Capnia, Inc.
Form 424B3
June 25, 2015
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Filed Pursuant to Rule 424(b)(3)
Registration No. 333-203162

Offer To Exchange (Exchange Offer)

Series C Warrants to purchase shares of Common Stock

for

the Cash Exercise of Series B Warrants to purchase shares of Common Stock

of

Capnia, Inc.

THE EXCHANGE OFFER WILL EXPIRE AT 5:00 PM

NEW YORK CITY TIME, ON JULY 24, 2015, UNLESS EXTENDED (SUCH DATE AND TIME, AS THE SAME MAY BE EXTENDED, THE EXPIRATION DATE)

We are offering to issue Series C Warrants (to purchase our Common Stock) in exchange for the valid tender and, upon acceptance, subsequent cash exercise of our Series B Warrants to purchase shares of our Common Stock. In order to participate in this Exchange Offer, a holder of Series B Warrants will cause the brokerage firm that is the depository for their Series B Warrants to electronically transfer their unexercised Series B Warrant holdings that they wish to exchange to the Exchange Agent (as defined below), where such Series B Warrants will be held by the Exchange Agent until accepted for exercise and exchange for Series C Warrants at the end of the Exchange Offer period. See Description of Warrants Included in the Exchange Offer and General Terms of the Exchange Offer.

In exchange for the tender and, upon acceptance, subsequent cash exercise of the Series B Warrants, a holder of the Series B Warrants will receive the number of shares of Common Stock underlying such tendered Series B Warrants and a Series C Warrant. Each Series C Warrant will: (i) be exercisable at $6.25 per share; (ii) be exercisable for the number of shares of Common Stock underlying the Series B Warrants that are tendered, and upon acceptance, subsequently cash exercised by such holders; (iii) be immediately exercisable upon issuance and until March 4, 2020; and (iv) not include the cashless exercise feature that is contained in the Series B Warrants, which results in an increasing number of shares of Common Stock issuable without consideration as the price of the Common Stock decreases.

We are making this offer upon the terms and subject to the conditions described in this prospectus and in the related Letter of Transmittal which together, as they may be amended from time to time, constitute the Exchange Offer.

Our Common Stock is currently listed on the NASDAQ Capital Market under the symbol CAPN.

Neither the Securities and Exchange Commission, or SEC, nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the

contrary is a criminal offense.

This prospectus is dated June 25, 2015.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein, contain forward-looking statements regarding management s expectations, beliefs, strategies, goals, outlook and other non-historical matters. In some cases you can identify these statements by forward-looking words, such as believe, may, will, estimate, continue, anticipate, could, would, project, plan, potential, seek, expect, goal, or the negative or plural of these words or sim expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expected uses of the net proceeds to us from the Exchange Offer;
- our ability to successfully build a sales force and commercial infrastructure for CoSense®
- the timing and the success of approvals of any of our planned Nasal CO_2 products pursuant to our clinical and regulatory efforts;
- whether the results of the trials will be sufficient to support domestic or global regulatory approvals for any of our planned Nasal CO_2 products;
- our ability to maintain regulatory approval of CoSense or to obtain and maintain regulatory approval of our planned products;
- our expectation that our existing capital resources and the net proceeds from the Exchange Offer will be sufficient to enable us to successfully meet the capital requirements for all of our current and future products;
- the benefits of the use of CoSense or any of our planned Nasal CO_2 products;
- the projected dollar amounts of future sales of established and novel diagnostics for neonatal hemolysis;
- our ability to successfully commercialize any planned products;
- the rate and degree of market acceptance of CoSense or any of our planned Nasal CO_2 products;
- our expectations regarding government and third-party payor coverage and reimbursement;

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

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

our reliance on third parties to conduct clinical studies;

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

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

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

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our ability to obtain and maintain intellectual property protection for CoSense or any of our planned Nasal CO_2 products;

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

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

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

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

our financial performance; and

developments and projections relating to our competitors or our industry.

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

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

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

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IMPORTANT INFORMATION

Series B Warrants tendered pursuant to the Exchange Offer may be withdrawn: (i) at any time during the period the Exchange Offer remains open, which is through and until the Expiration Date; or (ii) if not yet accepted for payment, after the expiration of forty business days from the commencement of the Exchange Offer.

Series B Warrants tendered, along with the aggregate cash exercise price and executed, completed and dated Letters of Transmittal and any other required documents, should be directed to American Stock Transfer & Trust Company LLC, or, its subsidiary, D.F. King & Co., Inc., who are, together, acting as the Information and Exchange Agent for the Exchange Offer (the Exchange Agent). Any requests for assistance in connection with the Exchange Offer or for additional copies of this prospectus or related materials should be directed to the Exchange Agent. Contact information for the Exchange Agent is set forth under Exchange Agent. We and our board of directors and the Exchange Agent have not made any recommendation as to whether or not holders should tender their Series B Warrants pursuant to the Exchange Offer.

Subject to the terms and conditions set forth in the Exchange Offer, the consideration to which an tendering holder of the Series B Warrants is entitled pursuant to the Exchange Offer will be paid on the settlement date, which is the date promptly following the applicable expiration date of the Exchange Offer, subject to satisfaction or waiver (to the extent permitted) of all conditions precedent to the Exchange Offer.

Notwithstanding any other provision of the Exchange Offer, our obligation to issue Common Stock and a Series C Warrant for any Series B Warrant validly tendered and not validly withdrawn pursuant to the Exchange Offer is subject to, and conditioned upon, the satisfaction or waiver of the conditions described herein.

Subject to applicable securities laws and the terms of the Exchange Offer, we reserve the right:

- to waive any and all conditions to the Exchange Offer that may be waived by us;
- to extend the Exchange Offer;
- to terminate the Exchange Offer; or
- to otherwise amend the Exchange Offer in any respect in compliance with applicable securities laws and stock exchange rules.

If the Exchange Offer is withdrawn or otherwise not completed, the consideration (the issuance of Common Stock and Series C Warrants) will not be made to holders of Series B Warrants who have validly tendered their Series B Warrants pursuant to the terms of the Exchange Offer, and the Series B Warrants tendered pursuant to the terms of the Exchange Offer will be promptly returned to the tendering holders.

Only registered holders of Series B Warrants are entitled to tender their Series B Warrants in the Exchange Offer. Beneficial owners of Series B Warrants that are held of record by a broker, bank or other nominee or custodian must instruct such nominee or custodian to tender their Series B Warrants for cash and exchange in the Exchange Offer on the beneficial owner s behalf. A letter of instructions is included in the materials provided along with this prospectus,

which may be used by a beneficial owner in this process to affect the tender of Series B Warrants for tender pursuant to the terms of the Exchange Offer. Tendering holders of the Series B Warrants will not be obligated to pay brokerage fees or commissions to the Exchange Agent or us. If a broker, bank or other nominee or custodian tenders Series B Warrants for tender on behalf of an tendering holder, such broker, bank or other nominee or custodian may charge a fee for doing so. Tendering holders who own Series B Warrants through a broker, bank or other nominee or custodian should consult their broker, bank or other nominee or custodian to determine whether any charges will apply.

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MARKET AND INDUSTRY DATA

In this prospectus, we rely on and refer to information and statistics regarding our industry. Where possible, we obtained this information and these statistics from third party sources, such as independent industry publications, government publications or reports by market research firms, including company research, trade interviews, and public filings with the SEC. Additionally, we have supplemented third party information where necessary with management estimates based on our review of internal surveys, information from our customers and vendors, trade and business organizations and other contacts in markets in which we operate, and our management s knowledge and experience. However, these estimates are subject to change and are uncertain due to limits on the availability and reliability of primary sources of information and the voluntary nature of the data gathering process. As a result, you should be aware that industry data included in this prospectus, and estimates and beliefs based on that data, may not be reliable.

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QUESTIONS AND ANSWERS ABOUT THE EXCHANGE OFFER

The following are some questions and answers regarding the Exchange Offer. It does not contain all of the information that may be important to you. You should carefully read this prospectus to fully understand the terms of the Exchange Offer, as well as the other considerations that are important to you in making your investment decision. You should pay special attention to the information provided under the captions entitled Risk Factors and Cautionary Note Regarding Forward-Looking Statements.

Who is making the Exchange Offer?

Capnia, Inc., a Delaware corporation and the issuer of the Series B Warrants, is making the Exchange Offer. The mailing address of our principal executive offices is 3 Twin Dolphin Drive, Suite 160, Redwood City, CA 94065. Our telephone number at these offices is (650) 213-8444. Our Common Stock is currently listed on the NASDAQ Capital Market under the symbol CAPN. See General Terms of the Exchange Offer.

Why are we making the Exchange Offer?

We are making the Exchange Offer in order to (i) receive cash proceeds from the exercise of the tendered Series B Warrants, which exercise will occur upon the acceptance of such tender pursuant to the terms of the Exchange Offer, and (ii) reduce the number of outstanding Series B Warrants that contain a cashless exercise feature that would result in an increasing number of shares of Common Stock issuable without consideration as the price of our Common Stock decreases. We believe that reducing the number of Series B Warrants outstanding is appropriate and will promote our long-term financial viability. See General Terms of the Exchange Offer.

On March 5, 2015, we entered into, and subsequently consummated, a private transaction pursuant to a Warrant Exercise Agreement (the Warrant Exercise Agreement) with certain holders of our Series B Warrants (the Private Transaction). The Series B Warrants were originally issued in connection with our IPO on November 18, 2014, and were exercisable for up to an aggregate of 2,449,605 shares of our Common Stock at an exercise price of $6.50 per share prior to their expiration on February 12, 2016. Pursuant to the Warrant Exercise Agreement, participating holders of Series B Warrants and we agreed that such Series B Warrant holders would cash exercise their Series B warrants in full and we would issue to the holders Series C Warrants at an exercise price of $6.25 per share to purchase up to an aggregate of 589,510 shares of Common Stock, which represented the aggregate number of shares of Common Stock underlying the Series B Warrants to be cash exercised pursuant to the Warrant Exercise Agreement. We received gross proceeds of approximately $3.8 million from the cash exercises of the Series B Warrants in connection with the Private Transaction. In consideration for the cash exercise of the Series B Warrants in connection with the Private Transaction and pursuant to the terms of the Warrant Exercise Agreement, we issued the Series C Warrants to such holders of the Series B Warrants.

The Company is now permitting all holders of Series B Warrants to tender their Series B Warrants and receive (i) the underlying shares of Common Stock issuable on the exercise of such Series B Warrants, which exercise will occur upon the acceptance of such tender pursuant to the terms of Exchange Offer, and (ii) the Series C Warrants. See General Terms of the Exchange Offer and Description of Warrants Included in the Exchange Offer Series C Warrants.

When does the Exchange Offer expire?

The Exchange Offer will expire on the Expiration Date at 5:00 p.m., New York City time, on July 24, 2015 unless the Exchange Offer is extended at our sole discretion. See General Terms of the Exchange Offer.

Can the Exchange Offer be extended?

Yes, we can extend the Exchange Offer. See General Terms of the Exchange Offer Extension, Termination or Amendment.

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What securities are subject to the Exchange Offer?

We are offering to issue Series C Warrants to the holders of outstanding Series B Warrants who tender such Series B Warrants on or prior to the Expiration Date, upon the terms and subject to the conditions described in this prospectus and as permitted under the terms of the Exchange Offer. Our acceptance of the Series B Warrants for exchange pursuant to the Warrant Exercise Agreement and the closing of the Exchange Offer is subject to the conditions described under General Terms of the Exchange Offer Conditions of the Exchange Offer.

The Series B Warrants were originally issued in connection with our initial public offering, or IPO, on November 18, 2014 and were exercisable for an aggregate of 2,449,605 shares of Common Stock, at an exercise price of $6.50 per share, with a term that expires on February 12, 2016. The Series B Warrants contain a cashless exercise feature that would result in an increasing number of shares of Common Stock issuable without consideration as the price of our Common Stock decreases. In connection with the Private Transaction and the separate cash exercise of certain of the Series B Warrants, we entered into a Warrant Exercise Agreement with certain holders of the Series B Warrants whereby we agreed to issue new Series C Warrants to these holders of Series B Warrants who chose to cash exercise their Series B Warrants. In consideration for the cash exercise of the Series B Warrants, and pursuant to the terms of the Warrant Exercise Agreement, the Company issued the Series C Warrants to such exercising holders of Series B Warrants. Each Series C Warrant issued in the Private Transaction and the Exchange Offer will: (i) be exercisable at $6.25 per share; (ii) be exercisable for the number of shares of Common Stock underlying the Series B Warrants that are cash exercised by such holders pursuant to the Warrant Exercise Agreement; (iii) be immediately exercisable upon issuance and until March 4, 2020; and (iv) not include the cashless exercise feature that is contained in the Series B Warrants, which feature results in an increasing number of shares of Common Stock issuable without consideration as the price of our Common Stock decreases.

The Series C Warrants in this Exchange Offer and the sale of the underlying shares of Common Stock will be registered pursuant to this registration statement at the time the Series C Warrants are issued.

The terms of the Series B Warrants as currently in effect are the same as the terms in effect at the time the Series B Warrants were originally issued as part of our IPO, and holders are referred to the form of Series B Warrant Agreement, filed with the Securities Exchange and Commission on November 12, 2014 as Exhibit 4.17 to our Form S-1/A Registration Statement, for a complete description of the terms governing the Series B Warrants.

What will I receive in the Exchange Offer?

If you validly tender your Series B Warrants pursuant to the Exchange Offer, then, subject to the terms and conditions of the Exchange Offer, you will receive, in addition to the underlying shares of Common Stock issuable on the exercise of such Series B Warrants, which exercise will occur upon the acceptance of the tendered Series B Warrants, Series C Warrants which: (i) are exercisable at $6.25 per share; (ii) are exercisable for the number of shares of Common Stock underlying the Series B Warrants that were tendered by such holders; (iii) are immediately exercisable upon issuance and until March 4, 2020, and (iv) do not include the cashless exercise feature that was contained in the Series B Warrant that results in an increasing number of shares of Common Stock issuable without consideration as the price of our Common Stock decreases. See Description of Warrants Included in the Exchange Offer Series C Warrants. The Exchange Offer is subject to the conditions described under General Terms of the Exchange Offer Conditions of the Exchange Offer.

When are the new Series C Warrants exercisable into shares of Common Stock of the Company?

The Series C Warrants will be immediately exercisable into shares of Common Stock at an exercise price of $6.25 per share. To the extent that any such holders of Series B Warrants do not choose to participate in the Exchange Offer, their Series B Warrants will remain outstanding, unmodified and unexercised, subject to their current terms.

See Description of Warrants Included in the Exchange Offer and General Terms of the Exchange Offer.

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What percentage of the ownership of the Issuer will holders of Series B Warrants beneficially hold if the Exchange Offer is completed?

Assuming all Series B Warrants originally issued in connection with our IPO (including the Series B Warrants that were previously cash exercised pursuant to the Private Transaction for 589,510 shares of Common Stock on or about March 5, 2015, but excluding (i) Series B Warrants to purchase an aggregate of 29,097 shares of Common Stock that were exercised subsequent to the Private Transaction but prior to commencement of the Exchange Offer (ii) Series B Warrants to purchase an aggregate of 84,281 shares of Common Stock that were cashless exercised, and (iii) Series B Warrants to purchase 468 shares of Common Stock that were contributed back to the Company) are tendered as of June 1, 2015, then such holders of the Series B Warrants shall have purchased an aggregate of 2,206,465 shares of the Common Stock, at an exercise price of $6.50 per share, and shall receive new Series C Warrants to purchase up to an aggregate of 2,206,465 shares of Common Stock based on the Series B Warrants outstanding prior to June 1, 2015, at an exercise price of $6.25 per share.

The total of 4,526,308 shares of Common Stock, consisting of:

(i) 589,510 shares of Common Stock issued on March 5, 2015 in the Private Transaction upon the exercise of Series B Warrants to purchase 589,510 shares of Common Stock;

(ii) 589,510 shares of Common Stock issuable upon the exercise of Series C Warrants to purchase 589,510 shares of Common Stock that were issued on March 5, 2015 in the Private Transaction;

(iii) 29,097 shares of Common Stock issued upon the exercise of Series B Warrants subsequent to the Private Transaction but prior to commencement of the Exchange Offer;

(iv) 1,616,955 shares of Common Stock issuable upon the exercise of outstanding Series B Warrants eligible for tender under the Exchange Offer;

(v) 1,616,955 shares of Common Stock issuable upon the exercise of Series C Warrants to purchase 1,616,955 shares of Common Stock to be issued in the Exchange Offer (assuming that all holders of eligible Series B Warrants tender their Series B Warrants in full in the Exchange Offer); and

(vi) 84,281 shares of Common Stock issued upon the cashless exercise of 213,575 Series B Warrants exercised prior to June 1, 2015;

would represent, in the aggregate, approximately 49.6% of our outstanding Common Stock immediately following the Exchange Offer, based on an aggregate of 9,128,439 shares of Common Stock immediately outstanding following the consummation of the Exchange Offer, consisting of:

(i) 7,448,389 shares of our Common Stock outstanding as of March 31, 2015, as reported on our Quarterly Report on Form 10-Q for the period ended March 31, 2015, filed with the SEC on May 4, 2015;

(ii) 1,616,955 shares of Common Stock issuable upon the exercise of outstanding Series B Warrants eligible for tender under the Exchange Offer based on the Series B Warrants outstanding prior to May 1, 2015; and

(iii) 63,095 shares of Common Stock issued upon the cashless exercise of 161,320 Series B Warrants exercised after March 31, 2015 but prior to June 1, 2015.

What is the aggregate number of shares of Common Stock underlying the Series C Warrants that the holders of Series B Warrants will receive pursuant to the Exchange Offer?

Assuming all Series B Warrants originally issued in connection with our IPO (but excluding (i) the Series B Warrants that were previously cash exercised pursuant to the Private Transaction for 589,510 shares of

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Common Stock on or about March 5, 2015, (ii) Series B Warrants to purchase an aggregate of 29,097 shares of Common Stock that were exercised prior to commencement of the Exchange Offer, (iii) Series B Warrants to purchase 468 shares of Common Stock that were contributed back to the Company, and (iv) Series B Warrants to purchase an aggregate of 84,281 shares of Common Stock that were cashless exercised) are tendered and accepted in full pursuant to the Exchange Offer, then such holders of the Series B Warrants shall have been issued Series C Warrants to purchase an aggregate of 1,616,955 shares of Common Stock.

Who may participate in the Exchange Offer?

All registered holders of outstanding Series B Warrants as of the date of the commencement of the Exchange Offer may participate in the Exchange Offer.

Are there any conditions to the Exchange Offer?

Yes. The Exchange Offer is conditioned on the closing conditions described under General Terms of the Exchange Offer Conditions of the Exchange Offer. We will not be required, but we reserve the right, to accept any tender of a Series B Warrant for cash exercise and exchange pursuant to the Exchange Offer (or, alternatively, we may terminate the Exchange Offer) if any of the conditions of the Exchange Offer as described under General Terms of the Exchange Offer Conditions of the Exchange Offer remain unsatisfied. Among the conditions precedent to the consummation of the Exchange Offer is that all conditions precedent to the closing of the Exchange Offer shall have been satisfied or waived by the holders in accordance with the terms of this prospectus and the Letters of Transmittal.

What rights will I lose if I tender my Series B Warrants in the Exchange Offer and receive the new Series C Warrants?

If you validly tender your Series B Warrants pursuant to the Exchange Offer, then, upon the acceptance of such tender and subject to the terms and conditions of the Exchange Offer, you will receive the shares of Common Stock underlying the Series B Warrants and also new Series C Warrants. The features of the Series C Warrant that differ from the features of the Series B Warrant are as follows: (i) the Series C Warrants are exercisable at $6.25 per share, whereas the Series B Warrants are exercisable at $6.50 per share; (ii) the Series C Warrants are immediately exercisable upon issuance and until March 4, 2020, whereas the Series B Warrants are exercisable upon issuance and until February 12, 2016, and (iii) the Series C Warrants do not include the cashless exercise feature that was contained in the Series B Warrant that results in an increasing number of shares of Common Stock issuable without consideration as the price of our Common Stock decreases. See Description of Warrants Included in the Exchange Offer. The Exchange Offer is subject to the conditions described under General Terms of the Exchange Offer Conditions of the Exchange Offer.

How can I determine the market value of the Series B Warrants?

The Series B Warrants are not listed on any securities exchange. To the extent that the Series B Warrants have traded, prices of the Series B Warrants have fluctuated depending, among other things, upon trading volume, the balance between buy and sell orders, prevailing interest rates, our operating results and financial conditions, our business prospects and the market for similar securities.

Will the new securities be freely tradable?

The shares of Common Stock issued upon cash exercise of the Series B Warrants and the shares of Common Stock underlying the Series C Warrants received in the Exchange Offer will be freely tradable in the United States, unless

you are an affiliate of the Company, as that term is defined in the Securities Act. The Company s Common Stock is listed on the NASDAQ Capital Market under the symbol CAPN. Our Common Stock may be delisted if we fail to maintain market capitalization thresholds or if our stock fails to maintain a minimum trading price of $1.00 per share over a consecutive 30-day trading period. We do not intend to list the

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Series C Warrants on the NASDAQ Capital Market or any national or regional securities exchange, and therefore no trading market for the Series C Warrants will exist upon consummation of the Exchange Offer, and none is likely to develop. However, the Series C Warrants and the sale of the underlying shares of Common Stock will be registered pursuant to this registration statement at the time the Series C Warrants are issued.

What risks should I consider in deciding whether or not to tender my Series B Warrants in the Exchange Offer?

In deciding whether to participate in the Exchange Offer, you should carefully consider the discussion of the risks and uncertainties relating to the Exchange Offer, our Company and our industry described in the section entitled Risk Factors, beginning on page 17 of this prospectus.

What happens if I do not participate in the Exchange Offer?

If you currently hold Series B Warrants and do not tender them pursuant to the Exchange Offer, then, following the expiration of the Exchange Offer, your Series B Warrants will continue to be outstanding according to their terms unmodified. The terms of the Series B Warrants as currently in effect are the same as the terms in effect at the time the Series B Warrants were originally issued in our IPO, and holders are referred to the form of Series B Warrant Agreement, filed with the Securities Exchange and Commission on November 12, 2014 as Exhibit 4.17 to our Form S-1/A Registration Statement, for a complete description of the terms governing the Series B Warrants.

How do I participate in the Exchange Offer?

To tender your Series B Warrants pursuant to the terms of the Exchange Offer, you must deliver to the Exchange Agent, on or prior to the Expiration Date, the aggregate cash exercise price for such Series B Warrants being tendered pursuant to the specified wire instructions and the executed, completed and dated Letter of Transmittal and other required documents. The Expiration Date is no later than 5:00 p.m., New York City time, July 24, 2015, unless extended as described in this prospectus. See General Terms of the Exchange Offer Extension, Termination or Amendment.

A holder of Series B Warrants who desires to tender their Series B Warrants pursuant to the Exchange Offer and is a DTC participant should transfer their Series B Warrants electronically through DTC s automatic tender offer program, subject to the terms and procedures of that system. See General Terms of the Exchange Offer Transfer of Series B Warrants Through DTC s Automated Tender Offer Program.

HOLDERS THAT TRANSFER THROUGH DTC NEED NOT SUBMIT A PHYSICAL LETTER OF TRANSMITTAL TO THE EXCHANGE AGENT IF SUCH HOLDERS COMPLY WITH THE TRANSMITTAL PROCEDURES OF DTC.

A holder whose Series B Warrants are held by a broker, dealer, commercial bank, trust company or other nominee must contact that nominee if that holder desires to tender its Series B Warrants and instruct that nominee to tender the Series B Warrants on the holder s behalf.

May I withdraw my tender of the Series B Warrants?

Yes. You can withdraw the tender of your Series B Warrants in connection with the Exchange Offer (i) at any time during the period the Exchange Offer remains open or (ii) if not yet accepted for payment, after the expiration of forty business days from the commencement of the Exchange Offer. See General Terms of the Exchange Offer Withdrawal

of Tender.

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What happens if the tender of my Series B Warrants is not accepted in the Exchange Offer?

If we decide for any valid reason not to accept the tender of your Series B Warrants in connection with the Exchange Offer, your Series B Warrants will not be deemed to be exercised pursuant to the Exchange Offer and your Series B Warrants will remain outstanding, unmodified and unexercised, subject to their current terms. The terms of the Series B Warrants as currently in effect are the same as the terms in effect at the time the Series B Warrants were originally issued in our IPO, and holders are referred to the form of Series B Warrant Agreement, filed with the SEC on November 12, 2014 as Exhibit 4.17 to our Form S-1/A Registration Statement, for a complete description of the terms governing the Series B Warrants. See General Terms of the Exchange Offer Withdrawal of Tender.

Do I need to do anything if I do not wish to tender my Series B Warrants and not receive a new Series C Warrant?

No. If you do not properly tender your Series B Warrants in connection with the Exchange Offer on or prior to the Expiration Date, then your Series B Warrants will remain outstanding, unmodified and unexercised, subject to their current terms. The terms of the Series B Warrants as currently in effect are the same as the terms in effect at the time the Series B Warrants were originally issued in our IPO.

If I choose to tender my Series B Warrants in the Exchange Offer, do I have to tender all of my Series B Warrants in full?

No. You may tender all of your Series B Warrants in their entirety, a portion of your Series B Warrants, or none of your Series B Warrants in connection with the Exchange Offer. See General Terms of the Exchange Offer.

How will I be taxed under United States federal income tax laws upon the cash exercise of my Series B Warrants and the issuance of my new Series C Warrants if I am a United States holder of Series B Warrants?

We have not obtained and do not intend to obtain a ruling from the Internal Revenue Service (IRS) regarding the U.S. federal income tax consequences of your participation in the Exchange Offer. You should consult with your own tax advisor with regard to the possibility of any federal, state, local or other tax consequences of this Exchange Offer. See Certain United States Federal Income Tax Considerations .

Has the Board of Directors adopted a position on the Exchange Offer?

Our board of directors, which we refer to as the Board of Directors or the Board, has approved the Exchange Offer. However, our directors do not make any recommendation as to whether you should tender your Series B Warrants and receive Series C Warrants pursuant to the Exchange Offer. You should consult your own financial, tax, legal and other advisors and must make your own decision as to whether to tender your Series B Warrants and receive Common Stock and Series C Warrants.

Who will pay the fees and expenses associated with the Exchange Offer?

We will bear all of our fees and expenses incurred in connection with consummating the Exchange Offer.

See General Terms of the Exchange Offer. No brokerage commissions are payable by the holders to the Exchange Agent or us. If your Series B Warrants or underlying shares of Common Stock issuable upon exercise of the Series B Warrants are held or will be held through a broker or other nominee on your behalf, your broker or other nominee may charge you a commission for doing so. You should consult with your broker or other nominee to determine whether

any charges will apply. See General Terms of the Exchange Offer.

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Do other holders of Series B Warrants support the Exchange Offer?

Yes. Pursuant to the Private Transaction, we have previously entered into a separately negotiated Warrant Exercise Agreement with certain holders of the Series B Warrants who, in the aggregate, hold 589,510 shares of Common Stock issued upon the cash exercise of Series B Warrants that occurred on or about March 5, 2015. These shares represent approximately 24.07% of the 2,449,605 shares of the Common Stock underlying Series B Warrants that were issued in our IPO and were outstanding immediately prior to the closing of the Private Transaction (as further described in the prospectus summary below), at an exercise price of $6.50 per share. See The Prior Private Transaction.

The total of 4,526,308 shares of Common Stock, consisting of:

(i) 589,510 shares of Common Stock issued on March 5, 2015 in the Private Transaction upon the issuance of exercise of Series B Warrants to purchase 589,510 shares of Common Stock;

(ii) 589,510 shares of Common Stock issuable upon the exercise of Series C Warrants to purchase 589,510 shares of Common Stock that were issued on March 5, 2015 in the Private Transaction;

(iii) 29,097 shares of Common Stock issued upon the exercise of Series B Warrants subsequent to the Private Transaction but prior to commencement of the Exchange Offer;

(iv) 1,616,955 shares of Common Stock issuable upon the exercise of outstanding Series B Warrants eligible for tender based on the Series B Warrants outstanding prior to June 1, 2015;

(v) 1,616,955 shares of Common Stock issuable upon the exercise of Series C Warrants to purchase 1,616,955 shares of Common Stock to be issued in the Exchange Offer (assuming that all holders of eligible Series B Warrants tender their Series B Warrants in full in the Exchange Offer); and

(vi) 84,281 shares of Common Stock issued upon the cashless exercise of 213,575 Series B Warrants exercised prior to June 1, 2015.

would represent, in the aggregate, approximately 49.6% of our outstanding Common Stock immediately following the Exchange Offer, based on an aggregate of 9,128,439 shares of Common Stock immediately outstanding following the consummation of the Exchange Offer, consisting of:

(i) 7,448,389 shares of our Common Stock outstanding as of March 31, 2015, as reported on our Quarterly Report on Form 10-Q for the three months ended March 31, 2015, filed with the SEC on May 4, 2015;

(ii) 1,616,955 shares of Common Stock issuable upon the exercise of outstanding Series B Warrants eligible for tender based on the Series B Warrants outstanding prior to June 1, 2015; and

(iii) 63,095 shares of Common Stock issued upon the cashless exercise of 161,320 Series B Warrants exercised after March 31, 2015, but prior to June 1, 2015.

Who can answer questions concerning the Exchange Offer?

Requests for assistance in connection with the tender of your Series B Warrants pursuant to the Exchange Offer may be directed to the Exchange Agent for the Exchange Offer, American Stock Transfer & Trust Company, LLC P.O.

Box 2042, New York, New York 10272-2042, Attention: Reorganization Department; phone: 877-248-6417 or 718-921-8317.

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PROSPECTUS SUMMARY

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

Company Overview

We develop novel products based on our proprietary technology for precision metering of gas flow. Our first product, CoSense®, aids in the diagnosis of hemolysis, a condition in which red blood cells degrade rapidly. When present in neonates with jaundice, hemolysis is a dangerous condition which can lead to long-term developmental disability. CoSense has 510(k) clearance for sale in the U.S., with a specific Indication for Use related to hemolysis issued, and has received CE Mark certification for sale in the European Union, or E.U. CoSense is commercially available in the U.S., with our first commercial sales occurring in February 2015. CoSense combines a portable detection device with a single-use disposable sampling set to measure carbon monoxide, or CO, in the portion of the exhaled breath that originates from the deepest portion of the lung, which is referred to as the end-tidal component of the breath.

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, or AR 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, or TN. We have also applied for orphan drug designation for TN the latter indication in the U.S.

We continue to focus our research and development efforts 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.

CoSense

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

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

assess the presence of hemolysis in neonates requiring phototherapy, neonates unresponsive to phototherapy or readmitted for phototherapy and neonates with bilirubin levels approaching

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

Today, CoSense is the only device commercially available for accurately measuring the ETCO levels associated with the rate of hemolysis in clinical practice in neonates. As a result, we believe that CoSense is the only device on the market that enables physicians to practice in accordance with the AAP guidelines when evaluating jaundiced neonates for potential treatment of hemolysis. Physicians are free to practice in accordance with their own judgment; however, we believe that the current AAP guidelines will be a significant factor in the adoption of CoSense.

Commercialization

Commercial activities for CoSense have been initiated and we announced the first commercial sales in early 2015. 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 sampling set to be the largest component of our revenue over time.

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 devices for diagnosing asthma in children, assessing blood carbon dioxide, or CO_2, concentration in neonates and malabsorption in infants with colic.

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 additional devices that leverage the capabilities of our Sensalyze Technology Platform. We expect to introduce additional products 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 infants and young children;

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.

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Nasal CO_2 Technology

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 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 have entered into a collaboration agreement with Clinvest, 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 headaches. 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. In March of 2015, we received a response from the FDA. We have responded to the FDA and will continue the orphan drug designation process for TN.

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. In episodic cluster headaches, episodes of pain typically last from 15 minutes to three hours and 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 headaches, which are characterized by continuing pain with no remission. The pain of cluster headache may be significantly greater than other conditions, such as severe migraine.

In January 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 CO_2 on up to 25 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.

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 in the U.S.

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In December 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. In March of 2015, we received a response from the FDA. We have responded to the FDA and will continue the orphan drug designation process for 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 has been 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 active
Relief from all nasal symptoms	Non-sedating

Mild side effect profile	Non-steroidal
No known long-lasting side effects	Usable on an as-needed basis

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Risks Associated With Our Business

Our business is subject to numerous risks and uncertainties related to the development and commercialization of CoSense, our reliance on third parties for manufacturing, our financial condition and need for additional capital, the operation of our business, our intellectual property, government regulation and the Exchange Offer and ownership of our securities. These risks include those highlighted in the section entitled Risk Factors immediately following this prospectus summary, including the following:

We have a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur substantial losses for the foreseeable future. As of March 31, 2015, we had an accumulated deficit of $82 million. We have only one product approved for sale, which, with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

CoSense, or any of our planned products, may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors, and others in the medical community necessary for commercial success.

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

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

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

After the Exchange Offer, our executive officers, directors and principal stockholders will continue to maintain the ability to control all matters submitted to stockholders for approval.

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

require us to relinquish rights to our planned products and technologies.

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

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

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

Corporate information

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year following the fifth anniversary of our 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 Common Stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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

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The Exchange Offer

We are making the Exchange Offer in order to (i) receive cash proceeds from the exercise of the tendered Series B Warrants, which exercise will occur upon the acceptance of such tendered Series B Warrants pursuant to the terms of the Exchange Offer, and (ii) reduce the number of outstanding Series B Warrants that contain a cashless exercise feature that would result in an increasing number of shares of Common Stock issuable without consideration as the price of the Common Stock decreases. We believe that reducing the number of Series B Warrants outstanding is appropriate and will promote our long-term financial viability.

On March 5, 2015, pursuant to the Private Transaction, we privately entered into a separately negotiated Warrant Exercise Agreement with certain holders of the Series B Warrants. Such holders cash exercised their Series B Warrants for an aggregate of 589,510 shares of Common Stock underlying such Series B Warrants, which shares represented 24.07% of the total number of shares of Common Stock underlying all Series B Warrants as of immediately prior to March 5, 2015. In consideration for the cash exercise of the Series B Warrants, and pursuant to the terms of the Warrant Exercise Agreement, we issued to such holders of the Series B Warrants the Common Stock underlying such Series B Warrants and the Series C Warrants representing the right to purchase up to 589,510 shares of Common Stock. Upon the cash exercise of such Series B Warrants, we received gross proceeds of approximately $3.8 million.

We are now permitting all current holders of Series B Warrants to tender their Series B Warrants and, upon acceptance of such tender and pursuant to the terms of the Exchange Offer, receive the underlying shares of Common Stock and the Series C Warrants through this Exchange Offer. You should read the discussions under the headings General Terms of the Exchange Offer, and Description of Warrants Included in the Exchange Offer Series C Warrants, respectively, for more information about the Exchange Offer and Series C Warrants. After the Exchange Offer is completed, you will no longer be entitled to tender your Series B Warrants in exchange for the issuance of new Series C Warrants and the shares of Common Stock underlying the Series C Warrants.

The Exchange Offer	Upon the terms and subject to the conditions described in this prospectus and in the Letter of Transmittal, we are offering to issue Series C Warrants, in addition to the shares of Common Stock underlying the Series B Warrants, to the holders of outstanding Series B Warrants who tender such Series B Warrants on or prior to the Expiration Date (defined below). All Series B Warrants that are: (i) not tendered prior to the Expiration Date; or (ii) tendered but withdrawn pursuant to the terms of the Exchange Offer or, for any reason, not accepted by us, will continue to be outstanding according to their terms unmodified.
Price	The cost to you for participating in the Exchange Offer is the aggregate cash exercise price of your Series B Warrants being tendered in connection therewith. No cash will be paid to you for participating in the Exchange Offer.

Expiration Date	The Exchange Offer will expire on the Expiration Date, which is at 5:00 p.m., New York City time, on July 24, 2015, unless extended by us at our sole discretion.
Procedure for Participating in the Exchange Offer	In all cases, the issuance of shares of Common Stock underlying the tendered Series B Warrants and the

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Series C Warrants pursuant to the Exchange Offer will be made only after timely receipt by the Exchange Agent of:

- the aggregate cash exercise price for such tendered Series B Warrants in accordance with the wire instructions specified in the Letter of Transmittal;
- a Book Entry Confirmation (as defined below) with respect to such tendered Series B Warrants;
- the Letter of Transmittal (or a facsimile thereof) properly completed and duly executed, or an Agent s Message (as defined below) in lieu thereof; and
- any required signature guarantees and other documents required by the Letter of Transmittal.

In lieu of physically completing and signing the Letter of Transmittal and delivering it to the Exchange Agent, DTC participants may electronically transmit their acceptance of the Exchange Offer through DTC s automated tender offer program, for which the transaction will be eligible.

By signing or agreeing to be bound by the Letter of Transmittal and other required documents, you will represent to us that, among other things:

- any Series C Warrants that you receive will be acquired in the ordinary course of your business;
- you have no arrangement or understanding with any person to participate in the distribution of the Series C Warrants;
- you are not our affiliate, as defined in Rule 405 under the Securities Act;

if you are not a broker-dealer, you are not engaged in and do not intend to engage in the distribution of the Series C Warrants; and

if you are a broker-dealer, that you will receive Series C Warrants for your own account in exchange for the tender of Series B Warrants that were acquired as a result of market-making activities or other trading activities and that you will deliver a prospectus in connection with any resale of such Series C Warrants.

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Procedures for Tendering Series B Warrants Held Through a Custodian	If you are a beneficial owner of Series B Warrants, but the holder of such Series B Warrants is a custodial entity such as a bank, broker, dealer, trust company or other nominee, and you seek to tender your Series B Warrants pursuant to the Exchange Offer, you must provide appropriate instructions to such holder of the Series B Warrants in order to participate through DTC s automated tender offer program with respect to such Series B Warrants.
Withdrawal of Participation in the Exchange	Your right to tender any Series B Warrants pursuant to the Exchange Offer will expire at the Expiration Date.
Return of Tendered Series B Warrants and Cash Exercise Price	If we do not accept any Series B Warrants tendered in the Exchange Offer for any reason described in the terms and conditions of the Exchange Offer or if a greater number of Series B Warrants are tendered than the holder of the Series B Warrants desires to tender in the Exchange Offer or if the Series B Warrants so tendered are withdrawn pursuant to the terms of the Exchange Offer, we will return such Series B Warrants and the cash exercise price associated therewith without expense to the tendering holder.
Conditions to the Exchange Offer	The Exchange Offer is subject to certain customary conditions, which we may amend or waive. We have the right, in our sole discretion, to terminate or withdraw the Exchange Offer if any of the conditions described in this prospectus are not satisfied or waived. The Exchange Offer is not conditioned on any minimum number of Series B Warrants being tendered. See General Terms of the Exchange Offer Conditions to the Exchange Offer.
Exchange Agent	American Stock Transfer & Trust Company, LLC is serving as the Exchange Agent in connection with the Exchange Offer. Deliveries should be addressed to: American Stock Transfer & Trust Company, LLC, Attn: Reorganization Department, P.O. Box 2042, New York, New York 10272-2042.
United States Federal Income Tax Considerations	

We recommend that you consult with your own tax advisor with regard to the possibility of any federal, state, local or other tax consequences of the Exchange Offer. See Certain United States Federal Income Tax Considerations for a discussion of the material U.S. Federal Income Tax Consequences of participating in the Exchange Offer.

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Use of Proceeds	We intend to use the net proceeds from the Exchange Offer as follows: (i) approximately zero to $6 million to fund expansion of marketing and medical affairs activities supporting CoSense, as well as in research, development, and launch expenses related to additional product candidates on the Sensalyze platform; (ii) approximately zero to $4.3 million to fund research and development, product development and clinical trials regarding our Nasal CO_2 Technology; and (iii) the remaining funds, if any, will be used to fund other general corporate purposes, which may include the acquisition or licensing of other products, businesses or technologies, although we have no plans regarding any specific acquisition candidates at this time. See Use of Proceeds .
Terms of Series C Warrants:	
Exercise Price	The Series C Warrants are exercisable at $6.25 per share of Common Stock, subject to adjustment.
Number of Underlying Shares of Common Stock	The Series C Warrants are exercisable for the number of shares of Common Stock underlying the Series B Warrants that you tendered.
Exercise Period	The Series C Warrants are exercisable immediately upon issuance and until March 4, 2020.
Registration and no Make Whole Cashless Exercise Feature	The Series C Warrants and the underlying shares of Common Stock will be registered pursuant to this registration statement at the time the Series C Warrants are issued. The Series C Warrants do not include the make whole cashless exercise feature that is contained in the Series B Warrants that results in an increasing number of shares of Common Stock issuable without consideration as the price of the Common Stock decreases.

	See Description of Warrants Included in the Exchange Offer Series C Warrants.
Risk Factors	See Risk Factors and other information included in this prospectus for a discussion of factors you should consider carefully before investing pursuant to the terms of this prospectus.

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The Series C Warrants Issued in the Exchange

In exchange for Series B Warrants tendered pursuant to the terms of the Exchange Offer, the Company will issue the underlying Common Stock issuable on the exercise of the Series B Warrants, which exercise shall occur upon the acceptance of such tender, and each of the Series C Warrants in registered form under a warrant agreement (the Series C Transfer Agent Agreement) between itself and American Stock Transfer & Trust Company, LLC, as warrant agent (the Warrant Agent). The material provisions of the Series B Warrants and the Series C Warrants are set forth herein but are only a summary and are qualified in their entirety by the provisions of, respectively, the Series B Warrant Agreement, which was filed with the SEC on November 12, 2014 as Exhibit 4.17 to our Form S-1/A Registration Statement, and the Series C Warrant Agreement, which has been filed as an exhibit to this registration statement, of which this prospectus forms a part. Copies of these documents are also available to security holders of the Company and prospective investors upon request.

Issuer	Capnia, Inc., a Delaware corporation.
Securities offered	Series C Warrants
Risk factors	See Risk Factors and other information included in this prospectus for a discussion of factors you should consider carefully before investing pursuant to the terms of this prospectus.

The Series C Warrants issued in the Exchange Offer entitle the registered holder to purchase one share of our Common Stock at an exercise price equal to $6.25 per share, subject to adjustment as discussed below, at any time commencing upon consummation of the Exchange Offer and terminating at 5:00 p.m., New York City time, on March 4, 2020.

The Series C Warrants and the underlying shares of Common Stock will be registered pursuant to this registration statement at the time the Series C Warrants are issued.

The Series C Warrants will not be listed on the NASDAQ Capital Market or any other securities exchange.

In addition, the Series C Warrants will not be exercisable to the extent that, after exercise, a holder of Series C Warrants and/or its affiliates would beneficially own more than 4.99% of the Common Stock outstanding immediately after giving effect to such exercise; provided, however, that if a holder of Series C Warrants and/or its affiliates already own 4.99% immediately prior to the issuance of the Series C Warrant, then such limitation will not apply.

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SUMMARY FINANCIAL AND OTHER DATA

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

We have derived the statement of operations data for the years ended December 31, 2013 and 2014 and the balance sheet data as of December 31, 2013 and 2014 from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the three month periods ended March 31, 2015 and March 31, 2014 and the balance sheet data as of March 31, 2015, are derived from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future.

(in thousands except share and per share data)

	Year Ended December 31,		Three Months Ended March 31,	
Statement of Operations Data:	**2014 (revised)**	**2013**	**2015**	**2014**
Revenue	$	$ 3,000	22	
Cost of revenue			18	
Gross profit			4	
Expenses				
Research and development	2,242	2,380	878	372
Sales and marketing	253		260	
General and administrative	2,665	1,467	1,292	312
Total expenses	5,160	3,847	2,430	684
Operating income (loss)	(5,160)	(847)	(2,426)	(684)
Interest and other income (expense)				
Interest income	1	2		
Interest expense	(4,130)	(2,860)	(1)	(388)
Change in value of warrants			(6,174)	246
Inducement charge for Series C warrants			(3,050)	
Other expense, net	(3,949)	(2)		(8)
Net loss	$ (13,238)	$ (3,707)	(11,651)	(834)
Weighted average common shares outstanding				
Basic and diluted	1,270,033	535,648	6,965,483	535,685
Net loss per share				

Basic and diluted	$ (10.42)	(6.92)	(1.67)	(1.56)

	As of March 31, 2015	
	Actual	**Pro Forma**
Balance Sheet Data:		
Cash and cash equivalents	$ 9,529	19,789[(1)]
Working capital	8,964	19,223
Total assets	10,067	20,327
Accumulated deficit	(81,989)	(88,980)[(2)]
Total stockholders equity (deficit)	(11,303)	6,147[(3)]

The pro forma column reflects the following adjustments:

(1) Cash proceeds from the exercise of Series B Warrants at an exercise price of $6.50 to purchase 1,616,955 shares of common stock to be issued in the Exchange Offer, with an estimated result of $10.3 million, all net of estimated expenses of $250,000.

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(2) The value of 1,616,955 Series C Warrants to be issued as an inducement in the Exchange Offer based on the Series B Warrants outstanding prior to June 1, 2015, using a Black-Scholes model resulting in an expense of $7.0 million.
(3) The issuance of 1,616,955 shares of Common Stock upon the exercise of the Series B Warrants in the Exchange Offer; the issuance of 63,095 shares of Common Stock upon the cashless exercise of 161,320 Series B Warrants after March 31, 2015 and the derecognition of the Series B Warrant liability for 1,778,275 of Series B Warrants based on the value, as of March 31, 2015, resulting in a reduction of the Series B Warrant liability and an increase to Additional paid-in-capital of $14.2 million and the recognition of a liability of $7.0 million for 1,616,955 Series C Warrants using a Black-Scholes model assuming a stock price of $6.40. The Series C Warrants are treated as a liability because the Company can be obligated to settle these warrants for cash at the option of the warrant holder upon the occurrence of a Fundamental Transaction, as described in the Series C Warrant agreement.

In addition, in making the adjustments to arrive at the pro forma balance sheet we made the following assumptions:

1. In determining the Series C Warrant value under the Black-Scholes model, we used inputs, including the Companies stock price, remaining term of 4.93 years, volatility of 86% and applicable discount rate of 1.4%.

2. The Series C Warrants are treated as an inducement to enter into the Exchange Offer. As such, the value of the Series C Warrants, assuming a stock price of $6.40, would be treated as a current expense, and was therefore an adjustment to Accumulated deficit in arriving at the pro forma balance sheet.

Background of the Exchange Offer

On November 18, 2014, in connection with our IPO, we issued Series B Warrants to purchase an aggregate of 2,449,605 shares of our Common Stock, at an exercise price of $6.50 per share and with an expiration date of February 12, 2016. The Series B Warrants contain a cashless exercise feature that results in an increasing number of shares of Common Stock issuable without consideration as the price of our Common Stock decreases. Such cashless exercise feature became available commencing on the 121st day after the IPO, or March 12, 2015 through the period ending on the 15 month anniversary of the date of the IPO, or February 12, 2016. A complete description of the terms governing the Series B Warrants, are contained in the form of Series B Warrant Agreement, filed with the SEC on November 12, 2014 as Exhibit 4.17 to our Form S-1/A Registration Statement. Also see Description of Warrant Included in the Exchange Offer in this prospectus.

On February 23, 2015, our board of directors met to discuss, among other matters, the proposed amendment or exchange of the Series B Warrants in order to revise or remove the cashless exercise feature contained therein. Our board of directors then authorized an independent and disinterested special Board sub-committee, or the Disinterested Committee, consisting of Steinar Engelsen, Stephen Kirnon, and William G. Harris, to review the transaction. Our board of directors was made aware that Steinar Engelsen held a de minimis number of Series B Warrants, which he subsequently contributed back to the capital of the company without consideration. As a result, none of the members of the Disinterested Committee, or their affiliates, hold any Series B Warrants.

The Disinterested Committee met on February 25, 2015. Also present were Anish Bhatnagar and David O Toole, as members of management, and Elton Satusky of Wilson Sonsini Goodrich & Rosati, our outside legal counsel. Management and legal counsel reviewed a number of different proposed scenarios regarding the alternatives for the Series B Warrants, whether through amendment or exchange of the Series B Warrants, including a discussion of the business and commercial aspects and other advice that management had received from Maxim Group LLC, our lead underwriter in our IPO. The Disinterested Committee asked specific questions on how the different proposed

scenarios would affect the various stakeholders, including holders of Common Stock, holders of warrants, affiliates and non-affiliates. The Disinterested Committee also inquired about the present circumstances of the company and other market variables, including the status of the existing Series B Warrants based on our stock

price and the fact that the Series B Warrants would become exercisable on a cashless basis on March 12, 2015. Legal counsel advised the Disinterested Committee of their duties to act in the best interests of all stockholders in contemplating the relative merits of amending or exchanging the Series B Warrants. The Disinterested Committee discussed various factors, including: (i) the pricing pressure on our Common Stock as a result of the Series B Warrants; (ii) the benefits of retiring or minimizing the effect of the cashless exercise feature of the Series B Warrants; (iii) the terms of any proposed amendment to the Series B Warrants, noting that the terms were likely to continue to be negotiated with the holders; and (iv) the retention of an advisor to manage the process. At the conclusion of the meeting, the Disinterested Committee then instructed management to gather additional information relating to the proposed amendment or exchange of the Series B Warrants.

The Disinterested Committee next met on March 2, 2015. Eric Cheng of Maxim Group LLC, Dr. Bhatnagar and Mr. O Toole as members of management, and outside legal counsel were in attendance at this meeting. The Disinterested Committee was informed of the current status of the proposed amendment or exchange to the Series B Warrants and the steps necessary to implement the amendment or exchange of Series B Warrants. Mr. Cheng discussed the benefits of amending or exchanging the Series B Warrants to the holders of Common Stock, including the raising of capital at $6.50 per share if the Series B Warrants were exercised in connection with any proposed amendment or extension, the removal of the dilutive cashless exercise feature of the Series B Warrants, and certain other related matters. Mr. Cheng then reviewed the proposed timing and process for the proposed amendment or exchange, and advised the Disinterested Committee on various pertinent matters. Mr. Satusky discussed the steps following the closing of the private aspect of a proposed amendment or exchange of Series B Warrants. Mr. Satusky next gave a presentation on the preliminary legal considerations relating to the proposed amendment or exchange of Series B Warrants, including fiduciary duties, such as the duty of care and the duty of loyalty of the Disinterested Committee, judicial review of board actions, and other considerations. Management was instructed to perform a Black Scholes analysis of the relative values of the alternatives being offered to the holders of Series B Warrants based on certain assumed models. The Disinterested Committee then discussed obtaining a fairness opinion in connection with the proposed amendment or exchange of Series B Warrants and directed management to determine the cost and timeline for a fairness opinion from its advisors. The Disinterested Committee informed management to call another meeting of the Disinterested Committee once additional information was obtained, including knowing the stock price on the date of the proposed implementation of the amendment or exchange of the Series B Warrants.

The Disinterested Committee next met on March 3, 2015. Dr. Bhatnagar and Mr. O Toole as members of management, and outside legal counsel were in attendance at this meeting. Dr. Bhatnagar reviewed the current status of the proposal to amend or exchange the Company s Series B Warrants with the Disinterested Committee. Mr. O Toole advised the committee that he had obtained a Black Scholes analysis of the relative values of the alternatives being offered to the holders of Series B Warrants based on certain assumed models. A detailed discussion regarding the various alternatives followed and the Disinterested Committee confirmed with management that the final deal terms for the proposed amendment or exchange of Series B Warrants were still not fully negotiated or finally determined. The Disinterested Committee also reviewed a number of additional scenarios that were proposed at different terms and the relative merits of such alternative scenarios were discussed.

The Disinterested Committee next met on March 4, 2015 at 1:00 p.m. Pacific time. Dr. Bhatnagar and Mr. O Toole as members of management, and Mr. Satusky and Ignacio Salceda as outside legal counsel, were in attendance at this meeting. At this meeting, Dr. Bhatnagar informed the Disinterested Committee of a new revised proposed structure pursuant to which only one option would be made available to existing holders of the Series B Warrants, whereby any existing holder of the Series B Warrants who exercised their Series B Warrant would receive a Series C Warrant in addition to the Common Stock underlying the Series B Warrant, in return and any holder of the Series B Warrants who did not elect to exercise the Series B Warrant would not receive any new consideration and retain their Series B Warrant unmodified. Legal counsel presented the Disinterested

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Committee with a litigation risk overview and counseled the Disinterested Committee regarding the ongoing process as being a key rubric to pursuing the proposed amendment or exchange of the Series B Warrants. As part of the presentation to the Disinterested Committee, Legal counsel discussed fiduciary duties of the Disinterested Committee in reviewing the proposed alternatives presented to the Disinterested Committee in connection with amending or exchanging the Series B Warrants prior to approving such transaction. Legal counsel also advised the Disinterested Committee on its duty of care in the decision-making process for reviewing and approving the transaction, and to consider all reasonably available information, to consult with management and external advisors, to consider the merits, risks and viable alternatives with respect to any transaction, and to fully consider and evaluate any proposed transaction. Legal counsel further discussed the duty of loyalty owed to the stockholders and potential conflicts of interest that may arise among members of the Disinterested Committee or our board of directors and the procedures used in order to have such conflicts of interest addressed and resolved by disinterested or independent members of any Disinterested Committee or member of our board of directors. Legal counsel discussed the Disinterested Committee s duty of candor and the business judgment rule advising that the members that any proposed transaction may be scrutinized in order to ensure that the entire transaction, including both the process of review and approval for the transaction, as well as the ultimate deal terms of the transaction, were fair and complied with law. Mr. O Toole next presented the terms of retaining Maxim Group LLC as financial advisor on this transaction. The Disinterested Committee resolved to proceed with engaging Maxim Group LLC as a financial advisor based on the terms as presented by management. The Disinterested Committee instructed management to pursue the one option structure discussed at the meeting, subject to approval of the final deal terms.

Later on March 4, 2015, at 9:30 p.m. Pacific time, the Disinterested Committee, with Dr. Bhatnagar and Mr. O Toole as members of management, in attendance at this meeting, met to discuss approving the proposed one option structure for the exercise and exchange of the Series B Warrants. Dr. Bhatnagar reviewed the current status of the proposed Series B Warrant exercise financing and exchange transaction, noting that final transaction documents, including the press release, Warrant Exercise Agreement and the form of Series C Warrant, had been previously circulated to the Disinterested Committee. The Disinterested Committee asked questions of management on the documents and management answered such questions. Mr. O Toole updated the Disinterested Committee on the status of various holders of Series B Warrants and their intended participation. It was noted that signature pages were not in hand from all of the funds and as a result it was determined to adjourn the meeting and reconvene at 4:30 a.m. Pacific time on March 5, 2015. At 4:30 a.m. Pacific time on March 5, 2015, the Disinterested Committee reconvened. Mr. O Toole updated the Disinterested Committee on the participation of the holders of the Series B Warrants in the proposed Series B Warrant exercise and financing transaction. Messrs. O Toole and Satusky reviewed the final transaction deal terms and documents in detail with the Disinterested Committee, noting the Series C Warrant key terms of $6.25 exercise price and 5-year term. The Disinterested Committee discussed the interests of the company and its stockholders and resolved to approve the final deal terms and transaction documents reviewed at the meeting.

On March 5, 2015, the final Warrant Exercise Agreement was signed by the holders of the Series B Warrants participating in the Private Transaction, with signatures placed into escrow, pending wires in the amounts necessary to exercise the Series B Warrants in accordance with the terms of the Warrant Exercise Agreement. The Private Transaction closed on March 5, 2015, with Series B Warrants to purchase 589,510 shares of Common Stock being exercised and exchanged for Series C Warrants, in addition to the shares of Common Stock underlying such Series B Warrants, to purchase 589,510 shares of Common Stock.

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INTERESTS OF DIRECTORS IN THE EXCHANGE OFFER

Entities affiliated with both Edgar Engleman, a member of our board of directors affiliated with Vivo Ventures, and Ernest Mario, our Chairman, each of whom are stockholders and major investors in our company, hold Series B Warrants to purchase an aggregate of 1,240,750 shares of Common Stock. In light of the interests that certain directors had in the Exchange Offer due to their affiliation with stockholders and major investors who hold Series B Warrants, our board of directors formed a Disinterested Committee and delegated to them the responsibility to review and evaluate the Exchange Offer. See Background of the Exchange Offer . Each member of our board of directors was made aware of any interests or potential interests related to the Exchange Offer and specifically (i) with respect to Dr. Engleman, the ownership by Vivo Ventures and their affiliates of Series B Warrants to purchase 940,792 shares of Common Stock, (ii) with respect to Dr. Mario, the ownership by Dr. Mario and his affiliates of Series B Warrants to purchase 299,958 shares of Common Stock, and (iii) with respect to Steinar Engelsen, his ownership of Series B Warrants to purchase 468 shares of Common Stock. In connection with his appointment to the Disinterested Committee, on March 3, 2015, Mr. Engelsen contributed his Series B Warrants to purchase 468 shares of Common Stock back to the company without consideration.

If Vivo Ventures and Dr. Mario, and any affiliated entities, tender all of their outstanding Series B Warrants in full, then they will be issued Series C Warrants to purchase an aggregate of 1,240,750 shares of Common Stock. If, following the Exchange Offer, and assuming that all holders of Series B Warrants, including our insiders, tendered all their Series B Warrants in exchange for the shares of Common Stock underlying such Series B Warrants and the corresponding issuance of Series C Warrants, then our insiders would hold approximately 51.20% of the outstanding Series C Warrants and 51.20% of the outstanding shares of Common Stock, in either case excluding (i) 29,097 shares of Common Stock issued upon the exercise of Series B Warrants subsequent to the Private Transaction but prior to April 1, 2015, the date we filed our original registration statement on this Form S-4, and (ii) 468 shares of Common Stock issuable upon the exercise of Series B Warrants contributed to the company, but including 589,510 shares of Common Stock issued upon cash exercise of Series B Warrants as part of the Private Transaction and the corresponding issuance of Series C Warrants to purchase 589,510 shares of Common Stock. Our insiders would beneficially own 67.92% of our Common Stock, including 57.68% by Vivo Ventures and affiliated entities and 16.80% by Dr. Mario and affiliated entities. None of our directors were or are affiliated, either directly or indirectly, with the parties who exercised their Series B Warrants and received Series C Warrants as part of the Private Transaction that occurred on March 5, 2015.

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RISK FACTORS

Prospective participants in the Exchange Offer should carefully consider all of the information contained in this prospectus, including the risks and uncertainties described below, 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.

Risks Related to the Exchange Offer

Your tender of Series B Warrants for the issuance of the underlying Common Stock and Series C Warrants will not be accepted if you fail to follow the Exchange Offer procedures.

We will issue you Common Stock and Series C Warrants pursuant to the Exchange Offer only after a timely receipt of your exercise notice and aggregate cash exercise price, a properly completed and duly executed Letter of Transmittal and all other required documents. Therefore, if you want to tender your Series B Warrants in connection with the Exchange Offer, please allow sufficient time to ensure timely processing. If we do not receive your cash exercise notice and aggregate cash exercise price, Letter of Transmittal and other required documents as part of the tender of your Series B Warrants by the Expiration Date, we will not accept your tender of Series B Warrants in exchange for the issuance of the underlying Common Stock and Series C Warrants. We are generally under no duty to give notification of defects or irregularities with respect to the tender of your Series B Warrants pursuant to the terms of the Exchange Offer. If there are defects or irregularities with respect to your tender of Series B Warrants, we may not accept your tender of Series B Warrants pursuant to the terms of the Exchange Offer.

If you do not properly tender your Series B Warrants in connection with the Exchange Offer, your original Series B Warrants will continue to remain unexercised and be subject to the existing terms contained therein unmodified, including transfer restrictions, and you may be unable to sell your outstanding Series B Warrants.

We have not registered the Series B Warrants and do not intend to do so following the Exchange Offer. Series B Warrants that are not tendered in connection with the Exchange Offer will therefore continue to remain unexercised and be subject to the existing transfer restrictions and may be transferred only in limited circumstances under applicable securities laws. As a result, if you hold original Series B Warrants after the Exchange Offer, you may be unable to sell your original Series B Warrants and the value of the original Series B Warrants may decline. We have no obligation, and do not currently intend, to file an additional registration statement to cover the resale of the Series B Warrants, although the shares of Common Stock underlying the Series B Warrants upon exercise thereof are subject to an effective registration statement.

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

The Series C Warrants offered as part of the Exchange Offer 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 C Warrant holders may exercise their right to acquire the underlying Common Stock and pay an exercise price of $6.25 per share prior to the expiration of the approximately five-year term. In certain circumstances, the Series C Warrants may be exercisable on a cashless basis. There can be no assurance that the market price of the Common Stock will ever equal or exceed the exercise price of the Series C Warrants, and, consequently, whether it will ever be profitable for holders of the Series C Warrants to exercise the Series C Warrants.

We will incur significant costs in conducting the Exchange Offer.

The Exchange Offer has also resulted, and will continue to result, in significant costs to us, including advisory and professional fees paid in connection with evaluating our alternatives under the Series B Warrants and pursuing the Exchange Offer and the issuance of the new Series C Warrants.

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We have not obtained a third party determination that the Exchange Offer is fair to holders of the Series B Warrants.

We are not making a recommendation as to whether holders of the Series B Warrants should tender their Series B Warrants in exchange for the issuance of underlying Common Stock and Series C Warrants. We have not retained and do not intend to retain any unaffiliated representative to act solely on behalf of the holders of the Series B Warrants for purposes of negotiating the Exchange Offer or preparing a report concerning the fairness of the Exchange Offer. We cannot assure holders of the Series B Warrants that the value of the consideration received in the Exchange Offer will in the future equal or exceed the value of the Series B Warrants tendered, and we do not take a position as to whether you ought to participate in the Exchange Offer.

If holders of the Series B Warrants have claims against us resulting from their acquisition or ownership of the Series B Warrants, they will give up those claims if they tender their Series B Warrants in the Exchange Offer.

By tendering the Series B Warrants in the Exchange Offer, upon closing of the Exchange Offer, holders of the Series B Warrants will be deemed to have released and waived any and all claims they, their successors and their assigns have or may have had against us, our affiliates and their stockholders, and our directors, officers, employees, attorneys, accountants, advisors, agents and representatives, in each case whether current or former, as well as the directors, officers, employees, attorneys, accountants, advisors, agents and representatives of our affiliates and our stockholders, arising from, related to, or in connection with their acquisition or ownership of the Series B Warrants, unless those claims arise under federal or state securities laws.

Because it is not possible to estimate the likelihood of their success in pursuing any legal claims or the magnitude of any recovery to which they ultimately might be entitled, it is possible that the consideration that the holders of Series B Warrants receive in the Exchange Offer will have a value less than what they own today. Moreover, holders who do not tender their Series B Warrants in the Exchange Offer will continue to have the right to prosecute their claims against us.

There will be no public trading market for the Series C Warrants, and your ability to sell such Series C Warrants will be limited.

There is no existing public market for the new Series C Warrants. No market for the new Series C Warrants may develop, and any market that develops may not persist. We cannot assure you as to the liquidity of any market that may develop for the new Series C Warrants, your ability to sell your new Series C Warrants or the price at which you would be able to sell your new Series C Warrants.

We do not intend to apply for listing of the new Series C Warrants on any securities exchange or other market; however, the Series C Warrants and the shares of Common Stock underlying the Series C Warrants received in the Exchange Offer will be registered pursuant to this registration statement.

As a holder of the new Series C Warrants, you will not be entitled to any rights with respect to our Common Stock, but you will be subject to all changes made with respect to our Common Stock.

If you hold any of our new Series C Warrants, you will not be entitled to any rights with respect to our Common Stock (including, without limitation, voting rights and rights to receive any dividends or other distributions, if any, on our Common Stock), but you will be subject to all changes affecting our Common Stock. You will have rights with respect to our Common Stock only when we deliver shares of Common Stock to you upon exercise of your new Series C Warrants. For example, if an amendment is proposed to our certificate of incorporation or bylaws requiring

stockholder approval and the record date for determining the shareholders of record entitled to vote on the amendment occurs prior to the delivery of Common Stock, if any, to you, you will not be entitled to vote on the amendment with respect to the shares of Common Stock that are subject to such delivery, although you will nevertheless be subject to any changes in the powers, preferences or special rights of our Common Stock.

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Income tax consequences of participation in this Exchange Offer.

We have not obtained and do not intend to obtain a ruling from the Internal Revenue Service, or IRS, regarding the U.S. federal income tax consequences of the Exchange Offer. You should consult with your own tax advisor with regard to the possibility of any federal, state, local or other tax consequences of this Exchange Offer. See Certain United States Federal Income Tax Considerations .

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 limited commercial sales to date, which, together with our limited operating history, makes it difficult to evaluate our business and assess our future viability.

We are a developer of therapeutics and diagnostics with a limited 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 March 31, 2015, we had an accumulated deficit of $82.0 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 generated limited product revenue and may never become profitable.

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

set a commercially viable price for CoSense and our other future products, if any;

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

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

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

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

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

complete development activities, including any potential Phase 3 clinical trials of Serenz, successfully and on a timely basis;

establish, maintain and protect our intellectual property rights and avoid third-party patent interference or patent infringement claims; and

attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with product development, including that 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 significant revenue 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;

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

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

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

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

changes in the competitive landscape of our industry, including consolidation among our competitors or potential partners;

any delays in regulatory review or approval of Serenz or any of our planned products;

the level of demand for CoSense, and for Serenz and any planned products, should they receive approval, which may fluctuate significantly and be difficult to predict;

the risk/benefit profile, cost and reimbursement policies with respect to our future products, if approved, and existing and potential future drugs that compete with our planned products;

competition from existing and potential future offerings that compete with CoSense, Serenz or any of our planned products;

our ability to commercialize CoSense or any planned product inside and outside of the U.S., either independently or working with third parties;

our ability to establish and maintain collaborations, licensing or other arrangements;

our ability to adequately support future growth;

potential unforeseen business disruptions that increase our costs or expenses;

future accounting pronouncements or changes in our accounting policies; and

the changing and volatile global economic environment.

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

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

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The commercialization of CoSense, as well as the completion of the development and the potential commercialization of planned products, will require substantial funds. As of March 31, 2015, we had approximately $9.5 million in cash and cash equivalents. Our future financing requirements will depend on many factors, some of which are beyond our control, including the following:

- the cost of activities and added personnel associated with the commercialization of CoSense, including marketing, manufacturing, and distribution;
- the cost of preparing to manufacture CoSense instruments and consumables on a larger scale;
- the degree and rate of market acceptance of CoSense, and the revenue that we are able to collect from sales of CoSense as a result;
- our ability to set a commercially attractive price for CoSense devices and consumables, and our customers perception of the value relative to the prices we set;
- our ability to clarify the regulatory path in the U.S. for Serenz, and the potential requirement for additional pivotal clinical studies;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and other regulatory authorities for Serenz and other planned products;
- our ability to obtain a partner for Serenz on attractive economic terms, or engage in commercial sales of Serenz on our own or through distributors;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights and/or the loss of those rights;
- our ability to enter into distribution, collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements;
- the emergence of competing technologies or other adverse market developments;
- the costs of attracting, hiring and retaining qualified personnel;

unforeseen developments during our clinical trials;

unforeseen changes in healthcare reimbursement for any of our approved products;

our ability to maintain commercial scale manufacturing capacity and capability with a commercially acceptable cost structure;

unanticipated financial resources needed to respond to technological changes and increased competition;

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.

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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.

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.

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Our ability to successfully market CoSense and our planned 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 planned products would materially harm our business, financial condition and results of operations.

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

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

In addition, although treatment guidelines recommend 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.

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

If we cannot compete successfully with other diagnostic modalities, we may be unable to increase or sustain our revenues or achieve and sustain profitability.

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

In addition, several larger companies have extensive sales presence in the neonatology area and could potentially develop non-invasive diagnostic tests that compete with CoSense or our planned products. These include General Electric Healthcare, Philips, Draeger, Covidien, Masimo, Natus Medical, and CAS Medical. Some of our present and potential competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced tests that payors and physicians could view as functionally equivalent to our current or 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 three months ended March 31, 2015, our research and development expenses were $0.9 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 launch. Also, any regulatory approval of Serenz, once obtained, may be withdrawn. Even if we obtain regulatory approval for Serenz in additional countries, the commercial success of the product will depend on a number of factors, including the following:

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

acceptance of Serenz as safe and effective by patients, caregivers and the medical community; and

a continued acceptable safety profile of Serenz following approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

If clinical studies of Serenz or any of our planned products fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the U.S. or do not otherwise produce positive results, we may incur additional costs, experience delays in completing or ultimately fail in completing the development and commercialization of Serenz or our planned products.

Before obtaining regulatory approval for the sale of any planned product we must conduct extensive clinical studies to demonstrate the safety and efficacy of our planned products in humans. Clinical studies are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. A failure of one or more of our clinical studies could occur at any stage of testing.

Numerous unforeseen events during, or as a result of, clinical studies could occur, which would delay or prevent our ability to receive regulatory approval or commercialize Serenz or any of our planned products, including the following:

- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate or patients may drop out of these clinical studies at a higher rate than we anticipate;
- the cost of clinical studies or the manufacturing of our planned products may be greater than we anticipate;
- third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

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

regulators may not approve our proposed clinical development plans;

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

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

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

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

- be delayed in obtaining marketing approval for our planned products;
- not obtain marketing approval at all;
- obtain approval for indications that are not as broad as intended;
- have the product removed from the market after obtaining marketing approval;
- be subject to additional post-marketing testing requirements; or
- be subject to restrictions on how the product is distributed or used.

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

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

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

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

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

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

business, financial condition, results of operations and growth prospects.

Even if Serenz or any planned products receive regulatory approval, these products may fail to achieve the degree of market acceptance by physicians, patients, caregivers, healthcare payors and others in the medical community necessary for commercial success.

If Serenz or any planned products receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, hospital administrators, patients, healthcare payors and others in the medical community. The degree of market acceptance of our planned products, if approved for commercial sale, will depend on a number of factors, including the following:

the prevalence and severity of any side effects;

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their efficacy and potential advantages compared to alternative treatments;

the price we charge for our planned products;

the willingness of physicians to change their current treatment practices;

convenience and ease of administration compared to alternative treatments;

the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

the strength of marketing and distribution support; and

the availability of third-party coverage or reimbursement.

For example, a number of companies offer therapies for treatment of AR patients based on a daily regimen, and physicians, patients or their families may not be willing to change their current treatment practices in favor of Serenz even if it is able to offer additional efficacy or more attractive product attributes. If Serenz or any planned products, if approved, do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable on a sustained basis or at all.

We currently have limited sales and distribution personnel, and limited marketing capabilities. If we are unable to develop a sales and marketing and distribution capability on our own or through collaborations or other marketing partners, we will not be successful in commercializing CoSense, Serenz, or other planned products.

We are currently building a sales and marketing infrastructure and have no experience in the sale, marketing or distribution of diagnostic or therapeutic products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. We intend to commercialize CoSense with our own specialty sales force in the U.S., Canada and potentially other geographies. If we obtain regulatory approval, we intend to commercialize Serenz through third-party partners or distributors.

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

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

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

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

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

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

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

The risk of failure of clinical development is high. It is impossible to predict when or if this or any planned products will prove safe enough to receive regulatory approval. Undesirable side effects caused by Serenz or any of our planned products could cause us or regulatory authorities to interrupt, delay or halt clinical trials They could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority.

Additionally, if Serenz or any of our planned products receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory bodies may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome

implementation requirements on us;

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

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

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

our reputation may suffer.

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

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

Alternatives exist for CoSense and for Serenz, and we will likely face competition with respect to any planned products that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, medical device companies, and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology companies that currently market and sell AR therapies to our target patient group. These companies may reduce prices for their competing drugs in an effort to gain or retain market share, and undermine the value proposition that Serenz or CoSense might otherwise be able to offer to payors. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Many of these competitors are attempting to develop therapeutics for our target indications.

Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified technical and management personnel, establishing clinical study sites and patient registration for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize CoSense, Serenz, or any planned products, or to obtain a partner to commercialize Serenz, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more planned products, even if our planned products obtain regulatory approval.

Our ability to commercialize CoSense or any planned products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any planned product that we successfully develop.

While we expect payments for CoSense to be part of a Diagnosis-Related Group, or DRG, (also known as a bundled payment) we may have to obtain reimbursement for it from payors directly. There may be significant delays in

obtaining reimbursement for CoSense, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if

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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;
- 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,

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including Dr. Anish Bhatnagar, our Chief Executive Officer, David D. O Toole, our Senior Vice President and Chief Financial Officer, Anthony Wondka, our Senior Vice President of Research and Development, Gina Phelps, our Vice President of Sales, Kristen Yen, our Vice President of Clinical & Regulatory and Ed Ebbers, our Senior Vice President and Chief Commercial Officer. 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, Senior Vice President and Chief Commercial Officer and Senior Vice President of Research and Development have employment agreements, however, the existence of an employment agreement does not guarantee retention of members of our executive management team and we may not be able to retain those individuals for the duration of or beyond the end of their respective terms. We have secured a $1,000,000 key person life insurance policy on our Chief Executive Officer, Dr. Anish Bhatnagar, but do not otherwise maintain key person life insurance on any of our employees.

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

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

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

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

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

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

and marketing employees. If we are unable to hire and retain qualified sales and marketing personnel, our business will suffer.

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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.

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

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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

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.

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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 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;

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- 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 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.

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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 March 31, 2015, we had 15 employees and 9 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;

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- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

Risks related to intellectual property

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

Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends upon our ability and the ability of our distributors, contract manufacturers, and suppliers to manufacture, market, and sell our planned products, and to use our proprietary technologies without infringing, misappropriating or otherwise violating the proprietary rights or intellectual property of third parties. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology.

Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we are found to infringe a third-party s intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our

products and technology. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our planned products or force us to cease some of our business operations, which could materially harm our business. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee s former employer. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

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

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.

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

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