property rights.

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

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

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

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

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

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

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

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

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

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.

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

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

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

Risks related to government regulation

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

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

warning letters;

civil or criminal penalties and fines;

injunctions;

suspension or withdrawal of regulatory approval;

suspension of any ongoing clinical studies;

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

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humans may produce undesirable side effects, which could interrupt, delay or cause suspension of clinical studies of our planned products and result in the FDA or other regulatory authorities denying approval of our planned products for any or all targeted indications.

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

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

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

If we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from a streamlined regulatory process as well as potential commercial benefits following approval. Currently, this designation provides market exclusivity in the U.S. and the EU for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is clinically superior to the original orphan drug.

We have applied for orphan drug designation from the FDA for our nasal, non-inhaled CO2 technology for the treatment of TN. If we seek orphan drug designations for this or other indications or in other jurisdictions, we may fail to receive such orphan drug designations and, even if we succeed, such orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

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

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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 certification for CoSense and it is therefore authorized for sale in the E.U.; however, in order to market our planned products in Asia, Latin America and other foreign jurisdictions, we must obtain separate regulatory approvals.

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

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

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

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

could result in the imposition of injunctions;

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

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

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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;
- 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.

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

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

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

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

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

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

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the 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.

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Risks related to ownership of our securities

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

Our stock price has been and is likely to continue to be volatile. The stock market in general, and the market for biotechnology and medical device companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Since shares of our common stock were sold in our initial public offering, or IPO, in November 2014 at a price of $6.50 per unit, the reported high and low prices of our common stock have ranged from $4.04 to $1.02 through February 2, 2015. As a result of this volatility, investors may not be able to sell their common stock at or above the purchase price. The market price for our common stock may be influenced by many factors, including the following:

- our ability to successfully commercialize, and realize 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;
- 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.

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

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

In connection with the IPO, we, our officers and directors and holders of 1% or more of our currently outstanding shares of common stock have agreed, subject to limited exceptions, not to sell or transfer any shares of common stock for 180 days after the date of pricing our IPO 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 2,406,299 shares of common stock may be sold in the public market by existing stockholders after the date of pricing our IPO and an additional 4,362,807 shares of common stock may be sold in the public market by existing stockholders on or about 181 days after the date of the pricing our IPO, 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 pricing of our IPO, or the perception that such sales could occur, could adversely affect the market price of our common stock and could materially impair our ability to raise capital through offerings of our common stock.

We have issued Series A warrants and Series B warrants to purchase a total of 3,795,000 shares of common stock in the IPO, each subject to adjustment. The Series B warrants include a cashless exercise feature that issues shares of common stock to the holders of Series B warrants without consideration in the event that the market price of our common stock is trading below $6.49 per share in the period between four and fifteen months after the IPO. As of February 2, 2015, based on our closing price of $1.69 per share, the Series B warrants would be cashless exercisable for an aggregate of approximately 14 million shares of our common stock. See Note 7 for additional information on the terms of our Series A warrants and Series B warrants.

We have also issued compensation warrants to the underwriters in the IPO to purchase an additional 82,500 shares of our common stock. In addition, as of December 31, 2014, we had outstanding options to purchase 1,072,011 shares of our common stock and additional outstanding warrants to purchase common stock issued prior to our IPO for an aggregate of 533,126 shares of our common stock. We have registered for offer and sale the shares of common stock that are reserved for issuance pursuant to outstanding options. Shares covered by such registration statements upon the exercise of stock options generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act of 1933, as amended. The issuance or sale of such shares could depress the market price of our common stock.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, which was enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive

compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to

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

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

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.

Our executive officers, directors and stockholders own a majority of our outstanding common stock. Entities associated with Vivo Ventures and our Chairman, Ernest Mario, own approximately 60% of our common stock. As a result, the forgoing group of stockholders are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these stockholders will control the election of directors and the approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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 became eligible upon the closing of the IPO, we may in the future avail ourselves of this exemption, which could make our common stock less attractive to some investors or otherwise harm our stock price.

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

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

We have incurred and will continue to incur significant legal, accounting and other expenses as a public company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the

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

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

We identified a material weakness in our internal control over financial reporting as of December 31, 2014, 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 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

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completion of the IPO, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for the IPO, we determined that material adjustments to various accounts were necessary, which required us to restate the financial statements for the year ended December 31, 2012, which had been previously audited by another independent audit firm. These adjustments leading to a restatement of those financial statements led us to conclude that we had a material weakness in internal 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 ended December 31, 2014.

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

For a discussion of our remediation plan and the actions that we have executed during 2014, see Item 9a. We believe these steps, which are now fully implemented, have remediated the material weakness previously identified and have enhanced our internal control over financial reporting, as well as our disclosure controls and procedures. However, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

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

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

We have issued Series A warrants and Series B warrants to purchase a total of 4,899,710 shares. In the event that the market price of our common stock remains 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 price of our common stock at the time. This may result in a number of shares issued, pursuant to the cashless exercise of Series B warrants, significantly in excess of the original 2,449,605 shares. If the price of our common stock were to fall to $1.00 per share, the minimum share price necessary for continued listing on the NASDAQ Capital Market, at any time more than four months, and less than fifteen months, after the IPO, the number of shares for which the Series B warrants may be exercised would exceed 18 million shares. This would result in majority ownership of our common

stock by Series B warrantholders, if all the Series B warrantholders exercised their warrants at that time. Under certain other circumstances, exercises of the Series A warrants and

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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.

As of December 31, 2014, options to purchase 1,072,011 shares of our common stock were issued and outstanding with a weighted average exercise price of $6.34 per share. As of December 31, 2014, options to purchase 578,889 of such shares are exercisable.

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

As our warrantholders exercise their 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 remains below the IPO offering price in the period between four and fifteen months after the IPO.

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

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

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

We have listed our common stock and Series A warrants on the NASDAQ Capital Market. We might not be able to maintain the listing standards of that exchange, which includes requirements that we maintain our shareholders equity, total value of shares held by unaffiliated shareholders, and market capitalization above certain specified levels. In particular, since we do not expect to become profitable for some time after the filing of this Annual Report on Form 10-K, 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.

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

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

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

The warrants offered as part of the units do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, following issuance of the warrants, Series A warrant holders may exercise their right to acquire the common stock and pay an exercise price of $6.49 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 $6.49 per share prior to the expiration of their 15-month term on February 12, 2016, after which date any unexercised Series B warrants will expire and have no further value. In certain circumstances, the Series A and Series B warrants may be exercisable on a cashless basis, and certain other circumstances may affect the number of shares into which the Series B warrants may be exercisable. Moreover, 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.

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our

current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the

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members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include the following:

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

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

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

Certain of our executive officers are parties to employment agreements that contain change in control and severance provisions providing for aggregate cash payments of up to approximately $0.6 million for severance and other benefits and acceleration of vesting of stock options with a value of approximately $0.2 million, in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

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

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

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Facilities

Our headquarters are located at 3 Twin Dolphin Drive, Suite 160, Redwood City, California 94065, where we lease approximately 6,000 square feet of office space, under a sublease that expires in May 2015. Under the terms of our sublease, we have the option to renew our lease for the remainder of the master lease term, which expires June 30, 2018 (see Note 15).

We believe that the facilities that we currently lease are adequate for our needs for the immediate future and that, should it be needed, additional space can be leased on commercially reasonable terms to accommodate any future growth.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Since our IPO on November 18, 2014, our common stock is quoted on NASDAQ under the symbol CAPN , and our Series A warrants are quoted on NSADAQ under the symbol CAPNW. Our Series B warrants are not traded on a national securities exchange.

The following table sets forth the high and low sales prices per share of the common stock as reported on NASDAQ. Such quotations represent inter dealer prices without retail markup, markdown or commission and may not necessarily represent actual transactions. Prior to the date of our IPO, there was no public market for our common stock. As a result, we have not set fourth quarterly information with respect to the high and low prices for our common stock for the two most recent fiscal years.

Fiscal 2014	High	Low
Fourth Quarter (since November 18, 2014)	4.04	1.49

As of March 3, 2015, there were approximately 86 shareholders of record for our common stock. A substantially greater number of stockholders may be street name or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividend Policy

We have never declared or paid cash dividends on our common stock, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. The payment of cash dividends in the future, if any, will be at the discretion of our board of directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our board of directors.

Unregistered Sales of Equity Securities and Use of Proceeds

(a) Recent Sales of Unregistered Equity Securities

During the year ended December 31, 2014, we issued the following unregistered securities:

On April 28, 2014, we: (i) issued and sold convertible promissory notes in the aggregate principal amount of $1,749,681.31 to existing stockholders or their affiliates; and (ii) issued and sold warrants to purchase shares of our capital stock to such existing stockholders or their affiliates.

On August 20, 2014, we: (i) issued and sold convertible promissory notes in the aggregate principal amount of $249,682.65 to existing stockholders or their affiliates; and (ii) issued and sold warrants to purchase

shares of our capital stock to such existing stockholders or their affiliates.

On October 30, 2014, we also (i) issued and sold convertible promissory notes in the aggregate principal amount of $493,407.26 to existing stockholders or their affiliates; and (ii) issued and sold warrants to purchase shares of our capital stock to such existing stockholders or their affiliates.

On September 29, 2014, we established a line of credit in the amount of up to an aggregate of $0.1 million. Entities associated with Vivo Ventures, a stockholder and major investor that is also affiliated with Edgar Engleman, M.D., a member of our board of directors, will fund 70% of the line of credit, up to a maximum of $70,000. Dr. Ernest Mario, who is the Chairman of our board of directors, a stockholder and a major investor, will fund 30% of the line of credit, up to a maximum of $30,000.

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Each drawdown on the line of credit will be funded by entities associated with Vivo Ventures and Dr. Mario in proportion to these commitment levels. 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.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering. The Registrant believes that these transactions were exempt from the registration requirements of the Securities Act under Section 4(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

For the year ended December 31, 2014, we granted to officers, directors, employees, consultants and other service providers options to purchase an aggregate of 12,682 shares of common stock under our 2010 Equity Incentive Plan.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering. The Registrant believes that these transactions were exempt from the registration requirements of the Securities Act under Rule 701 promulgated under the Securities Act as offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. The recipients of securities in these transactions represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the stock certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

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

(b) Use of Proceeds

On November 18, 2014, we closed our IPO and issued 1,650,000 units, each of which consisted of one share of common stock, one Series A warrant and one Series B warrant, at an initial offering price of $6.50 per unit. In addition, we issued 247,500 Series A and Series B warrants to the underwriter under the terms of the over allotment provisions of the underwriter s agreement. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-196635), which was declared effective by the SEC on November 12, 2014, and a registration statement on Form S-1 under Rule 462(b) of the Securities Act of 1933, as amended (File No. 333-200164), which was effective immediately upon filing on November 12, 2014. The sole book-running manager for the IPO was Maxim Group LLC with Dawson James Securities, Inc. being the co-manager. The aggregate offering price to the public for the shares sold in the IPO was $10.8 million. We received net proceeds from the IPO of approximately $8.0 million, after deducting underwriting discounts and commissions of approximately $0.8 million and expenses of approximately $2.0 million payable by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

There has been no material change in the planned use of proceeds from the IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b).

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ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read together with our consolidated financial statements and accompanying notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this Annual Report on Form 10-K. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

We derived the statements of operations data for the fiscal years ended December 31, 2014 and 2013 and the balance sheets data as of December 31, 2014 and 2013 from our audited financial statements appearing elsewhere in this filing. The data should be read in conjunction with the financial statements, related notes, and other financial information included herein.

(in thousands except share and per share data)

	Year Ended December 31,	
Statement of Operations Data:	**2014**	**2013**
Revenue	$	$ 3,000
Expenses		
Research and development	2,242	2,380
Sales and marketing	253	
General and administrative	2,665	1,467
Total expenses	5,160	3,847
Operating income (loss)	(5,160)	(847)
Interest and other income (expense)		
Interest income	1	2
Interest expense	(4,130)	(2,860)
Other income (expense), net	(4,586)	(2)
Net loss	$ (13,875)	$ (3,707)
Weighted average common shares outstanding		
Basic and diluted	1,270,033	535,648
Net loss per share		
Basic and diluted	$ (10.92)	(6.92)

	December 31	
Balance Sheet Data	**2014**	**2013**
Cash and cash equivalents	$ 7,957	$ 1,269
Working capital (deficit)	7,049	(12,655)
Total assets	8,396	1,587

Convertible promissory notes		13,992
Total stockholders equity (deficit)	(10,333)	(37,864)

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ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our audited consolidated financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as may, will, expect, believe, anticipate, intend, could, should, estimate, plan, or continue, and similar expressions or variations. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled Risk Factors, set forth in Part I, Item 1A of this Annual Report on Form 10-K and elsewhere in this report. The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Business Overview

We develop novel products based on our proprietary technology for precision metering of gas flow. Our first product, CoSense, aids in the detection 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 clearance for sale in the E.U. in the third quarter of 2013. We initiated our commercialization of CoSense in October 2014 using our own sales efforts, and intend to direct a significant portion of the use of proceeds of the IPO to sales and marketing of CoSense. We may also apply our research and development efforts to additional 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. We have previously obtained CE Mark certification in the E.U. for Serenz, an as-needed treatment for AR that has shown statistically significant improvements in AR symptoms in randomized, controlled Phase 2 clinical trials completed by us. We outlicensed Serenz to GSK in 2013, realizing revenue in the form of a non-refundable up-front payment of $3.0 million. In June 2014, the agreement terminated and GSK returned the licensed rights to Serenz back to us. We have no further monetary obligations to GSK related to the terminated agreement. We intend to engage in further research and development of Serenz prior to obtaining a partner for the final development and commercialization of the product.

In November, 2014, we completed our IPO, pursuant to which we issued 1,650,000 units (each unit consisting of one share of common stock, one Series A warrant and one Series B warrant) and received net proceeds of approximately $8.0 million, after deducting underwriting discounts and commissions and IPO related expenses. In connection with the completion of our IPO, all shares of convertible preferred stock converted into 865,429 shares of common stock and all of our convertible preferred stock warrants were converted into warrants to purchase 523,867 shares of common stock. In addition, the outstanding convertible notes and accrued interest issued during 2010 and 2012 converted into an aggregate of 3,165,887 shares of common stock. The outstanding convertible notes issued during April, August and October, 2014 converted into an aggregate of 552,105 units in the IPO.

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Financial overview

Summary

We have not generated net income from operations, and, at December 31, 2013 and December 31, 2014, we had an accumulated deficit of $57.1 million and $71.0 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.

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 primarily comprised of changes in the fair value of the stock warrant liabilities.

Critical Accounting Policies and Significant Judgments and Estimates

Our management s discussion and analysis of financial condition and results of operations are based upon our audited financial statements, which have been prepared in accordance with GAAP. The preparation of these

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financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an on-going basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable in the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions and conditions. Our significant accounting policies are more fully described in Note 2 to our audited financial statements contained herein.

Series B Warrants

We account for the Series B warrants issued in connection with our IPO in accordance with the guidance in Accounting Standards Codification (ASC) 815-40. The warrants have a cashless exercise provision that allows for exercise of the warrants at any time between four and fifteen months after issuance, 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 price of our common stock at the time. The terms of the Series B warrants do not explicitly limit the potential number of shares, thereby the exercise of the B warrants could result in our obligation to deliver potentially unlimited number of shares upon settlement. As such, share settlement in not within our control and as provided under ASC 815-40, the warrants do not meet the criteria for equity treatment and are recorded as a liability. Accordingly, we classified the Series B warrants as liabilities at their fair market value at the date of the IPO and will re-measure the warrants at each balance sheet date until they are exercised or they expire. Any change in the fair value is recognized as other income (expense) in our statement of operations.

The fair value of the warrant liability was determined using a Monte Carlo simulation model. This model is dependent upon several variables such as the warrant s term, exercise price, current stock price, risk-free interest rate estimated over the expected term, estimated volatility of our stock over the term of warrant and the estimated market price of our stock during the cashless exercise period. The risk-free rate is based on U.S. Treasury securities with similar maturities as the expected terms of the warrants. The volatility is estimated based on blending the volatility rates for a number of similar publicly-traded companies.

In addition to the Series B warrants, we issued Series A warrants in connection with our IPO, have other warrants issued prior to the IPO in connection with convertible debt and have other warrants classified as part of our permanent equity. Under ASC 815-40-35, we have adopted a sequencing policy that reclassifies contracts from equity to assets or liabilities for those with the latest inception date first. We have taken the position that the Series A warrants issued in the IPO have an earlier inception date than the Series B warrants issued as part of our IPO, and accordingly are treated as an equity instrument.

Future issuance of securities will be evaluated as to reclassification as a liability under our sequencing policy of latest inception date first until either all of the Series B warrants are settled or expire.

In accordance with the guidance under ASC 815-40-25, we have evaluated that we have a sufficient number of authorized and unissued shares as December 31, 2014, to settle all existing commitments.

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

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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, 2013 and December 31, 2014 stock-based compensation expense was $38,417 and $345,435, respectively. As of December 31, 2013 and December 31, 2014 we had $8,287 and $539,087, respectively, of total unrecognized compensation expense, which we expect to recognize over a period of approximately 0.4 years and 3.88 years, respectively. The intrinsic value of all outstanding stock options as of December 31, 2014 was approximately $20,000. We expect to 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,

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net loss and net loss per share of common stock could have been significantly different. These assumptions include:

Expected volatility: We calculate the estimated volatility rate based on a peer index of common stock of comparable companies.

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 2013. There were 12,683 options granted in February 2014 and 913,701 options granted in November 2014 to employees and directors in connection with the IPO. 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.

Income Taxes

We use the liability method of accounting for income taxes, whereby deferred tax assets or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are provided when necessary to reduce deferred tax assets to the amount that will more likely than not be realized.

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of tax credits, benefits and deductions and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenues and expenses for tax and financial statement purposes. Significant changes to these estimates may result in an increase or decrease to our tax provision in a subsequent period.

In assessing the realizability of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will be realized on a jurisdiction by jurisdiction basis. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income in the future. We have recorded a deferred tax asset in jurisdictions where ultimate realization of deferred tax assets is more likely than not to occur.

We make estimates and judgments about our future taxable income that are based on assumptions that are consistent with our plans and estimates. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted. Any adjustment to the deferred tax asset valuation allowance would be

recorded in the income statement for the periods in which the adjustment is determined to be required.

We account for uncertainty in income taxes as required by the provisions of ASC Topic 740, *Income Taxes*, which clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to estimate and measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. It is inherently difficult and

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subjective to estimate such amounts, as this requires us to determine the probability of various possible outcomes. We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments and may not accurately anticipate actual outcomes.

The Tax Reform Act of 1986 and similar state provisions limit the use of net operating loss carryforwards in certain situations where equity transactions result in a change of ownership as defined by Internal Revenue Code Section 382. In the event we should experience an ownership change, as defined, utilization of our federal and state net operating loss carryforwards could be limited.

Results of Operations

Comparison of the Years Ended December 31, 2014 and 2013

	Year Ended December 31,		Increase (decrease)	
	2014	**2013**	**Amount**	**Percentage**
Revenue	$	$ 3,000,000	$ (3,000,000)	(100)%
Operating expenses:				
Research and development	2,242,216	2,379,832	(137,616)	(6)%
Sales and marketing	252,359		252,359	100%
General and administrative	2,665,154	1,466,951	1,198,203	82%
Total	5,159,729	3,846,783	1,312,946	34%
Income (Loss) from operations	(5,159,729)	(846,783)	(4,312,946)	(509)%
Interest income	1,085	1,772	(687)	(39)%
Interest expense	(4,130,394)	(2,860,267)	(1,270,127)	(44)%
Other income (expense), net	(4,585,475)	(1,965)	(4,583,510)	N/A
Net loss	$ (13,874,513)	$ (3,707,243)	$ (10,167,270)	(294)%

Revenue

No revenue was recognized in fiscal year ended December 31, 2014. The $3.0 million of revenue recognized in the fiscal year ended December 31, 2013 represented the revenue recognized from the non-refundable up-front payment pursuant to our license agreement with GSK.

Research and development expense

Research and development expense decreased $0.1 million for the fiscal year December 31, 2014, as compared to the same period in 2013. The decrease was primarily due to employee-related costs due to decreased headcount in 2014 versus 2013.

Sales and marketing expense

Sales and marketing expense increased $0.2 million for the fiscal year ended December 31, 2014, as compared to the same period in 2013. The increase was primarily due to the addition of the Vice President of Sales in June 2014 and commercial launch activities for CoSense.

General and administrative expense

General and administrative expense increased $1.2 million for the fiscal year ended December 31, 2014, as compared to the same period in 2013. The increase was primarily due to increases in consulting costs of $0.4 million, employee related expenses due to increased executive headcount of $0.1 million, stock compensation expense of $0.3 million and legal and accounting due to being a public company of $0.4 million in 2014 versus 2013.

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Interest income

Interest income was not material and remained relatively consistent for both fiscal years ended December 31, 2013 and 2014.

Interest expense

Interest expense increased $1.3 million in the fiscal year December 31, 2014, as compared to the same period in 2013. This increase was primarily due to the write-off of the unamortized balance of the debt discount associated with the 2014 convertible notes as of November 18, 2014.

Other income (expense), net

Other expense increased $4.6 million for the fiscal year ended December 31, 2014, compared to the same period in 2013. This increase was due to an increase of $5.8 million in the fair value of the Series B warrant liability from November 18, 2014 to December 31, 2014, offset by a net decrease of $1.2 million in fair value of the preferred stock warrants. The preferred stock warrants were converted to common stock warrants upon the IPO.

Liquidity and Capital Resources

Since our inception and through November 18, 2014, we have financed our operations primarily through private placements of our equity securities and debt financing. On November 18, 2014, the Company completed its IPO, pursuant to which the Company issued 1,650,000 units (each unit consisting of one share of common stock, one Series A warrant and one Series B warrant) and received net proceeds of approximately $8.0 million, after deducting underwriting discounts and commissions and IPO related expenses. At December 31, 2014, we had cash and cash equivalents of $8.0 million, a majority of which is invested in a money market fund at an AAA-rated financial institution. We believe that, based on our current level of operations, our existing cash resources will provide adequate funds for ongoing operations, planned capital expenditures and working capital requirements for at least the next 12 months.

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. We will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. 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.

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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,	
	2014	2013
Cash Flows from Continuing Operations:		
Net cash provided by (used in) operating activities	$ (4,484,362)	$ (885,218)
Net cash used in investing activities	(30,683)	(1,274)
Net cash provided by financing activities	11,202,985	
Net increase (decrease) in cash and cash equivalents	$ 6,687,940	$ (886,492)

Cash provided by (used in) operating activities

During the fiscal year ended December 31, 2014, net cash used in operating activities was $4.5 million, which was primarily due to the use of funds in our operations related to the development of our products. Net cash used in operating activities in the fiscal year ended December 31, 2013 was primarily due to the use of funds in our operations related to the development of our products, offset by the receipt of $3.0 million from GSK.

Cash used in investing activities

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

Cash provided by (used in) financing activities

During the fiscal year ended December 31, 2014, cash provided by financing activities was $11.2 million, consisting primarily of net proceeds of $2.5 from issuance of convertible promissory notes in April, August and October 2014 and proceeds of $10.7 million from the IPO, offset by IPO related expenses paid.

As of December 31, 2014, we had cash and cash equivalents of approximately $8.0 million. We believe that our cash resources are sufficient to meet our cash needs for at least the next 12 months.

Contractual obligations and commitments

As of December 31, 2014, we had lease obligations totaling $18,000 consisting of an operating lease for our operating facility. We signed a sublease in May 2014, which expires at the end of May 2015, for a new office space in Redwood City, California. The sublease is for one year from June 1, 2014, with an option to renew to June 2018 (See Note 15). We prepaid rent for the last four months of the initial lease term. Minimum payments under the agreement were

$199,000 in 2014 and $18,000 in calendar 2015.

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The following table summarizes our contractual obligations as of December 31, 2014.

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
	(in thousands)				
Lease obligations	$ 18	$	$	$	$ 18
Short term line of credit and interest[(1)]	102				102
Total	$ 120	$	$	$	$ 120

(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 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.

Off-Balance Sheet Arrangements

As of December 31, 2014, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

Accounting Guidance Update

Recently Adopted Accounting Guidance

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

On June 10, 2014, the FASB issued ASU 2014-10, *Elimination of Certain Financial Reporting Requirements, Including Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* The pending content resulting from the issuance of ASU 2014-10 eliminates the definition of development stage entity, thereby removing the distinction between the development stage entities and other reporting entities. As a consequence, inception-to-date presentation and other incremental disclosure requirements in ASC Topic 915 for entities previously considered development stage entities are eliminated. For public business entities, the ASU s elimination of the inception-to-date information and the other disclosures in Topic 915 is effective for annual reporting periods beginning after December 15, 2014, and interim periods therein. For other entities, this portion of the ASU is effective for annual reporting periods beginning after December 15, 2014, and interim reporting periods beginning after

December 15, 2015. While the changes resulting from the issuance of ASU 2014-10 are not yet effective, early adoption of either the amendments to Topic 915 or Topic 810 is permitted for any annual or interim period for which a reporting entity s financial statements have not yet been issued (public business entities) or made available for issuance (other entities.)

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

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

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

We had unrestricted cash and cash equivalents totaling $8.0 million at December 31, 2014. These amounts were invested primarily in money market funds and are held for working capital purposes. We do not enter into investments for trading or speculative purposes. We believe we do not have material exposure to changes in fair value as a result of changes in interest rates. Declines in interest rates, however, will reduce future investment income.

Series B Warrants

We have issued Series A warrants and Series B warrants to purchase a total of 4,899,210 shares. In the event that the market price of our common stock remains 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 shares of common stock that increases as the market price of our common stock decreases, and exercisable at no cost to the holder. This may result in a number of shares issued, pursuant to the cashless exercise of Series B warrants, significantly in excess of the original 2,449,605 shares. If the price of our common stock were to fall to $1.00 per share, the minimum share price necessary for continued listing on the NASDAQ Capital Market, at any time more than four months, and less than fifteen months, after the IPO, the number of shares of common stock for which the Series B warrants may be exercised would exceed 18 million shares. This would result in majority ownership of our common stock by Series B warrantholders, if all the Series B warrantholders exercised their warrants at that time. Under certain other circumstances, exercises of the Series A and Series B warrants may be on a cashless basis, resulting in dilutive issuance of common shares of the Company without cash proceeds to the Company.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Capnia, Inc.

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Report of Independent Registered Public Accounting Firm

To the Audit Committee of the

Board of Directors and Shareholders

of Capnia, Inc.

We have audited the accompanying balance sheets of Capnia, Inc. (the Company) as of December 31, 2014 and 2013, and the related statements of operations, convertible preferred stock and stockholders deficit and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Capnia, Inc., as of December 31, 2014 and 2013, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum LLP

Marcum LLP

New York, NY

March 13, 2015

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Capnia, Inc.

Balance Sheets

	December 31, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 7,956,710	$ 1,268,770
Restricted cash	20,000	20,000
Accounts receivable		149,605
Inventory	109,336	
Prepaid expenses and other current assets	252,272	85,149
Total current assets	8,338,318	1,523,524
Long-term assets		
Property and equipment, net	57,607	63,167
Total assets	$ 8,395,925	$ 1,586,691
Liabilities, convertible preferred stock and stockholders deficit		
Current liabilities		
Accounts payable	$ 986,799	$ 57,721
Accrued compensation and other current liabilities	201,457	128,651
Line of credit and accrued interest	101,529	
Convertible promissory notes and accrued interest		13,991,857
Total current liabilities	1,289,785	14,178,229
Long-term liabilities		
Series B warrant liability	17,438,731	
Convertible preferred stock warrant liability		1,464,877
Commitments (Note 9)		
Convertible Preferred Stock		
Series A convertible preferred stock, $0.001 par value, 40,000 shares authorized, 0 and 31,250 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively; (aggregate liquidation preference of $1,500,000)		1,500,000
Series B convertible preferred stock, $0.001 par value, 320,000 shares authorized, 0 and 119,140 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively; (aggregate liquidation preference of $6,862,939)		6,862,939
Series C convertible preferred stock, $0.001 par value, 1,500,000 shares authorized, 0 and 715,039 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively; (aggregate liquidation preference of $15,445,109)		15,445,109
Stockholders deficit		

Common stock, $0.001 par value, 100,000,000 shares authorized at December 31, 2014 and 10,000,000 shares authorized at December 31, 2013; 6,769,106 and 535,685 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively.	6,769	536
Additional paid-in-capital	60,635,664	19,235,512
Accumulated deficit	(70,975,024)	(57,100,511)
Total stockholders deficit	(10,332,591)	(37,864,463)
Total liabilities and stockholders deficit	$ 8,395,925	$ 1,586,691

See accompanying notes to financial statements

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Capnia, Inc.

Statements of Operations

	Fiscal Year Ended December 31,	
	2014	2013
Revenue	$	$ 3,000,000
Expenses		
Research and development	2,242,216	2,379,832
Sales and marketing	252,359	
General and administrative	2,665,154	1,466,951
Total expenses	5,159,729	3,846,783
Operating income (loss)	(5,159,729)	(846,783)
Interest and other income (expense)		
Interest income	1,085	1,772
Interest expense	(4,130,394)	(2,860,267)
Other income (expense)	(4,585,475)	(1,965)
Net loss	$ (13,874,513)	$ (3,707,243)
Basic and diluted net loss per common share	$ (10.92)	$ (6.92)
Weighted-average common shares outstanding used to calculate basic and diluted net loss per common share	1,270,033	535,648

See accompanying notes to financial statements.

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CAPNIA, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS DEFICIT

Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit
31,250	$ 1,500,000	119,140	$ 6,862,939	715,039	$ 15,445,109	522,360	$ 522	$ 19,197,109	($ 53,393,268)
						13,325	$ 14	$ 23,972	
								$ 14,431	
									($ 3,707,243)
31,250	$ 1,500,000	119,140	$ 6,862,939	715,039	$ 15,445,109	535,685	$ 536	$ 19,235,512	($ 57,100,511)
								$ 345,435	
(31,250)	($ 1,500,000)	(119,140)	($ 6,862,939)	(715,039)	($ 15,445,109)	865,429	$ 865	$ 23,807,183	
								$ 1,220,718	
						1,650,000	$ 1,650	$ 9,844,902	
								$ 18,975	
								$ 1,723,984	

						3,165,887	$ 3,166	$ 15,406,944	
						552,105	$ 552	$ 2,511,567	
								($ 1,830,450)	
								($ 11,649,106)	
									($ 13,874,513)
0	0	0	0	0	0	6,769,106	$ 6,769	$ 60,635,664	($ 70,975,024)

See accompanying notes to financial statements

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Capnia, Inc.

Statements of Cash Flows

	Fiscal Year Ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (13,874,513)	$ (3,707,243)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	28,516	42,114
Stock-based compensation expense	345,435	38,417
Loss on disposition of property and equipment	7,727	1,446
Change in fair value of stock warrants	4,578,232	105,320
Non-cash interest expense relating to convertible promissory notes & amortization of discount on notes	4,128,863	2,860,267
Non-cash interest expense relating to line of credit	1,529	
Change in operating assets and liabilities:		
Accounts receivable	149,605	(149,605)
Inventory	(109,336)	
Other receivables		150,782
Prepaid expenses and other assets	(167,123)	(2,557)
Accounts payable	353,897	(161,803)
Accrued compensation & other current liabilities	72,806	(62,356)
Net cash used in operating activities	(4,484,362)	(885,218)
Cash flows from investing activities:		
Purchase of property and equipment	(30,683)	(1,274)
Net cash used in investing activities	(30,683)	(1,274)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock warrants	1,946	
Proceeds from issuance of convertible notes payable	2,490,781	
Proceeds from line of credit	100,000	
Proceeds from Initial Public Offering	10,727,475	
Initial Public Offering costs paid	(2,117,217)	
Net cash provided by financing activities	11,202,985	
Net increase (decrease) in cash and cash equivalents	6,687,940	(886,492)
Cash and cash equivalents, beginning of period	1,268,770	2,155,262
Cash and cash equivalents, end of period	$ 7,956,710	1,268,770

Supplemental disclosures of noncash investing and financing information		
Initial Public Offering costs accrued and included in Accounts Payable	$ 575,181	
Issuance of restricted common stock in exchange for intellectual property	$	$ 23,986
Beneficial conversion feature related to the warrants to purchase shares of convertible preferred stock in connection with convertible promissory notes	$ 1,723,984	
Issuance of warrants for the purchase of convertible preferred stock in connection with notes payable	$ 966,978	
2014 notes payable converted into units in the IPO	$ 2,512,119	
2010/2012 notes payable converted into common stock in conjunction with IPO	$ 15,410,110	

See accompanying notes to financial statements.

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Capnia, Inc.

December 31, 2014

Notes to Financial Statements

Note 1. Description of Business

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

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

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

Initial Public Offering

On November 18, 2014, the Company completed its initial public offering (IPO), pursuant to which the Company issued 1,650,000 units (each unit consisting of one share of common stock, one Series A warrant and one Series B warrant) and received net proceeds of approximately $8.0 million, after deducting underwriting discounts and commissions and IPO related expenses. The following table summarizes the results of the Company s IPO:

Transaction	Number of Units	Common Stock	Proceeds
Units Issued in IPO	1,650,000	1,650,000	$ 10,708,500
Issuance of A & B Warrants (overallotment to underwriters)			$ 18,975
Conversion of preferred Stock (one for one conversion ratio)		865,429	
2010/2012 Convertible notes		3,165,887	
2014 Convertible Notes	552,105	552,105	
Totals	2,202,105	6,233,421	$ 10,727,475

In addition to the above, upon the completion of the IPO, the 2009, 2010 and 2012 preferred stock warrants were converted into warrants to purchase 523,867 shares of the Company s common stock (see Note 6).

As part of the IPO, the Company issued 2,449,605 Series A warrants to purchase 2,449,605 shares of the Company s common stock. The Company also issued 2,449,605 Series B warrants to purchase an adjustable number of shares of the Company s common stock (see Note 7).

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Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and the applicable rules and regulations of the Securities and Exchange Commission (SEC). The balance sheet at December 31, 2013 has been derived from the audited financial statements at that date.

Significant Risks and Uncertainties

The Company has experienced losses since its inception and, as of December 31, 2014, has an accumulated deficit of approximately $71.0 million and cash and cash equivalents of approximately $8.0 million. In 2013 the Company received payments totaling approximately $3.0 million pursuant to the license agreement with GSK pertaining to Serenz. This agreement terminated in June 2014, and the Company does not expect additional revenue to result from it. The Company plans to commercialize Serenz in the E.U. via a partnership or distributorship arrangements. In the U.S., the Company intends to determine the regulatory approval pathway for Serenz in dialogue with the FDA, and subsequently to seek partnership or distributorship arrangements for commercialization.

On November 18, 2014 the Company completed its IPO and received net proceeds of $8.0 million, after deducting underwriting discounts and commissions and IPO related expenses. On March 5, 2015 the Company received approximately $3.8M as a result of Series B warrant holders exercising warrants to purchase shares of the Company s common stock.

The Company initiated its commercialization of CoSense starting in October of 2014, and will achieve profitability only if it can generate sufficient revenue from sales of the Company s CoSense instruments and consumables, or from license fees, milestone payments, and research and development payments in connection with potential future strategic partnerships. Although management has been successful in raising capital in the past, most recently in April 2014, August 2014, October 2014, November 2014 and March 2015, there can be no assurance that the Company will be successful, or that any needed financing will be available in the future at terms acceptable to the Company.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and reported amounts of expenses in the financial statements and accompanying notes. Actual results could differ from those estimates. Key estimates included in the financial statements include the valuation of deferred income tax assets and the valuation of debt and equity instruments and stock-based compensation.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents at two commercial banks that management believes are of high credit quality. Cash and cash equivalents deposited with these commercial banks exceeded the Federal Deposit Insurance Corporation insurable limit at December 31, 2014 and 2013. The Company expects this to continue.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting, making operating decisions, and assessing financial performance. All long-lived assets are maintained in the United States of America.

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Cash and Cash Equivalents

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

Prepaid Expenses and Other Current Assets

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

Accounts Receivable

Accounts receivable as of December 31, 2013 consist of balances due from GSK pursuant to the license agreement executed in 2013. The Company did not record an allowance for doubtful accounts as this balance was deemed fully collectible.

Inventory

Inventory as of December 31, 2014 consist of raw materials to be used in the manufacture of CoSense monitors and single-use nasal cannulas. Inventory is stated at the lower of cost or market under the first-in, first-out (FIFO) method.

Property and Equipment, Net

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

Convertible Instruments

The Company evaluates and accounts for conversion options embedded in its convertible instruments in accordance with ASC 815 Derivatives and Hedging.

ASC 815 generally provides three criteria that, if met, require companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments. These three criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not remeasured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument subject to the requirements of ASC 815. ASC 815 also provides an exception to this rule when the host instrument is deemed to be conventional (as that term is described in the implementation guidance to ASC 815).

The Company applies the accounting standards for derivatives and hedging and for distinguishing liabilities from equity when accounting for hybrid contracts that feature conversion options. The Company accounts for convertible debt instruments when the Company has determined that the embedded conversion options should not be bifurcated from their host instruments in accordance with ASC 470-20 *Debt with Conversion and Other Options.* The Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the

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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, using the effective interest method (see Note 5).

Convertible Preferred Stock Warrant Liability

The Company has issued freestanding warrants to purchase shares of its convertible preferred stock. Prior to the IPO, the Company classified the fair value of these warrants as liabilities on the balance sheet as they corresponded to the treatment of the preferred stock as temporary equity. The Company accounted for the warrants as derivative instruments. Changes in the fair value of the warrants were presented separately as other income (expense) in the Company s statements of operations for each reporting period. The Company used the Monte Carlo simulation model to determine the fair values of the warrants. As a result, the valuation of this derivative instrument is subjective because the option-valuation model requires the input of highly subjective assumptions, including the expected stock price volatility and the probability of a future occurrence of a fundamental transaction. Changes in these assumptions can materially affect the fair value estimate and, such impacts can, in turn, result in material non-cash charges or credits, and related impacts on earnings or loss per share, in the statements of operations. At the time of the IPO, all of the warrants to purchase preferred stock were exchanged for warrants to purchase common stock, that met the conditions necessary for equity classification and are therefore no longer subject to adjustment to fair value.

Series B Warrant Liability

The Company has issued Series B warrants to purchase shares of its common stock. In the event that the market price of the Company s common stock falls below $6.50 at any time between March 12, 2015 and February 12, 2016, the Series B warrants will become exercisable on a cashless basis for a number of common shares that increases as the market price of the Company s common stock decreases, and exercisable at a discount to the tracking price of the common stock at the time. The Company classified the fair value of these Series B warrants as liabilities on the balance sheet in accordance with the guidance in ASC 815-40. The Company accounted for the warrants as derivative instruments, as the value is derived from the performance of an underlying entity, the Company s common stock. The Company used 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. Changes in these assumptions can materially affect the fair value estimate and, such impacts can, in turn, result in material non-cash charges or credits, and related impacts on earnings or loss per share, in the statements of operations. The Company recorded changes in fair value of the Series B warrants as a component of other income (expense).

In addition to the Series B warrants, the Company issued Series A warrants in connection with its IPO, has other warrants issued prior to the IPO in connection with convertible debt and has other warrants classified as part of its permanent equity. Under ASC 815-40-35, the Company adopted a sequencing policy that reclassifies contracts from equity to assets or liabilities for those with the latest inception date first. The Company has taken the position that the Series A warrants issued in the IPO have an earlier inception date than the Series B warrants issued as part of our IPO, and accordingly Series A warrants are treated as an equity instrument.

The Company will evaluate future issuance of securities as to reclassification as a liability under its sequencing policy of latest inception date first until either all of the Series B warrants are settled or expire.

In accordance with the guidance under ASC 815-40-25, the Company has determined that it has a sufficient number of authorized and unissued shares, to settle all existing commitments as of December 31, 2014.

Convertible Preferred Stock

At the time of the IPO, all outstanding shares of preferred stock converted into common stock at a conversion rate of one to one, and were reclassified to permanent equity.

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Revenue Recognition

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

Research and Development

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

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

Income Taxes

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

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

Stock-Based Compensation

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

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

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Comprehensive Income (Loss)

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

Net Income (Loss) per Share of Common Stock

Basic net income (loss) per common share is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration for potentially dilutive securities. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net income (loss) per share calculation, convertible preferred stock, convertible promissory notes, stock options and stock warrants are considered to be potentially dilutive securities. Because the Company has reported a net loss for the years ended December 31, 2014 and 2013, diluted net loss per common share is the same as basic net loss per common share for those periods.

The following is a reconciliation of the number of shares used in the calculation of basic earnings per share and diluted earnings per share during the years ended December 31, 2014 and 2013:

	Fiscal Year Ended December 31,	
	2014	**2013**
Net loss	$ (13,874,513)	$ (3,707,243)
Weighted-average shares used in computing basic and diluted net loss per common share	1,270,033	535,648
Basic and diluted net loss per common share	$ (10.92)	$ (6.92)

Effective as of the completion of the IPO, all of the Company s preferred stock was converted to common stock.

The following potentially dilutive securities outstanding have been excluded from the computations of diluted weighted-average shares outstanding because such securities have an antidilutive impact due to losses reported (in common stock equivalent shares):

	December 31,	
	2014	**2013**
Convertible preferred stock		865,429
Warrants issued to 2010/2012 convertible note holders to purchase stock	523,867	Adjustable
Stock issuable upon conversion of convertible notes		Adjustable
Options to purchase common stock	1,072,011	239,606
Warrants issued in 2009 to purchase stock	9,259	9,259
	82,500	

Warrants issued to Underwriter to purchase common stock	
Series A Warrants to purchase common stock	2,449,605
Series B Warrants to purchase common stock	Adjustable

Reverse Stock Split

The Company s board of directors and stockholders approved an amendment to the Company s amended and restated certificate of incorporation to effect a 1-for-12 reverse split of shares of the Company s common

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stock and convertible preferred stock, and to change the total authorized number of common stock and convertible preferred stock, which amendment was filed with the Secretary of State of the State of Delaware on July 28, 2014. All issued and outstanding common stock, convertible preferred stock, options for common stock, warrants for preferred stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse split for all periods presented. All authorized common stock and convertible preferred stock numbers contained in the financial statements have been adjusted to reflect the modifications effected pursuant to the July 28, 2014 amendment to the Company s amended and restated certificate of incorporation.

Recent Accounting Pronouncements

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

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

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

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

Note 3. Fair Value of Financial Instruments

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

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

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

Level I Unadjusted quoted prices in active markets for identical assets or liabilities;

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Level II Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level III Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

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

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

	Fair Value Measurements at December 31, 2013			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$ 1,256,752	$ 1,256,752	$	$
Liabilities				
Convertible preferred stock warrant liability	$ 1,464,877	$	$	$ 1,464,877

	Fair Value Measurements at December 31, 2014			
	Total	Level 1	Level 2	Level 3
Assets				
Money market fund	$ 7,891,888	$ 7,891,888	$	$
Liabilities				
Series B warrant liability	$ 17,438,731	$	$	$ 17,438,731

For the fiscal year ended December 31, 2013, the fair value measurement of the convertible preferred stock warrant liability is based on significant inputs not observed in the market and thus represents a Level 3 measurement. The Company s estimated fair value of the convertible preferred stock warrant liability is calculated using a Monte Carlo simulation and key assumptions including the probabilities of settlement scenarios, enterprise value, time to liquidity, risk-free interest rates, discount for lack of marketability and volatility (see Note 6). The estimates are based, in part, on subjective assumptions. Generally, increases or decreases in the fair value of the underlying convertible preferred stock would result in a directionally similar impact in the fair value measurement of the warrant liability. In connection with the completion of the Company s IPO in November 2014, all of the outstanding warrants to purchase convertible preferred stock converted into warrants to purchase shares of common stock and were reclassified to permanent equity.

For the fiscal year ended December 31, 2014, the fair value measurement of the Series B warrant liability is based on significant inputs not observed in the market and thus represents a Level 3 measurement. The Company s estimated fair value of the Series B warrant liability is calculated using a Monte Carlo simulation and key assumptions including the volatility, of the Company s stock, expected dividend yield and risk-free interest rates (see Note 7). The estimates

are based, in part, on subjective assumptions. Generally, increases or decreases in the trading price of the Company s stock would result in a directionally opposite impact in the fair value measurement of the Series B warrant liability.

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

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Note 4. Property and Equipment, Net

Property and equipment consisted of the following:

	December 31, 2014	December 31, 2013
Furniture and fixtures	$ 170,811	$ 180,238
Computer hardware	27,555	27,555
Leasehold improvements	4,075	10,726
	$ 202,441	$ 218,519
Less accumulated depreciation and amortization	(144,834)	(155,352)
Total	$ 57,607	$ 63,167

Depreciation expense was $42,114 and $28,516 for the fiscal years ended December 31, 2013 and December 31, 2014, respectively.

Note 5. Related Party Convertible Promissory Notes

2010/2012 Convertible Promissory Notes

In 2010 and 2012 the Company entered into convertible promissory notes with various investors for a total principal amount of $10,200,413. These notes were collateralized by substantially all of the assets of the Company and bore interest at a compounded interest rate of 12% per annum. As of the completion of the IPO on November 18, 2014, the Company had $15,410,110 in aggregate principal amount and accrued interest outstanding under the 2010/2012 convertible promissory notes, which automatically converted into 3,165,887 shares of common stock in conjunction with the IPO based on a conversion price of $4.87 per share of common stock which represented the contractual conversion price of 75% of the price of common stock issued in the IPO. The Company incurred $2,860,267 and $1,416,554 of interest expense related to these notes in the years ended December 31, 2013 and December 31, 2014, respectively.

In connection with the 2010/2012 convertible promissory notes the Company issued warrants for the purchase of preferred stock (see Note 6).

2014 Convertible Promissory Notes

In April 2014, the Company entered into convertible promissory notes with various investors for a total principal amount of $1,747,681. These notes bore interest at the rate of 2% per annum in the event that the note is automatically converted into units, equal to one share of common stock and a warrant to purchase one share of common stock, upon the Company s Contemplated IPO, prior to the maturity date of September 30, 2015. These notes automatically converted to units upon completion of the Company s IPO based on a conversion price of $4.55 per unit, which represented the contractual conversion price of 70% of the price per unit issued in the IPO.

In connection with the April 2014 convertible notes, the Company issued a warrant for the purchase of preferred stock. The number of shares for which the warrant may be exercised is to be determined by dividing an amount equal to 25% of the unpaid principal by the exercise price prior to the expiration of this warrant. The exercise price for the warrant is 75% of the price per share of the next financing securities issued in the next financing or $16.20 per share if converted into the Series C preferred stock. The warrants are exercisable: (1) after the earlier of (a) the closing date of a next financing that occurs prior to the Company s consummation of the IPO or (b) the note maturity date and (2) prior to the expiration of this warrant on the earlier of 10 years or the date of a qualified IPO. The estimated fair value of the warrants at issuance was determined to be $600,148, which was recorded as a debt discount and amortized using the effective interest method over the term of the convertible notes. The Company estimated the fair value of its preferred stock warrant liability at issuance

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utilizing a Monte Carlo simulation based on expected volatility range of 35%-60%, expected time to liquidity event of 1.50-5 years and risk-free interest rate range of 0.2-2.6%. The Company determined that these warrants met the conditions necessary for liability classification (see Note 6).

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

In August 2014, the Company entered into convertible promissory notes with various investors for a total principal amount of $249,693. These notes bore interest at the rate of 2% per annum in the event that the note is automatically converted into units, equal to one share of common stock and a warrant to purchase one share of common stock, upon the Company s Contemplated IPO, prior to the maturity date of September 30, 2015. These notes automatically converted to units upon completion of the Company s IPO based on a conversion price of $4.55 per unit, which represented the contractual conversion price of 70% of the price per unit issued in the IPO.

In connection with the August 2014 convertible notes, the Company issued a warrant for the purchase of preferred stock. The number of shares for which the warrant may be exercised is to be determined by dividing an amount equal to 25% of the unpaid principal by the exercise price prior to the expiration of this warrant. The exercise price for the warrant is 75% of the price per share of the next financing securities issued in the next financing or $16.20 per share if converted into Series C preferred stock. The warrants are exercisable: (1) after the earlier of (a) the closing date of a next financing that occurs prior to the Company s consummation of the IPO or (b) the note maturity date and (2) prior to the expiration of this warrant on the earlier of 10 years or the date of a qualified IPO. The estimated fair value of the warrants at issuance was determined to be $113,295, which was recorded as a debt discount and amortized using the effective interest method over the term of the convertible notes. The Company estimated the fair value of its preferred stock warrant liability at issuance utilizing a Monte Carlo simulation based on expected volatility range of 35%-60%, expected time to liquidity event of 1.25-5 years and risk-free interest rate of 0.2-2.26%. The Company determined that these warrants met the conditions necessary for liability classification (see Note 6).

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

In October 2014, the Company entered into convertible promissory notes with various investors for a total principal amount of $493,407. These notes bore interest at the rate of 2% per annum in the event that the note is automatically converted into units, equal to one share of common stock and a warrant to purchase one share of common stock, upon the Company s Contemplated IPO, prior to the maturity date of September 30, 2015. These notes automatically converted to units upon completion of the Company s IPO based on a conversion price of $4.55 per unit, which represented the contractual conversion price of 70% of the price per unit issued in the IPO.

In connection with the October 2014 convertible notes, the Company issued a warrant for the purchase of preferred stock. The number of shares for which the warrant may be exercised is to be determined by dividing an amount equal to 25% of the unpaid principal by the exercise price prior to the expiration of this warrant. The exercise price for the warrant is 75% of the price per share of the next financing securities issued in the next

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financing or $16.20 per share if converted into the Series C preferred stock. The warrants are exercisable: (1) after the earlier of (a) the closing date of a next financing that occurs prior to the Company s consummation of the IPO or (b) the note maturity date and (2) prior to the expiration of this warrant on the earlier of 10 years or the date of a qualified IPO. The estimated fair value of the warrants at issuance was determined to be $253,535, which was recorded as a debt discount and amortized using the effective interest method over the term of the convertible notes. The Company estimated the fair value of its preferred stock warrant liability at issuance utilizing a Monte Carlo simulation based on expected volatility range of 35%-60%, expected time to liquidity of event of 1.0 years-5 years and risk-free interest rate of 0.2-2.26%. The Company determined that these warrants met the conditions necessary for liability classification. (See Note 6).

After allocating $253,535 to the warrants issued in connection with the October 2014 convertible notes as discussed above, the Company determined the intrinsic value of the beneficial conversion feature to be $239,872, which was recorded as a debt discount to the convertible notes and within additional paid-in capital. The debt discount was amortized using the effective interest rate method over the term of the convertible notes. The discount to convertible notes for the intrinsic value of the beneficial conversion feature embedded in debt instruments is based upon the differences between the fair value of the underlying preferred stock at the commitment date of the note transaction and the effective conversion price embedded in the note.

In relation to the April, August and October 2014 convertible notes payable, the Company recognized interest expense through November 18, 2014 of $21,348. The Company recorded interest expense in connection with the amortization of the debt discount through November 18, 2014 of $835,509. In addition, the Company recorded interest expense of $1,855,452 related to the write-off of the unamortized portion of the debt discount upon the conversion of the notes upon the date of the IPO.

Prior to the completion of the IPO on November 18, 2014, the Company had $2,512,119 in aggregate principal amount and accrued interest outstanding under the April, August and October 2014 convertible promissory notes. The 2014 convertible promissory notes automatically converted into units of common stock and warrants issued in the IPO. Based on the IPO price of $6.50 per unit, the April, August and October 2014 convertible promissory notes automatically converted into 552,105 units (which consisted of 552,105 shares of common stock, Series A warrants to purchase 552,105 shares of common stock, and Series B warrants to purchase 552,105 shares of common stock).

Note 6. Convertible Preferred Stock Warrants

In 2010 and 2012, in conjunction with the related party convertible note financings, the Company issued preferred stock warrants. The number of shares for which the warrant may be exercised is to be determined by dividing an amount equal to 25% of the unpaid principal by (a) 75% of the price per share of the equity securities issued in the next round of equity financing under certain conditions or (b) if converting into Series C preferred stock, $16.20 per share. The exercise price for the warrant is 75% of the price per share of equity securities issued in such financing or $16.20 per share if converted into the Series C preferred stock. The warrants are immediately exercisable and will expire 10 years from the original issuance date. The Company re-measured the associated fair value of the convertible preferred stock warrant liability at each reporting period.

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

	December 31, 2013
Volatility	38% - 47%
Expected Term (years)	0.75 - 2.00
Expected dividend yield	0.0%
Risk-free rate	0.12% - 0.38%

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

The Company changed the methodology described above to calculate the fair value of its preferred stock warrant upon the IPO, as all of preferred stock warrants converted into warrants to purchase shares of common stock and the IPO was completed. The Company used a Black Scholes model to calculate the value of these warrants on November 18, 2014 using the following inputs:

	November 18, 2014
Volatility	61% - 71.2%
Contractual Term (years)	4.5 - 7.5
Expected dividend yield	0.0%
Risk-free rate	1.50% - 2.09%
Stock Price	$4.00
Exercise Price	$4.87 - $21.60

As of December 31, 2013 and November 18, 2014 (IPO date), outstanding convertible preferred stock warrants consisted of:

Issuance date	Contractual Term	Exercise price per share	Number of shares underlying warrant	Fair Value at December 31, 2013	Fair Value at November 18, 2014
January 2009	10 years	$ 21.60	9,259	$ 42,444	2,911
2010/2012	10 years	Adjustable	Adjustable	1,422,433	1,217,808
Total				$ 1,464,877	1,220,719

The decrease in the fair value of the 2009 and 2010/2012 warrants between 12/31/2013 and the IPO date of $244,151 was recorded as other income during the year ended December 31, 2014. In connection with the completion of the Company s IPO, the 2009 and 2010/2012 outstanding warrants to purchase convertible preferred stock converted into warrants to purchase 523,867 shares of the Company s common stock with an exercise price of $4.87 and are no longer subject to adjustment to fair value as they were reclassified to permanent equity upon conversion.

In addition to the above, the preferred stock warrants that were issued in connection with the Company s 2014 convertible promissory notes expired upon the IPO. The fair value of the preferred stock warrant liability related to the 2014 notes was derecognized as a liability and accordingly the Company recorded a gain of $967,234 as other income during the year ended December 31, 2014.

As of December 31, 2013 all warrants issued by the Company prior to the IPO were issued to related parties consisting of investors and the Chairman of the Board.

Upon the IPO, the January 2009 warrants became exercisable for 9,259 of the Company s common stock, with an exercise price of $21.60.

Note 7. Series A Warrants and Series B Warrants

Series A Warrants

The Company has issued Series A warrants to purchase shares of its common stock at an exercise price of $6.49 per share. The Series A warrants are exercisable prior to the expiration of the five-year term on

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November 12, 2019. Pursuant to the terms of the Series A warrant agreement, the Company is not obligated to settle the exercise of the A warrants in cash under any circumstances. Upon the completion of the IPO, the Series A warrants started trading on the NASDAQ under the symbol CAPNW. The total proceeds from the issuance of the Series A warrants in the IPO was $9,488.

Upon completion of the Company s IPO on November 18, 2014, the 2014 convertible promissory notes automatically converted into 552,105 units (which consisted of 552,105 shares of common stock, Series A warrants to purchase 552,105 shares of common stock and Series B warrants to purchase 552,105 shares of common stock). In addition, the Company issued 1,897,500 Series A warrants in connection with its IPO. The value of the Series A warrants exercisable for 2,449,605 shares of common stock as of November 18, 2014 were classified as permanent equity.

Series B Warrants

The Company has issued Series B warrants to purchase shares of its common stock. In the event that the market price of the Company s common stock falls below $6.50 at any time between March 12, 2015 and February 12, 2016, the Series B warrants will become exercisable on a cashless basis for a number of common shares that increases as the market price of the Company s common stock decreases, and exercisable at a discount to the tracking price of the common stock at the time. The total proceeds from the issuance of the Series B warrants in the IPO was $9,488.

The Company accounts for the Series B warrants in accordance with the guidance in ASC 815-40. The terms of the Series B warrants do not explicitly limit the potential number of shares, thereby the exercise of the B warrants could result in the Company s obligation to deliver a potentially unlimited number of shares upon settlement. As such, share settlement is not considered to be within the control of the Company and as provided under ASC 815-40, the warrants do not meet the criteria for equity classification and are recorded as a liability. Accordingly, the Company classified the Series B warrants as liabilities at their fair value at the date of the IPO and will re-measure the warrants at each balance sheet date until they are exercised or expire. Any change in the fair value is recognized as other income (expense) in the Company s statement of operations.

As of November 18, 2014 and December 31, 2014, the Company used a Monte Carlo simulation to calculate the fair value of its Series B warrant liability. This model is dependent upon several variables such as the warrant s term, exercise price, current stock price, risk-free interest rate estimated over the contractual term, estimated volatility of our stock over the term of warrant and the estimated market price of our stock during the cashless exercise period. The risk-free rate is based on U.S. Treasury securities with similar maturities as the expected terms of the warrants. The volatility is estimated based on blending the volatility rates for a number of similar publicly-traded companies. The Company used the following inputs:

	November 18, 2014	December 31, 2014
Volatility	55.1%	60.2%
Expected Term (years)	1.25	1.1
Expected dividend yield	0.0%	0.0%
Risk-free rate	0.20%	0.26%

In addition to the assumptions above, the Company s estimated fair value of the Series B warrant liability is calculated using other key assumptions. Management, with the assistance of an independent valuation firm, makes these subjective determinations based on available current information; however, as such information changes, so might management s determinations and such changes could have a material impact of future operating results.

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As of November 18, 2014 and December 31, 2014, the outstanding Series B warrants and fair market values were:

Issuance date	Contractual Term	Exercise price per share	Number of warrants	Shares underlying warrants	Fair Value at November 18, 2014	Fair Value at December 31, 2014
November 2014	15 months	Adjustable	2,449,605	Adjustable	$ 11,649,106	$ 17,438,731

The increase in the fair value of the Series B warrants between the IPO date and 12/31/2014 of $5,789,625 was recognized as an other expense during the year ended December 31, 2014.

In addition to the Series B warrants, the Company issued Series A warrants in connection with its IPO, has other warrants issued prior to the IPO in connection with convertible debt and has other warrants classified as part of its permanent equity. Under ASC 815-40-35, the Company has adopted a sequencing policy that reclassifies contracts from equity to assets or liabilities for those with the latest inception date first. The Company has taken the position that the Series A warrants issued in the IPO have an earlier inception date than the Series B warrants issued as part of its IPO, and accordingly are treated as an equity instrument.

In accordance with the guidance under ASC 815-40-25, the Company has evaluated that it has a sufficient number of authorized and unissued shares, to settle all existing commitments as of December 31, 2014.

Note 8. Line of Credit

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

In October, 2014, the Company drew down the full amount of $0.1 million provided for by the line of credit.

Note 9. Commitments

Facility Leases

The Company leases its headquarters facility under a non-cancelable operating lease agreement set to expire the end of May 2015. The Company previously leased two other facilities under non-cancelable operating lease agreements that expired in January 2014 and May 2014, respectively. Rent expense was $304,000 and $230,000 during the fiscal years ended December 31, 2013 and December 31, 2014, respectively.

As of December 31, 2014, the Company s future minimum commitment under the non-cancelable operating lease is approximately $18,000.

Product Development Agreement

In 2010 the Company entered into an asset purchase agreement with BioMedical Drug Development, Inc. Pursuant to the agreement, the Company made a payment of $150,000 for the acquisition of intellectual property which the Company used to develop its product, CoSense. As part of the terms of the agreement, the Company is contingently

committed to make development and sales-related milestone payments of up to $200,000 under certain circumstances, as well as single-digit-percentage royalties relating to potential planned product sales of CoSense. The amount, timing and likelihood of these payments are unknown, as they are dependent on the occurrence of future events that may or may not occur. During the fiscal years ended December 31, 2013 and December 31, 2014, the Company made no payments and incurred no liabilities in connection with the agreement, and there are no outstanding payments due as of December 31, 2013 and December 31, 2014.

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Note 10. Capital Stock

Common Stock:

The Company is authorized to issue 100,000,000 shares of common stock as of December 31, 2014 with a par value of $0.001 per share. As of December 31, 2013 and December 31, 2014, the Company had 535,685 and 6,769,106 shares, respectively, of common stock issued and outstanding.

Upon the completion of the IPO on November 18, 2014, the 6,769,106 shares of common stock issued and outstanding consisted of the following:

Legacy Shareholders	535,685
Issued in connection with the IPO	1,650,000
Issued upon conversion of the 2014 convertible notes	552,105
Issued upon conversion of the 2010/2012 convertible notes	3,165,887
Issued upon conversion of the preferred stock	865,429
Total	6,769,106

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

Convertible Preferred Stock:

The Company is authorized to issue 1,860,000 shares of convertible preferred stock. The shares outstanding as of December 31, 2013 and December 31, 2014 are as follows:

			Shares Outstanding	
Series	**Par Value**	**Shares Authorized**	**December 31, 2013**	**December 31, 2014**
A	$ 0.001	40,000	31,250	
B	0.001	320,000	119,140	
C	0.001	1,500,000	715,039	
		1,860,000	865,429	

In connection with the completion of the Company s IPO on November 18, 2014, all shares of convertible preferred stock converted into 865,429 shares of common stock at a conversion ratio of one to one.

Note 11. Stock Option Compensation

Stock Option Plan

The Company has adopted the 1999 Incentive Stock Plan, the 2010 Equity Incentive Plan, and the 2014 Equity Incentive Plan (together, the Plans). The 1999 Incentive Stock Plan expired in 2009, and the 2010 Equity Incentive Plan has been closed to new issuances. Therefore, the Company may issue options to purchase shares of common stock to employees, directors, and consultants only under the 2014 Equity Incentive Plan. Options granted under the 2014 Plan may be incentive stock options (ISOs) or nonqualified stock options (NSOs). ISOs may be granted only to Company employees and directors. NSOs may be granted to employees, directors, advisors, and consultants. The Board of Directors has the authority to determine to whom options will be granted, the number of options, the term, and the exercise price.

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Options are to be granted at an exercise price not less than fair value for an ISO or 85% of fair value for an NSO. For individuals holding more than 10% of the voting rights of all classes of stock, the exercise price of an option will not be less than 110% of fair value. The vesting period is normally monthly over a period of four years from the vesting date. The contractual term of an option is no longer than five years for ISOs for which the grantee owns greater than 10% of the voting power of all classes of stock and no longer than ten years for all other options.

The Company recognized stock-based compensation expense related to options granted to employees for the fiscal years ended December 31, 2013 and 2014 of $38,417 and $345,435, respectively. The compensation expense is allocated on a departmental basis, based on the classification of the option holder. No income tax benefits have been recognized in the statements of operations for stock-based compensation arrangements as of December 31, 2013 and December 31, 2014.

Stock compensation expense was allocated between departments as follows

	Year ended	
	December 31, 2014	December 31, 2013
Research & Development	$ 64,020	$ 14,431
Sales & Marketing	$ 8,335	
General & Administrative	$ 273,080	$ 23,986
Total	$ 345,435	$ 38,417

The Company did not grant any stock options and no options were exercised during the year ended 12/31/2013. The Company granted options to purchase 926,384 of the Company s common stock in 2014. The fair value of each award granted was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for the year ended December 31, 2014:

	Year Ended December 31, 2014
Expected life (years)	5.8 - 6.1
Risk-free interest rate	1.6 - 1.8%
Volatility	43% - 59%
Dividend rate	0%

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

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

	Options Available	Number of Shares	Average Exercise Price	Weighted Average Grant Date Fair Value Per Option
Balances, December 31, 2013	124,824	239,606	3.36	
2014 Plan authorized	1,437,165			
Closed 2010 Plan	(123,523)			
Granted	(926,384)	926,384	7.15	$ 1.03
Forfeited	93,979	(93,979)	6.75	$ 1.03
Balances, December 31, 2014	606,061	1,072,011	6.34	

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At December 31, 2013 and at December 31, 2014, there were 232,302 and 578,889 options to purchase shares, respectively, vested with a weighted-average exercise price of $3.36 and $5.58 per share, respectively, a weighted average contractual life of 3.86 and 7.46 years, respectively and a weighted average grant date fair value per option of $0.1 and $0.66, respectively. As of December 31, 2014, the outstanding stock options had an intrinsic value of $20,228. The weighted average remaining contractual term of the outstanding options was 8.67 years as of December 31, 2014.

Future stock-based compensation for unvested employee options granted and outstanding as of December 31, 2014 is approximately $539,087 to be recognized over a remaining requisite service period of 3.88 years.

The fair value of an equity award granted to a non-employee generally is determined in the same manner as an equity award granted to an employee. In most cases, the fair value of the equity securities granted is more reliably determinable than the fair value of the goods or services received. Stock-based compensation related to its grant of options to non-employees has not been material to date.

Note 12. GSK License Agreement

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

Note 13. Income Taxes

Due to net losses in 2014 and 2013, the Company had no material current, deferred, or total income tax expense in the years ended December 31, 2014 and 2013. A reconciliation of income tax expense with amounts determined by applying the statutory U.S. federal income tax rate to income before income taxes is as follows:

	Years Ended December 31,	
	2014	2013
Tax on the loss before income tax expense computed at the federal statutory rate of 34%	$ (4,717,063)	$ (1,260,190)
State tax (benefit) at statutory rate, net of federal benefit	(13,020)	43,265
Change in Valuation Allowance	1,578,347	779,869
Change in research and development credits	316,311	(71,856)
Change in fair value of warrants	2,960,766	
Other	(125,341)	508,912
Income tax expense	$	$
Effective income tax rate	0%	0%

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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company s deferred tax assets and liabilities are as follows at December 31, 2014 and 2013:

	December 31,	
	2014	2013
Current Deferred Tax Assets:		
Accruals	$ 71,953	$ 36,571
Non-Current Deferred Tax Assets:		
Net Operating Loss Carryforwards	22,125,807	20,124,059
Research and development credits	1,345,833	1,792,798
Intangible Assets	46,784	48,733
Fixed Assets	(10,505)	(636)
Total Non-Current Deferred Tax Assets	23,507,919	21,964,954
Total Deferred Tax Assets	23,579,872	22,001,525
Valuation Allowance	(23,579,872)	(22,001,525)
Net Deferred Tax Assets	$	$

The Company has recorded a full valuation allowance against its net deferred tax assets as it believes that it is more likely than not that such assets will not be realized. The valuation allowance increased by $1,578,347 from December 31, 2013 to December 31, 2014 primarily due to the generation of current year net operating losses and research and development credits claimed.

As of December 31, 2014, the Company had $56,626,541 of federal and $ 49,238,708 of state net operating loss, respectively, available to offset future taxable income. The federal net operating loss carryforwards begins to expire in 2019 and the state net operating loss carryforwards will begin to expire in 2015, if not utilized. As of December 31, 2014, the Company also had $1,298,450 of federal and $ 945,710 of state research and development credit carryforwards, respectively. The federal research and development credit carryforward begins to expire in 2024 and the state research and development credit can be carryforward indefinitely.

In addition, the use of net operating loss and tax credit carryforwards may be limited under Section 382 of the Internal Revenue Code in certain situations where changes occur in the stock ownership of a company. In the event that the Company has had a change in ownership, utilization of the carryforwards could be restricted.

The following tables summarize the activities of gross unrecognized tax benefits:

	December 31,	
	2014	2013
Beginning balance		
Increase related to prior year tax positions	628,383	

Decreases related to prior year tax positions	
Increase related to Current year tax positions	44,864
Decreases related to current year tax positions	
Ending Balance	$ 673,247

The amount of unrecognized tax benefits that would impact the effective tax rate were approximately none and none as of December 31, 2014 and December 31, 2013, respectively. As of December 31, 2014, $673,248 of unrecognized tax benefits would be offset by a change in valuation allowance.

In July 2013, the FASB issued guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss or tax carryforward exists. FASB concluded that an unrecognized tax benefit

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should be presented as a reduction of a deferred tax asset except in certain circumstances the unrecognized tax benefit should be presented as a liability and should not be combined with deferred tax assets. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. The Company adopted this guidance during the year ended December 31, 2014 and presented its unrecognized tax benefit as a reduction of deferred tax assets as of December 31, 2014.

The Company files income tax returns in the U.S. federal jurisdiction and certain state jurisdictions. In the normal course of business, the Company is subject to examination by federal, state and local jurisdictions, where applicable. In the U.S. federal jurisdiction, tax years 1999 forward remain open to examination, and in the state tax jurisdiction, years 2004 forward remain open to examination.

As a result of the expiration of the Company s net operating loss carry-forwards, the Company has adopted the provisions set forth in FASB ASC Topic 740, to account for uncertainty in income taxes. In the preparation of income tax returns in federal and state jurisdictions, the Company asserts certain tax positions based on its understanding and interpretation of the income tax law. The taxing authorities may challenge such positions, and the resolution of such matters could result in recognition of income tax expense in the Company s financial statements. Management believes it has used reasonable judgments and conclusions in the preparation of its income tax returns.

The Company uses the more likely than not criterion for recognizing the tax benefit of uncertain tax positions and to establish measurement criteria for income tax benefits. The Company has determined it has no material unrecognized assets or liabilities related to uncertain tax positions as of December 31, 2014. The Company does not anticipate any significant changes in such uncertainties and judgments during the next 12 months. In the event the Company should need to recognize interest and penalties related to unrecognized tax liabilities, this amount will be recorded as a component of other expense.

Note 14. Defined Contribution Plan

The Company sponsors a 401(k) Plan, which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company s sole discretion. To date, the Company has not made any matching contributions.

Note 15. Subsequent Events

On January 9, 2015, the Company entered into an agreement with Lucile Packard Foundation for Children s Health, a charitable organization, to provide gifts totaling $210,000 during 2015. The purpose of the donation is to provide unrestricted support of the translational research efforts for Neonatal-Perinatal and Developmental Medicine under the direction of Dr. Vinod Bhutani. A portion of the funds may be provided to Beaumont Children s Hospital, Royal Oak, MI; Albert Einstein Medical Center, Philadelphia, PA and McKay Dee Hospital & Intermountain Medical Center, Ogden, UT for research efforts provided by these collaborators.

On February 2, 2015, the Company signed an amendment to its current lease agreement, extending the lease through June 2018. The amendment provides for monthly lease payments of $21,719 for the first year starting in June 2015, with modest increases in the following two years.

On March 5, 2015, the Company entered into separate agreements with certain holders of the Company s Series B warrants, who agreed to exercise their Series B warrants to purchase an aggregate of 589,510 shares of the Company s common stock at an exercise price of $6.50 per share, resulting in gross proceeds to the Company of approximately

$3.8 million. In connection with this exercise of the Series B warrants, the Company issued to each investor who exercised Series B warrants, new Series C warrants for the number of shares of the Company s common stock underlying the Series B warrants that were exercised. Each Series C warrant will be exercisable at $6.25 per share and will expire on March 5, 2020. The new Series C warrants are exercisable into 589,510 shares of the Company s common stock.

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The Company intends to offer all remaining holders of Series B warrants, through a formal tender/registered exchange offer, the opportunity to exercise the Series B warrants held by them and receive Series C warrants with the same terms indicated above.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer and with the participation of our audit committee, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2014. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2014 at the reasonable assurance level.

Management s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). 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 for external reporting purposes in accordance with United States generally accepted accounting principles.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2014 based on the guidelines established in *Internal Control-Integrated Framework* (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on the results of our evaluation, our management concluded that there was a material weakness in our internal control over financial reporting as of December 31, 2014. We reviewed the results of management s assessment with our Audit Committee.

Material Weakness in Internal Control over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected and corrected on a timely basis.

In connection with our preparation for the IPO which closed on November 18, 2014, 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, 2014. The material weakness we identified related to not maintaining sufficient compliment of resources with an appropriate level of accounting knowledge, experience and training commensurate with our

structure and financial reporting requirements.

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Management s Remediation Activities

With the oversight of senior management and our audit committee, we executed the implementation of remediation steps in 2014, which continued in 2015. These efforts focused on (i) the hiring of a Chief Financial Officer on July 7, 2014 with technical accounting and financial reporting experience; (ii) the implementation of improved accounting and financial reporting 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, and (iii) utilizing outside technical accounting consultants when necessary.

We believe these steps, which were fully implemented as of the date of the filing of this 10-K, have remediated the material weakness previously identified and have enhanced our internal control over financial reporting, as well as our disclosure controls and procedures. However, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

Other than the changes described above under Management s Remediation Activities, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rules 13a-15 or 15d-15 that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item to our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS,

AND DIRECTOR INDEPENDENCE

The information required by this item to our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to our Definitive Proxy Statement for our 2015 Annual Meeting of Stockholders. The Definitive Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See Index to Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K

2 Financial Schedules: All schedules have been omitted because the information called for is not required or is shown either in the financial statements or in the notes thereto.

3. Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CAPNIA, INC.

Date: March 13, 2015 By: /s/ ANISH BHATNAGAR

President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Anish Bhatnagar and David O Toole, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ ANISH BHATNAGAR Anish Bhatnagar	President, Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2015
/s/ DAVID D. O TOOLE David D. O Toole	Chief Financial Officer (Principal Financing and Accounting Officer)	March 13, 2015
/s/ ERNEST MARIO Ernest Mario	Chairman	March 13, 2015
/s/ EDGAR G. ENGLEMAN Edgar G. Engleman	Director	March 13, 2015
/s/ STEINAR J. ENGELSEN Steinar J. Engelsen	Director	March 13, 2015

/s/ Stephen Kirnon Stephen Kirnon	Director	March 13, 2015
/s/ William James Alexander William James Alexander	Director	March 13, 2015
/s/ William G. Harris William G. Harris	Director	March 13, 2015

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EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by Reference from Registrant s Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
3.2	Amended and Restated Certificate of Incorporation of Capnia, Inc.	S-1/A	August 7, 2014	3.2	
3.4	Amended and Restated Bylaws of Capnia, Inc.	S-1/A	July 1, 2014	3.4	
4.1	Form of the common stock certificate.	S-1/A	August 5, 2014	4.1	
4.2	Amended And Restated Investors Rights Agreement, dated March 20, 2008, by and among Capnia, Inc. and certain holders of the Capnia, Inc. s capital stock named therein	S-1	June 10, 2014	4.2	
4.3	Form of Series A Warrant Agreement.	S-1/A	November 12, 2014	4.3	
4.4	Form of the Series A warrant certificate.	S-1/A	November 12, 2014	4.4	
4.5	Form of Underwriters Compensation Warrant.	S-1/A	August 5, 2014	4.5	
4.6	Form of Convertible Promissory Note issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.6	
4.7	Form of Warrant to Purchase Shares issued in February 2010 and March 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.7	
4.8	Form of Convertible Promissory Note issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.8	
4.9	Form of Warrant to Purchase Shares issued in November 2010 in connection with the 2010 convertible note financing.	S-1	June 10, 2014	4.9	
4.10	Form of Convertible Promissory Note issued in January 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.10	

4.11	Form of Warrant to Purchase Shares issued in January 2012 in connection with Capnia, Inc. s 2012 convertible note financing.	S-1	June 10, 2014	4.11
4.12	Form of Convertible Promissory Note issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.12
4.13	Form of Warrant to Purchase Shares issued in July 2012 and August 2012 in connection with the 2012 convertible note financing.	S-1	June 10, 2014	4.13

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Exhibit Number	Description of Document	Incorporated by Reference from Registrant s Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
4.14	Form of Convertible Promissory Note issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.14	
4.15	Form of Warrant to Purchase Shares issued in April, August and October 2014 in connection with the 2014 convertible note financing.	S-1	June 10, 2014	4.15	
4.16	Form of unit certificate.	S-1/A	August 5, 2014	4.16	
4.17	Form of Series B Warrant Agreement.	S-1/A	November 12, 2014	4.17	
4.18	Form of the Series B warrant certificate.	S-1/A	November 12, 2014	4.18	
10.1	Form of Indemnification Agreement between Capnia, Inc. and each of its directors and executive officers.	S-1	June 10, 2014	10.1	
10.2	1999 Incentive Stock Plan and forms of agreements thereunder.	S-1	June 10, 2014	10.2	
10.3	2010 Equity Incentive Plan and forms of agreements thereunder.	S-1	June 10, 2014	10.3	
10.4	2014 Equity Incentive Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.4	
10.5	2014 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	July 1, 2014	10.5	
10.6	Offer Letter, dated June 22, 2007, by and between Capnia, Inc. and Ernest Mario, Ph.D.	S-1	June 10, 2014	10.6	
10.7	Employment Agreement, dated April 6, 2010, by and between Capnia, Inc. and Anish Bhatnagar.	S-1	June 10, 2014	10.7	
10.8	Offer Letter, dated May 29, 2013, between Capnia, Inc. and Anthony Wondka.	S-1	June 10, 2014	10.8	
10.9	Offer Letter, dated April 17, 2014, by and between Capnia, Inc. and Antoun Nabhan.	S-1	June 10, 2014	10.9	
10.10	Asset Purchase Agreement dated May 11, 2010, by and between Capnia, Inc. and BioMedical Drug	S-1	June 10, 2014	10.10	

	Development Inc.			
10.11	Convertible Note and Warrant Purchase Agreement, dated February 10, 2010, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.11
10.12	Amendment No. 1 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated November 10, 2010, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.12

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Exhibit Number	Description of Document	Incorporated by Reference from Registrant s Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
10.13	Amendment No. 2 to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated January 17, 2012, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.13	
10.14	Convertible Note and Warrant Purchase Agreement, dated January 16, 2012, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.14	
10.15	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated July 31, 2012, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.15	
10.16	Omnibus Amendment to Convertible Promissory Notes and Warrants to Purchase Shares, dated April 28, 2014, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.16	
10.17	Convertible Note and Warrant Purchase Agreement, dated April 28, 2014, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.17	
10.18	Omnibus Amendment to Convertible Note and Warrant Purchase Agreement, Convertible Promissory Notes and Warrants to Purchase Shares, dated May 5, 2014, by and among Capnia, Inc. and the investors named therein.	S-1	June 10, 2014	10.18	
10.19	Sublease, dated May 20, 2014, by and among Capnia, Inc. and Silicon Valley Finance Group.	S-1/A	July 1, 2014	10.19	
10.20	Offer Letter, dated June 24, 2014, by and between Capnia, Inc. and David D. O Toole.	S-1/A	July 22, 2014	10.20	
10.21		S-1/A	September 29, 2014	10.21	

	Loan Agreement by and between Capnia, Inc. and the investors named therein, dated September 29, 2014.			
10.22	Revised Second Tranche Closing Notice and Letter Amendment dated August 18, 2014 relating to the August 2014 Notes.	S-1/A	November 4, 2014	10.22
10.23	Second Tranche Subsequent Closing Notice and Letter Amendment dated October 22, 2014 relating to the October 2014 Notes.	S-1/A	November 4, 2014	10.23

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Exhibit Number	Description of Document	Incorporated by Reference from Registrant s Form	Date Filed with the SEC	Exhibit Number	Filed Herewith
24.1	Power of Attorney (included on signature page).				
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as amended.				X
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. §1350.				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				X

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