NeuroMetrix, Inc.
Form S-3
October 02, 2009
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As filed with the Securities and Exchange Commission on October 2, 2009

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

NEUROMETRIX, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**04-3308180**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

62 Fourth Avenue

Waltham, Massachusetts 02451

(781) 890-9989

(Address, including zip code, and telephone number, including area code of

Registrant s principal executive offices)

Shai N. Gozani, M.D., Ph.D.

Chairman, Chief Executive Officer and President

NeuroMetrix, Inc.

62 Fourth Avenue

Waltham, Massachusetts 02451

(781) 890-9989

(Name, address, including zip code, and telephone number, including area code,

of agent for service)

Copies to:

Phillip D. Torrence, Esq.

Honigman Miller Schwartz and Cohn LLP

444 West Michigan Avenue

Kalamazoo, MI 49007

(269) 337-7700

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. o

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. o

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of Each Class Of Securities To Be Registered	Amount to Be Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value $0.0001 per share (3), (4)	19,037,215	$ 3.26	$ 62,061,320.90	$ 3,463.02

(1) Includes 8,375,694 shares of common stock that may be issued upon the exercise of warrants, upon the redemption of those warrants following certain major transactions and events of default, and upon the occurrence of certain events specified in the warrants. This registration statement also relates to an indeterminate number of shares of common stock that may be issued upon stock splits, stock dividends or similar transactions in accordance with Rule 416 under the Securities Act.

(2) Determined pursuant to Rule 457(c) under the Securities Act solely for the purpose of calculating the registration fee based on the average of the high and low sales prices of the registrant s common stock on September 29, 2009 as reported on the NASDAQ Global Market.

(3) Consists of 10,661,521 shares of common stock and 8,375,694 shares of common stock that may be issued upon the exercise of warrants.

(4) This Registration Statement also relates to the Rights to purchase shares of Series A Junior Participating Cumulative Preferred Stock of the registrant which are attached to all shares of common stock pursuant to the terms of the registrant s Shareholder Rights Agreement dated

March 7, 2007, as amended. Until the occurrence of certain prescribed events, the Rights are not exercisable, are evidenced by the certificates for the common stock and will be transferred only with such stock.

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

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, Dated October 2, 2009

PROSPECTUS

NEUROMETRIX, INC.

19,037,215 Shares

Common Stock

This prospectus relates to the disposition from time to time of up to 19,037,215 shares of our outstanding common stock, which includes 8,375,694 shares of our common stock issuable upon the exercise of warrants to purchase shares of common stock, held by the stockholders named in this prospectus, including their transferees, pledgees or donees or their respective successors. The selling stockholders acquired the warrants and common stock from us in a private placement that closed on September 9, 2009 and that is more fully described on pages 19 and 20 of this prospectus under Selling Stockholders. In addition, the stock offered hereby includes 1,845,000 shares of common stock previously acquired by two of the selling stockholders. We are not selling any common stock under this prospectus and will not receive any of the proceeds from the sale of shares by the selling stockholders.

The selling stockholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how the selling stockholders may sell their shares of common stock in the section entitled Plan of Distribution on pages 22 and 23 of this prospectus. We will not be paying any underwriting discounts or commissions in this offering.

Our common stock is listed on the NASDAQ Global Market under the symbol NURO. On September 29, 2009, the last reported sale price of our common stock on the NASDAQ Global Market was $3.31.

Investing in our securities involves various risks. You should carefully consider the risks and uncertainties set forth in the section titled Risk Factors beginning on page 3 of this prospectus as well as in the documents we file with the Securities and Exchange Commission that are incorporated by reference in this prospectus.

Neither the Securities and Exchange Commission 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.

The date of this prospectus is , 2009

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ABOUT THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference in this prospectus and any applicable prospectus supplement. We have not, and the selling stockholders have not, authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus and any applicable prospectus supplement. You must not rely on any unauthorized information or representation. The selling stockholders are offering to sell, and seeking offers to buy, shares of our common stock, but only under circumstances and in jurisdictions where it is lawful to do so.

This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than the shares of common stock to which it relates or an offer to, or a solicitation of, any person in any jurisdiction where such an offer or solicitation would be unlawful. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create any implication that there has been no change in the affairs of our company or that information contained herein is correct as of any time subsequent to the date hereof.

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PROSPECTUS SUMMARY

This summary only highlights the more detailed information appearing elsewhere in this prospectus or incorporated herein by reference. As this is a summary, it may not contain all information that is important to you. You should read this entire prospectus carefully, including the section entitled Risk Factors, beginning on page 3 before deciding whether to invest in our common stock.

This prospectus contains forward-looking statements. You should read the explanation of the qualifications and limitations on such forward-looking statements on page 19 of this prospectus. You should not place undue reliance on our forward-looking statements.

Unless the context otherwise requires, all references to we, us, our company or the Company in this prospectus refers to NeuroMetrix, Inc., a Delaware corporation.

About NeuroMetrix, Inc.

NeuroMetrix was founded in June 1996. We are a science-based health care company transforming patient care through neurotechnology. We provide innovative products for preservation and restoration of nerve and spinal cord function, and pain control. To date, our focus has been primarily on the assessment of neuropathies. Neuropathies affect the peripheral nerves and parts of the spine and are frequently caused by or associated with carpal tunnel syndrome, diabetes, sciatica, and other clinical disorders. We market systems for the performance of nerve conduction studies and needle electromyography procedures. Our product pipeline includes a system designed to deliver pharmacologic agents such as anesthetics and corticosteroids in close proximity to nerves for regional anesthesia, pain control and the treatment of focal neuropathies. We are also developing devices and pharmaceutical agents to treat peripheral nerve and spinal cord injuries.

We have two medical devices cleared by the United States Food and Drug Administration, or FDA, which are used for the assessment of neuropathies. The ADVANCE NCS/EMG System, or the ADVANCE System, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. This system is used primarily by neurologists, physical medicine and rehabilitation, or PM&R, physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians. The ADVANCE System is comprised of: (1) single use surface electrodes and needles, (2) the ADVANCE device and related modules, and (3) a communication hub that enables the physician s office to network their device to our internet portal for data archiving, report generation and other network services. The NC-stat System is a point-of-care device for the performance of nerve conduction studies. The NC-stat System, our initial product for the assessment of neuropathies, has been sold historically to a broad group of physicians, including primary care physicians and specialists since its initial market launch in May 1999. The NC-stat System is comprised of: (1) single use electrodes, (2) the NC-stat device and related components, and (3) the NC-stat docking station, an optional device that enables the physician s office to transmit data to our onCall Information System. Our neurodiagnostic equipment is used in over five thousand physician offices, clinics and hospitals. Over one and a half million patients have been tested with our neurodiagnostic equipment since 1999.

We are presently focusing our sales efforts on the NC-Stat System to primary care physicians and clinics and the ADVANCE System to specialist physicians with peripheral nerve expertise, including neurologists, PM&R physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians.

NeuroMetrix, Inc. is a Delaware corporation. Our principal executive offices are located at 62 Fourth Avenue, Waltham, Massachusetts 02451 and our telephone number is (781) 890-9989. Our website is http://www.neurometrix.com. The information found on our website is not part of this prospectus.

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The Offering

Common stock offered by the selling stockholders	19,037,215 shares(1)
Common stock outstanding as of September 29, 2009	22,907,234 shares(2)
Use of Proceeds	We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the proceeds upon exercise of the warrants, if any, which would be used for working capital and other general corporate purposes.
NASDAQ Global Market ticker symbol	NURO

We are registering the common stock covered by this prospectus in order to fulfill our contractual obligations to do so, which we undertook at the time of the original issuance of the shares in a private placement in September 2009. Registration of the common stock does not necessarily mean that all or any portion of such stock will be offered for sale by the selling stockholders.

We have agreed to bear the expenses of the registration of the common stock under federal and state securities laws, but we will not receive any proceeds from the sale of any common stock offered under this prospectus.

(1) Includes 8,375,694 shares of common stock that may be issued upon the exercise of warrants held by the selling stockholders.
(2) Excludes shares that are issuable upon the exercise of warrants held by the selling stockholders, which are not exercisable prior to March 8, 2010 and other shares issuable upon exercise of outstanding options to purchase our common stock.

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RISK FACTORS

Our business is subject to numerous risks as discussed more fully in the section entitled Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2008, which is incorporated by reference in this prospectus. Principal risks of our business include the following, among others:

Risks Related to Our Business

We have incurred significant operating losses since inception and cannot assure you that we will again achieve profitability.

The extent of our future operating income or losses is highly uncertain, and we may not be able to reach and sustain profitability. We have incurred significant cumulative net losses since our inception. Our net losses for the six months ended June 30, 2009, and for the years ended December 31, 2008 and 2007, were approximately $3.0 million, $27.7 million, and $8.4 million, respectively, as a result of a decline in revenues and increases in operating expenses and other charges. At June 30, 2009, we had an accumulated deficit of approximately $92.8 million. We cannot assure you that we will be able to reach profitability.

Disruption in global financial markets could have a negative effect on our business.

Global financial markets have been experiencing extreme disruption in recent months, resulting in extreme volatility in security prices and severely diminished liquidity and availability of credit and equity capital. There can be no assurance that there will not be a further deterioration in financial markets, which may lead to challenges in the operation of our business including challenges to our manufacturers or suppliers. The current tightening of credit in financial markets adversely affects the ability of customers and suppliers to obtain financing for significant purchases and operations and could result in decrease in demand for our products and services.

If physicians or other health care providers are unable to obtain sufficient reimbursement from third-party health care payers for procedures performed using our products, the adoption of our products and our future product sales will be severely harmed.

Widespread adoption of our products by the medical community is unlikely to occur if physicians do not receive sufficient reimbursement from third-party payers for performing procedures using our products. If physicians are unable to obtain adequate reimbursement for procedures performed using our products, we may be unable to sell our products and our business would suffer significantly. Additionally, even if these procedures are reimbursed by third-party payers, adverse changes in payers policies toward reimbursement for the procedures would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, workers compensation programs, private health insurers and other organizations. These organizations may deny coverage if they determine that a procedure was not reasonable or necessary, for example, if its use was not considered medically appropriate, or was experimental, or was performed for an unapproved indication. In addition, some health care systems are moving towards managed care arrangements in which they contract to provide comprehensive health care for a fixed cost per person, irrespective of the amount of care actually provided. These providers, in an effort to control health care costs, are increasingly challenging the prices charged for medical products and services and, in some instances,

have pressured medical suppliers to lower their prices. If we are pressured to lower our prices, our revenues may decline and our profitability could be harmed. The Centers for Medicare & Medicaid Services, or CMS, guidelines set the reimbursement rates for procedures covered by Medicare. Future regulatory action by CMS or other governmental agencies or negative clinical results may diminish reimbursement payments to physicians for performing procedures using our products. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not reimburse physicians for performing procedures using our products in an adequate amount, if at all. Additionally, some private payers do not follow the CMS and Medicaid guidelines and may reimburse for only a portion of these procedures or not at all. We are unable to predict what changes will be made in the reimbursement methods used by private or governmental third-party payers.

During the second half of 2006 and in 2007, several local Medicare carriers issued draft local coverage determinations, or LCDs, final LCDs or coding articles particularly addressing coverage and reimbursement policies under Medicare for nerve conduction studies performed using the NC-stat System. Several of these carriers indicated that they will not reimburse physicians under Medicare for nerve conduction studies performed using the NC-stat System under the three existing Current Procedural Terminology, or CPT, codes for conventional nerve conduction studies (95900, 95903 and 95904), which provide for levels of reimbursement fixed by CMS, but rather that physicians must submit claims for

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reimbursement for these procedures under a miscellaneous CPT code (95999), in which case the local carriers may determine the level of reimbursement to be paid, if any. In certain regions impacted by these reimbursement decisions, our customers have experienced lower levels of reimbursement and higher levels of claims denials. If physicians do not receive adequate reimbursement under the miscellaneous CPT code from those local carriers, our existing customers may continue to limit or curtail their use of the NC-stat System and we may be unable to obtain new customers, both of which could materially and adversely impact our revenues and profitability.

The CPT Panel has been reviewing the reimbursement coding for nerve conduction studies and formed a work group in early 2007 to examine the reimbursement coding of nerve conduction studies performed using nerve conduction equipment, including the NC-stat System. The findings of this work group were presented to the CPT Panel at a meeting in February 2008. At this meeting, the CPT Panel approved a Category III code describing nerve conduction studies performed with pre-configured electrode arrays. However, prior to publishing a new Category III CPT code for nerve conduction studies, the CPT Panel decided to reconsider its decision. In October 2008, the CPT Panel again considered nerve testing as an agenda item and, at this meeting, approved a new Category I CPT code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-stat System. The outcome of the most recent vote was first made public in January 2009 when the CPT Panel minutes from the October 2008 meeting were reported by a financial analyst. We believe that the new code will be published in the Federal Register in the second half of 2009 for implementation on January 1, 2010. Before this new CPT code is implemented, the amount of reimbursement that physicians will receive under the code will need to be determined. CMS will determine the Relative Value Units, or RVUs, on which the amount of reimbursement is based and publish the final RVUs in the Federal Register for implementation January 1 of the next year. This CPT code, when issued, may improve our customers ability to submit claims efficiently and for these claims to be processed expeditiously and may help to stabilize the process for obtaining reimbursement under Medicare for nerve conduction studies performed using the NC-stat System.

The LCDs and coding articles issued by local Medicare carriers have also addressed a number of other issues, including (1) the background and training of physicians supervising or performing nerve conduction studies, (2) the level of training requirements for technicians performing a nerve conduction study, (3) whether nerve conduction tests should be required to be performed concomitantly with a needle electromyography procedure and (4) whether the NC-stat System is comparable to conventional nerve conduction testing equipment. We do not believe that these LCDs prohibit physicians from receiving reimbursement under Medicare for medically necessary nerve conduction studies performed using the NC-stat System. However, these LCDs do appear to be targeted at limiting access to perform and/or reimbursement for nerve conduction studies. In certain cases, these LCDs are being interpreted or implemented in a manner that impacts the ability of physicians to receive reimbursement under Medicare, including lower levels of reimbursement and an increase in the number of claims being denied, for nerve conduction studies performed using the NC-stat System, which are having an adverse impact on our revenues.

A significant number of commercial payers, including the majority of regional Blue Cross Blue Shield carriers, and other major private payers, have adopted policies indicating that they will not provide reimbursement for the use of the NC-stat System. These commercial payers have cited various reasons for their reimbursement policies, including, among others, that the NC-stat System is experimental and investigational. Third-party payers may also impose requirements on physicians to submit additional paperwork supporting the medical necessity of nerve conduction studies performed using the NC-stat System. We believe these requirements are negatively impacting the use of the NC-stat System by existing customers and our sales to new customers, both of which are having an adverse impact on our revenues.

Additional third-party payers, including local Medicare carriers and commercial payers, could potentially take a position that could reduce or eliminate the reimbursement for nerve conduction studies performed with the NC-stat System which could have the impact of deterring usage by our customers and could have an adverse impact on our revenues.

In the second quarter of 2008, we received 510(k) clearance from the FDA for the marketing in the United States of the ADVANCE System, a system for the performance of traditional nerve conduction studies and needle electromyography procedures. The ADVANCE System was

cleared by the FDA with the primary predicate, or comparable, device being the Keypoint device originally manufactured and marketed by Medtronic, Inc. to neurologists and physical medicine and rehabilitation physicians for the performance of nerve conduction studies and needle electromyography procedures. The ADVANCE System is a traditional system that supports nerve conduction testing with any electrode methodology, real-time waveform review and cursor editing, needle electromyography procedures and conventional reports with the results of the testing. We launched our sales and marketing efforts for the ADVANCE System to specialists with peripheral nerve expertise such as neurologists, physical medicine and rehabilitation physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians in May 2008. Our success in selling the ADVANCE System will be dependent, among other things, on our customers receiving, and our potential customers belief that they will receive, sufficient reimbursement from third-party payers for performing procedures using

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the ADVANCE System. We do not believe that the final LCDs or policies adopted by major private payers impacting reimbursement for procedures performed using the NC-stat System will apply to procedures performed by specialists with peripheral nerve expertise using the ADVANCE System. However, these final LCDs and policies are subject to the interpretation of, and may be modified by, the applicable third-party payer, whose interpretations may differ from ours. Additionally, the outcome of the ongoing process with the CPT Panel regarding reimbursement coding of nerve conduction studies could impact future reimbursement of procedures performed using the ADVANCE System.

We face uncertainty relating to health care reform, which may make it difficult or impossible to sell our products on commercially reasonable terms.

The efforts of governments and third-party payers to contain or reduce the cost of health care will continue to affect the business and financial condition of medical device companies such as us. A number of legislative and regulatory proposals to change the health care system are currently being discussed and could reduce or cap the reimbursement amounts for procedures performed using our products. Lower-than-expected, or decreases in reimbursement amounts for procedures performed using our products, may decrease the amounts physicians and other practitioners are able to charge patients, which in turn may adversely affect the willingness of physicians and other practitioners to purchase our products at the prices we target, or at all. If we are not able to sell or products at target prices, then we will suffer a decrease in expected profitability that would likely adversely affect our business, financial condition and results of operations.

We may be unable to expand the market for the NC-stat and ADVANCE Systems, which would limit our ability to increase our revenues.

For our future growth, we are relying, in part, on increased use of nerve conduction studies. A number of factors could limit the increased use of nerve conduction studies and the NC-stat and ADVANCE Systems, including:

- third-party payers challenging, or the threat of third-party payers challenging, the necessity of increased levels of nerve conduction studies;
- third-party payers reducing or eliminating reimbursement for procedures performed by physicians using the NC-stat System;
- unfavorable experiences by physicians using the NC-stat or ADVANCE System;
- physicians reluctance to alter their existing practices; and

- the failure of other companies existing drug development programs to produce an effective treatment for DPN, which may limit the perceived need and the actual use of the NC-stat System in connection with this disease, and thereby limit or delay our growth in the DPN market, which we have estimated to be our largest potential market for our NC-stat System.

If we are unable to expand the market for the NC-stat and Advance Systems, our ability to increase our revenues will be limited and our business prospects will be adversely affected.

If we are unable to successfully sell our products to primary care, specialist physicians and other health care providers, our ability to increase our revenues will be limited.

We are focusing our sales and marketing efforts for the NC-stat System on primary care physicians and the ADVANCE System to specialist physicians. We may be unable to convince these physicians that our products provide effective diagnostic solutions. In addition, these physicians may be reluctant to make the capital investment required to purchase the NC-stat System or ADVANCE System. If we are unable to successfully sell our products to primary care physicians and specialist physicians, our ability to increase our revenues will be severely limited.

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We are dependent on several single source manufacturers to produce the NC-stat and ADVANCE Systems and any changes in the relationships with these manufacturers could prevent us from delivering products to our customers in a timely manner and may adversely impact our future revenues or costs.

We rely on third-party manufacturers to manufacture all of the components of the NC-stat and ADVANCE Systems. In the event that our manufacturers cease to manufacture sufficient quantities of our products in a timely manner and on terms acceptable to us, we would be forced to locate alternate manufacturers. Additionally, if our manufacturers experience a failure in their production process, are unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fail to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products, particularly our electrodes, for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. We have entered into exclusive manufacturing and supply agreements with Parlex for the manufacture of the electrodes, and Sunburst for the manufacture of our NC-stat and ADVANCE monitors, docking stations and communication hubs.

We do occasionally experience transient inventory shortages on new products during the initial production ramp-up phase. If any of the changes in our relationships with these manufacturers as described above occurs, our ability to supply our customers will be severely limited until we are able to engage an alternate manufacturer or, if applicable, resolve any quality issues with our existing manufacturer. This situation could prevent us from delivering products to our customers in a timely manner, lead to decreased sales or increased costs, or harm our reputation with our customers.

If our manufacturers are unable to supply us with an adequate supply of products as we expand our markets, we could lose customers, our potential future growth could be limited and our business could be harmed.

In order for us to successfully expand our business within the United States and internationally, our contract manufacturers must be able to provide us with our products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable cost and on a timely basis. Our potential future growth could strain the ability of our manufacturers to deliver products and obtain materials and components in sufficient quantities. Manufacturers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance. If we are unable to obtain sufficient quantities of high quality products to meet customer demand on a timely basis, we could lose customers, our growth may be limited and our business could be harmed.

We currently rely entirely on sales of the products that comprise the NC-stat and ADVANCE Systems to generate substantially all of our revenues, and any factors that negatively impact our sales of these products could significantly reduce our ability to generate revenues.

We introduced the NC-stat System to the market in May 1999 and the ADVANCE System in June 2008. We derive substantially all of our revenues from sales of the products that comprise these two systems, and we expect that sales of these products will continue to constitute the majority of our sales for the foreseeable future. Accordingly, our ability to generate revenues is reliant on our ability to market and sell the products that comprise the NC-stat and ADVANCE Systems, particularly electrodes, sales of which accounted for approximately 86-91% of our total revenues in each of the past three years. Our sales of these products may be negatively impacted by many factors, including:

- changes in reimbursement rates or policies relating to our products by third-party payers;

- decisions made by the CPT Panel relating to the reimbursement of nerve conduction studies performed using the NC-stat System;

- Medicare reimbursement rate established for a potential new Category I CPT Code for nerve conduction studies performed with pre-configured electrode arrays, such as are utilized with the NC-stat System;

- the failure of the market to accept our products;

- manufacturing problems;

- claims that our products infringe on patent rights or other intellectual property rights owned by other parties;

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- adverse regulatory or legal actions relating to our products;

- competitive pricing and related factors; and

- results of clinical studies relating to our products or our competitors products.

If any of these events occurs, our ability to generate revenues could be significantly reduced.

The patent rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would harm our ability to compete in the market.

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect these rights adequately. The risks and uncertainties that we face with respect to our patents and other related rights include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;

- the claims of any patents that are issued may not provide meaningful protection;

- we may not be able to develop additional proprietary technologies that are patentable;

- other parties may challenge patents, patent claims or patent applications licensed or issued to us; and

- other companies may design around technologies we have patented, licensed or developed.

We also may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection. Our patent rights underlying our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to our technology and

products without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. If any of these events were to occur, our ability to compete in the market would be harmed.

Other rights and measures we have taken to protect our intellectual property may not be adequate, which would harm our ability to compete in the market.

In addition to patents, we rely on a combination of trade secrets, copyright and trademark laws, confidentiality, nondisclosure and assignment of invention agreements and other contractual provisions and technical measures to protect our intellectual property rights. In particular, we have sought no patent protection for the technology and algorithms we use in our onCall Information System. We rely on trade secrets to protect this information. While we currently require employees, consultants and other third parties to enter into confidentiality, non-disclosure or assignment of invention agreements or a combination thereof where appropriate, any of the following could still occur:

- the agreements may be breached;
- we may have inadequate remedies for any breach;
- trade secrets and other proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

If, for any of the above reasons, our intellectual property is disclosed or misappropriated, it would harm our ability to protect our rights and our competitive position.

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We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the medical device industry are generally uncertain. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

- assert claims of infringement;
- enforce our patents;
- protect our trade secrets or know-how; or
- determine the enforceability, scope and validity of the proprietary rights of others.

Any lawsuits that we initiate could be expensive, take significant time and divert management s attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events could harm our business, our ability to compete in the market or our reputation.

Claims that our products infringe on the proprietary rights of others could adversely affect our ability to sell our products and increase our costs.

Substantial litigation over intellectual property rights exists in the medical device industry. We expect that our products could be increasingly subject to third-party infringement claims as the number of competitors grows and the functionality of products and technology in different industry segments overlap. Third parties may currently have, or may eventually be issued, patents on which our products or technologies may infringe. Any of these third parties might make a claim of infringement against us. Any litigation regardless of its impact would likely result in the expenditure of significant financial resources and the diversion of management s time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays or require us to develop non-infringing technology, make substantial payments to third parties, or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenues may decrease substantially and we could be exposed to significant liability.

We are subject to extensive regulation by the FDA, which could restrict the sales and marketing of the NC-stat or ADVANCE Systems and could cause us to incur significant costs.

We sell medical devices that are subject to extensive regulation in the United States by the FDA for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive 510(k) clearance, grant of a *de novo* classification or pre-marketing approval, or PMA, from the FDA, unless an exemption applies. Medical devices may be marketed only for the indications for which they are approved or cleared. We may also be required to obtain a new 510(k) clearance*, de novo* classification or PMA for significant post-market modifications to our products including changes to the intended use. Each of these processes can be expensive and lengthy. The FDA s process for granting 510(k) clearance usually takes approximately three months, but it can be significantly longer. The process for obtaining *de novo* classification involves a level of scrutiny similar to the 510(k) clearance process, but may require more data. The process for obtaining PMA is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA.

Our clearances can be rescinded if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or pre-market approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect

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our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. If any of these events occur or if the FDA takes other administrative or judicial actions, we may not be able to provide our customers with the quantity of products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs. In particular, our business could be adversely impacted in the event that we do not obtain 510(k) clearance for the portions of the onCall Information System that are the subject of our 510(k) filing in the fourth quarter of 2006. Because the portions of the onCall Information System under review are currently in use, if the FDA does not clear them, we may be required to modify or remove the portions of the onCall Information System that are under review. Any such modifications could make the NC-stat System more time consuming for physicians, which could adversely impact our ability to generate revenues from the NC-stat System, or more expensive for us to operate. Either of these could have a material adverse impact on our business.

We also are subject to numerous post-marketing regulatory requirements, including quality system regulations, which relate to the design, manufacture, packaging, labeling, storage, installation and servicing of our products, labeling regulations, medical device reporting regulations and correction and removal reporting regulations. Our failure or the failure by any manufacturer of our products to comply with applicable regulatory requirements could result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, product seizures, consent decrees and civil penalties;
- requiring repair, replacement, refunds, notifications or recall of our products;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or PMA of new products, new intended uses, or modifications to existing products;
- rescinding 510(k) clearances or withdrawing PMAs that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our reputation, our ability to generate revenues and our profitability.

Also, from time to time, legislation is introduced into Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in

ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

If the FDA does not approve the Humanitarian Device Exemption, or HDE, application for our recently acquired Andara Oscillating Field Stimulator (OFS) System, we will not be able to market this system in the United States.

In September 2006, the FDA designated the Andara OFS device as a Humanitarian Use Device, or HUD, a designation based on a potential U.S. patient population of less than 4,000 patients per year. As the second of two steps in the HUD approval process, Cyberkinetics filed a HDE application in February 2007. Approval of the HDE by the FDA requires that we demonstrate the device would not expose patients to an unreasonable or significant risk of illness or injury and that the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternate forms of treatment.

In May 2007, the FDA sent Cyberkinetics a letter informing them that it had completed an initial scientific review of the application and indicating that it required additional information to determine if the device meets the statutory criteria for approval. In response to the FDA s letter, Cyberkinetics amended the HDE application in July 2007. In December 2007, the FDA sent a letter indicating that it had completed an initial scientific review of the July amendment and that it required additional information to determine if the device met the statutory criteria for approval. The letter requested additional

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information related to clinical data, study analysis, biocompatibility, sterilization, device description, and labeling. In February 2008, Cyberkinetics met with members of the FDA review staff, including the Director and Deputy Director of the division responsible for the HDE review, regarding Cyberkinetics HDE application. Following this meeting, in March 2008, Cyberkinetics submitted an amendment addressing the specific questions contained in the December 2007 letter from the FDA. In November 2008, the FDA sent Cyberkinetics a letter requesting additional information. NeuroMetrix responded to this letter in July 2009.

The FDA s review of the HDE application is ongoing, and we cannot provide any assurance that (1) NeuroMetrix s July 2009 response will be satisfactory to the FDA or that we would not have to conduct additional clinical trials, which may be lengthy and/or expensive, or satisfy other requirements before the FDA would grant its approval to market the Andara OFS device, or (2) the FDA will ever grant such approval. If the FDA does not grant its approval, we will not be able to market the Andara OFS device in the United States.

If we or the manufacturers of our products fail to comply with the FDA s quality system regulations, the manufacturing and distribution of our products could be interrupted, and our product sales and operating results could suffer.

We and our contract manufacturers are required to comply with the FDA s quality system regulations, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its quality system regulations through periodic inspections. We cannot assure you that our facilities or the facilities of the manufacturers of our products would pass any future quality system inspection. If our or any of the facilities of the manufacturers of our products fail a quality system inspection, the manufacturing or distribution of our products could be interrupted and our operations disrupted. Failure to take adequate and timely corrective action in response to an adverse quality system inspection could result in a suspension or shutdown of our packaging and labeling operations and the operations of the manufacturers of our products or a recall of our products, or other administrative or judicial sanctions. If any of these events occurs, we may not be able to provide our customers with the quantity of products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

Our products may be subject to recalls even after receiving FDA clearance or approval, which would harm our reputation, business and financial results.

We are subject to the medical device reporting regulations, which require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or have malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to occur. We are also subject to the correction and removal reporting regulations, which require us to report to the FDA any field corrections and device recalls or removals that we undertake to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health. In addition, the FDA and similar governmental bodies in other countries have the authority to require the recall of our products if there is a reasonable probability that the products would cause serious adverse health consequences or death. A government-mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers. A recall involving the NC-stat or ADVANCE Systems would be particularly harmful to our business and financial results because the products that comprise the NC-stat and ADVANCE Systems currently produce substantially all of our revenues.

We are subject to federal and state laws prohibiting kickbacks and false or fraudulent claims, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity

and be costly to respond to, and thus could harm our business.

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit any remuneration that is intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of health care products or services. These laws constrain a medical device company s sales, marketing and other promotional activities by limiting the kinds of business relationships and financial arrangements, including sales programs we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other third-party payers that are false or fraudulent, or for items or services that were not provided as claimed. From time to time, we may provide coding and billing information as product support to purchasers of our products. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance,

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which can be quite substantial including exclusion from participation in federal health care programs. In the event that we are found to have violated these laws or determine to settle a claim that we have done so, our business may be materially adversely affected as a result of any payments required to be made, restrictions on our future operations or actions required to be taken, damage to our business reputation or adverse publicity in connection with such a finding or settlement or other adverse effects relating thereto. Additionally, even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

On February 9, 2009, we announced that we had reached a resolution with the United States Department of Justice, or DOJ, and the Office of Inspector General, or OIG, of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of our past sales and marketing practices relating to our NC-stat System. We had been cooperating with the investigation since it began in 2006.

In February 2009, we entered into a three-year Deferred Prosecution Agreement with the DOJ and a five-year Corporate Integrity Agreement with the OIG. Failure to comply with the terms of the Deferred Prosecution Agreement and the Corporate Integrity Agreement could result in substantial civil or criminal penalties and being excluded from government health care programs, which could materially reduce our sales and adversely affect our financial condition and results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. Although we do not believe that we are subject to the HIPAA rules, the exact scope of these rules has not been clearly established. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

The use of our products could result in product liability claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of medical devices. The medical device industry historically has been litigious, and we face financial exposure to product liability claims if the use of our products were to cause or contribute to injury or death. In particular, the NC-stat or ADVANCE Systems may be susceptible to claims of injury because they involve the electric stimulation of a patient s nerves. Although we maintain product liability insurance for our products and other commercial insurance, the coverage limits of these policies may not be adequate to cover future claims. As sales and use of our products increase, we may be unable to maintain sufficient product liability or other commercial insurance on acceptable terms or at reasonable costs, and this insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our financial condition and results of operations. A product liability claim, regardless of its merit or eventual outcome, could result in substantial costs to us, a substantial diversion of management attention and adverse publicity. A product liability claim could also harm our reputation and result in a decline in revenues and an increase in expenses.

Our products are complex in design, and defects may not be discovered prior to shipment to customers, which could result in warranty obligations or product liability or other claims, reducing our revenues and increasing our costs and liabilities.

We depend upon third parties for the manufacture of our products. Our products, particularly our electrodes, require a significant degree of technical expertise to produce. If these manufacturers fail to produce our products to specification, or if the manufacturers use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised.

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If our products contain defects that cannot be repaired quickly, easily and inexpensively, we may experience:

- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- inability to attract new customers;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal action.

The occurrence of any one or more of the foregoing could harm our reputation and materially reduce our revenues and increase our costs and liabilities.

If we lose any of our officers or key employees, our management and technical expertise could be weakened significantly.

Our success largely depends on the skills, experience and efforts of our officers, including Shai N. Gozani, M.D., Ph.D., our founder, Chairman, President and Chief Executive Officer; Thomas T. Higgins, our Senior Vice President and Chief Financial Officer; Walter Christensen, our Senior Vice President of Global Sales; Guy Daniello, our Senior Vice President of Information Technology; Michael Williams, Ph.D., our Senior Vice President of Engineering; and our other key employees. We do not maintain key person life insurance policies covering any of our employees. The loss of any of our officers or key employees could weaken our management and technical expertise significantly and harm our business.

If we are unable to recruit, hire and retain skilled and experienced personnel, our ability to manage and expand our business will be harmed, which would impair our future revenues and profitability.

We are a small company with only 100 employees as of August 31, 2009, and our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining our future performance. We may not be able to meet our future hiring needs or retain existing personnel, particularly given the challenges our business has recently faced. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees. Failure to attract and retain personnel, particularly technical and sales and marketing personnel would materially harm our ability to compete effectively and grow our business.

If we do not effectively manage our future potential growth, our business resources may become strained, we may not be able to deliver our products in a timely manner and our results of operations may be adversely affected.

Future potential growth of our business may provide challenges to our organization and may strain our management and operations. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver our products in a timely manner and our results of operations may be adversely affected.

If we are unable to successfully expand, develop and retain our sales force, our revenues may decline, our future revenue growth may be limited and our expenses may increase.

As of August 31, 2009, we employed approximately 34 regional sales managers, 5 regional sales directors and a Senior Vice President of Global Sales. We are highly dependent on our regional sales managers to generate our revenues. Our ability to build and develop a strong sales force will be affected by a number of factors, including:

- our ability to attract, integrate and motivate sales personnel;

- our ability to effectively train our sales force;

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- the ability of our sales force to sell an increased number of products;

- the length of time it takes new sales personnel to become productive;

- the competition we face from other companies in hiring and retaining sales personnel;

- our ability to effectively manage a multi-location sales organization;

- our ability to enter into agreements with prospective members of our sales force on commercially reasonable terms; and

- our ability to get our independent international sales distributors who may sell products of multiple companies to commit the necessary resources to effectively market and sell our products.

If we are unable to successfully build, develop and retain a strong sales force and international sales distributors, our revenues may decline, our revenue growth may be limited and our expenses may increase.

Failure to develop or enter into relationships to sell products other than our existing products or enhance our existing products could have an adverse effect on our business prospects.

For the year ended December 31, 2008, the majority of our revenues were derived from selling the NC-stat and ADVANCE Systems. Our future business and financial success will depend, in part, on our ability to continue to introduce or sell new products and upgraded products into the marketplace. Developing new products and upgrades to existing and future products imposes burdens on our research and development department and our management. This process is costly, and we cannot assure you that we will be able to successfully develop new products or enhance the current systems or any of our other current or future products. We also may not be able to enter into relationships with other companies to sell additional products. In addition, as we develop the market for our products, future competitors may develop desirable product features earlier than we do which could make our competitors products less expensive or more effective than our products and could render our products obsolete or unmarketable. If our product development efforts are unsuccessful, we will have incurred significant costs without recognizing the expected benefits and our business prospects may suffer.

We currently compete, and may in the future need to compete, against other medical device companies with potentially greater resources, more established distribution channels and other competitive advantages, and the success of these competitors may harm our ability to generate revenues.

We currently do, and in the future may need to, compete directly and indirectly with a number of other companies that may have competitive advantages over us. We compete with companies that sell traditional NCS/nEMG equipment including Cardinal Healthcare, Cadwell Laboratories, Inc. and Natus. Additionally, we are aware of one company, Neumed, Inc., that markets a nerve conduction study system to the point-of-service market. Of these companies, Cardinal Healthcare, in particular, enjoys significant competitive advantages, including:

- greater resources for product development, sales and marketing;
- more established distribution networks;
- greater name recognition;
- more established relationships with health care professionals, customers and third-party payers; and
- additional lines of products and the ability to offer rebates or bundle products to offer discounts or incentives.

As we develop the market for point-of-service nerve conduction studies, we may be faced with competition from these companies or others that decide and are able to enter this market. Some or all of our future competitors in the point-of-service market may enjoy competitive advantages such as those described above. If we are unable to compete effectively against existing and future competitors, our sales will decline and our business will be harmed.

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We are dependent upon the computer and communications infrastructure employed and utilized by our onCall Information System and any failures or disruptions in this infrastructure could impact our revenues and profit margins or harm our reputation.

We are dependent upon the computer and communications infrastructure employed and utilized by our onCall Information System. Our computer and communications infrastructure consists of standard hardware, off-the-shelf system software components, database servers, proprietary application servers, a modem bank and desktop applications. Our future success will depend, in part, upon the maintenance and growth of this infrastructure. Any failures or outages of this infrastructure as a result of a computer virus, intentional disruption of our systems by a third-party, manufacturing failure, telephone system failure, fire, storm, flood, power loss or other similar events, could prevent or delay the operation of our onCall Information System, which could result in increased costs to eliminate these problems and address related security concerns and harm our reputation with our customers. In addition, if our infrastructure fails to accommodate growth in customer transactions, customer satisfaction could be impaired, we could lose customers, our ability to add customers could be impaired or our costs could be increased, any of which would harm our business.

If future clinical studies or other articles are published, or physician associations or other organizations announce positions, that are unfavorable to our products, our sales efforts and revenues may be negatively affected.

Future clinical studies or other articles regarding our existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor s product is more accurate or effective than our products or that our products are not as accurate or effective as we claim or previous clinical studies have concluded. Additionally, physician associations or other organizations that may be viewed as authoritative or have an economic interest in nerve conduction studies and in related electrodiagnostic procedures or other procedures that may be performed using our products could endorse products or methods that compete with our products or otherwise announce positions that are unfavorable to our products. We have experienced this with the professional societies representing the neurology community. Any of these events may negatively affect our sales efforts and result in decreased revenues.

Our future capital needs are uncertain and will depend on many factors.

Although we believe that our current cash and cash equivalents together with our short-term investments and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements for the next 12 to 24 months, our capital requirements are uncertain and will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with our sales and marketing efforts;
- the expenses we incur in manufacturing and selling our products;

- the costs of developing new products or technologies and enhancements to existing products;

- the cost of obtaining and maintaining FDA approval or clearance of our products and products in development;

- the costs associated with any expansion; and

- the number and timing of any acquisitions or other strategic transactions.

As a result of these factors, we may need to raise additional funds, and these funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

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If we choose to acquire or invest in new businesses, products or technologies, instead of developing them ourselves, these acquisitions or investments could disrupt our business and could result in the use of significant amounts of equity, cash or a combination of both.

From time to time we may seek to acquire or invest in businesses, products or technologies, instead of developing them ourselves. On January 20, 2009, for example, we acquired certain assets of Cyberkinetics.

Acquisitions and investments involve numerous risks, including:

- the inability to complete the acquisition or investment;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated synergies, cost savings or growth;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning and maintaining key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

In addition, any future acquisitions or investments may result in one or more of the following:

- issuances of dilutive equity securities, which may be sold at a discount to market price;
- the use of significant amounts of cash;
- the incurrence of debt;
- the assumption of significant liabilities;
- increased operating costs or reduced earnings;
- financing obtained on unfavorable terms;
- large one-time expenses; and
- the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

Any of these factors could materially harm our stock price, our business or our operating results.

As we continue to expand into foreign markets, we will be affected by new business risks that may adversely impact our financial condition or results of operations.

We had our initial revenues in the United Kingdom in the third quarter of 2007, representing our initial launch in Europe and had initial revenues in Latin America in 2008, representing our initial launch in Latin America. As we continue to expand into foreign markets, we will be subject to new business risks, including:

- failure to fulfill foreign regulatory requirements to market our products;

- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;

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- adapting to the differing business practices and laws in foreign countries;

- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign distributors or sales or marketing agents;

- limited protection for intellectual property rights in some countries;

- difficulty in collecting accounts receivable and longer collection periods;

- costs of enforcing contractual obligations in foreign jurisdictions;

- recessions in economies outside of the United States;

- political instability and unexpected changes in diplomatic and trade relationships;

- currency exchange rate fluctuations; and

- potentially adverse tax consequences.

If we are successful in introducing our products into foreign markets, we will be affected by these additional business risks, which may adversely impact our financial condition or results of operations. In addition, expansion into foreign markets imposes additional burdens on our executive and administrative personnel, research and sales departments, and general managerial resources. Our efforts to introduce our products into foreign markets may not be successful, in which case we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the revenues generated from this expansion.

Our operating results may fluctuate due to various factors and, as a result, period-to-period comparisons of our results of operations will not necessarily be meaningful.

Factors relating to our business make our future operating results uncertain and may cause them to fluctuate from period to period. These factors include:

- changes in the availability of third-party reimbursement in the United States or other countries;
- the timing of new product announcements and introductions by us or our competitors;
- market acceptance of new or enhanced versions of our products;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- the gain or loss of significant distribution outlets or customers;
- increased research and development expenses;
- the timing of any future acquisitions; or
- general economic conditions.

Because our operating results may fluctuate from quarter to quarter, it may be difficult for us or our investors to predict our future performance by viewing our historical operating results.

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If we are unsuccessful in pending and potential litigation matters, our financial condition may be adversely affected.

We are currently involved in various pending and potential legal proceedings, including a class action lawsuit and a stockholders derivative lawsuit against certain of our current and former officers and directors relating to allegedly making false and misleading statements and failing to disclose material information to the investing public and engaging in improper business practices. If we are ultimately unsuccessful in any of these matters, we could be required to pay substantial amounts of cash to the other parties including any legal fees not covered by our insurance. The amount and timing of any of these payments could adversely affect our financial condition.

Risks Related to this Offering

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology, medical device and other life science company stock. These wide fluctuations have often been unrelated to the operating performance of these companies. The trading price of our common stock has been highly volatile; our stock price has fluctuated from a low of $0.50 to a high of $3.60 over the past 12 months. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals of our product or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development milestones;
- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- changes in government regulations and standards affecting the medical device industry and our product;
- ability of new products, if they receive regulatory approval, to achieve market success;
- the performance of third-party contract manufacturers and component suppliers;

- our ability to develop sales and marketing capabilities;

- actual or anticipated variations in our results of operations or those of our competitors;

- announcements of new products, technological innovations or product advancements by us or our competitors;

- developments with respect to patents and other intellectual property rights;

- sales of common stock or other securities by us or our stockholders in the future;

- additions or departures of key scientific or management personnel;

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

- trading volume of our common stock;

- changes in earnings estimates or recommendations by securities analysts, failure to obtain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;

- public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;

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- decreases in market valuations of medical device companies; and

- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

Sales of a substantial number of shares of our common stock in the public market by existing stockholders, or the perception that they may occur, could cause our stock price to decline.

Sales of substantial amounts of our common stock by us or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital or in connection with acquisitions or corporate alliances and we plan to issue additional shares to our employees, directors or consultants in connection with their services to us. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time and could reduce the market price of our common stock.

There may be issuances of shares of blank check preferred stock in the future.

Our certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, none of which are issued or currently outstanding. The Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, the Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption of such shares, together with other rights, none of which will be afforded to holders of our common stock.

Anti-takeover provisions in our organizational documents and Delaware law, and those anti-takeover provisions adopted by the Company in 2007, may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;

- provide for a classified board of directors, with each director serving a staggered three-year term;

- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;

- provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and

- require advance written notice of stockholder proposals and director nominations.

We have adopted a Shareholder Rights Plan that could make it more difficult for a third party to acquire, or could discourage a third party from acquiring, the Company or a large block of our common stock. A third party that acquires 15% or more of our common stock (an acquiring person) could suffer substantial dilution of its ownership interest under the terms of the Shareholder Rights Plan through the issuance of common stock to all stockholders other than the acquiring person. We amended the Shareholder Rights Plan in connection with the private placement to provide that the acquisition of common stock in that placement by an existing stockholder would not be considered a triggering event thereunder.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current

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board of directors, including a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of any future debt or credit facility may preclude us from paying any dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders sole source of potential gain for the foreseeable future.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, statements regarding our or our management s expectations, hopes, beliefs, intentions or strategies regarding the future. The words believe, may, will, estimate, continue, anticipate, intend, expect, plan and similar expressions may identify forward-looking statements, but the abse these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this prospectus are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled Risk Factors. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

USE OF PROCEEDS

We will not receive any proceeds and the selling stockholders will receive all of the net proceeds from the sale of the securities covered by this prospectus. However, upon exercise of the warrants covered by this prospectus for cash, the selling stockholders would pay us an exercise price of $2.20 per share, or an aggregate of $18,426,527 if such warrants are exercised for cash in full. Under certain circumstances set forth in the warrants, the warrants are exercisable on a cashless basis. If the warrants are exercised on a cashless basis, we would not receive any cash payment from the selling stockholders upon any exercise of the warrants.

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SELLING STOCKHOLDERS

On September 9, 2009, we issued an aggregate of 8,816,521 shares of common stock and warrants to purchase an additional 8,375,694 shares of common stock in a private placement to the selling stockholders for an aggregate gross purchase price of approximately $18.68 million. The shares of common stock and warrants were sold as a unit for a price of $2.12 per unit. The consolidated closing bid for our common stock as reported on the NASDAQ Global Market on September 4, 2009 was $2.00.

The warrants are exercisable at any time six months after the closing date through the fifth anniversary of the closing date. The warrants have an exercise price of $2.20 per share, reflecting a 10% premium over the consolidated closing bid price for the Company s common stock as reported on the NASDAQ Global Market on September 4, 2009. In accordance with the terms of the offering, the warrants will become exercisable for a period of 4.5 years beginning on March 8, 2010. The warrants contain certain limitations that prevent the holder of any warrants from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it and its affiliates to exceed 19.99% of the total number of shares of our common stock then issued and outstanding (with a separate threshold of 9.99% of the total number of shares outstanding for any shareholder who has not exceeded that threshold as of the date of closing). The number of shares for which the warrants are exercisable and the associated exercise prices are subject to certain adjustments as set forth in the warrants. The holder has the right to net exercise any outstanding warrants for shares of our common stock. In addition, upon certain changes in control of the Company, the holder can elect to receive, subject to certain limitations and assumptions, cash equal to the Black-Scholes value of the outstanding warrants.

Pursuant to the securities purchase agreements, dated September 8, 2009, related to this private placement, we agreed to file the registration statement of which this prospectus is a part with the Securities and Exchange Commission to register the disposition of the shares of our common stock sold in the private placement (including common stock issuable upon the exercise of the warrants) and an aggregate of 1,845,000 shares of common stock owned by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations Fund International Limited prior to consummation of the private placement in the manner contemplated under Plan of Distribution. We also agreed to keep the registration statement effective until the earlier of (a) such time as all of the shares registered hereunder shall have been resold, or (b) such time as all of the shares registered hereunder may be resold without restrictions pursuant to Rule 144 under the Securities Act. Under the securities purchase agreements, if the registration statement of which this prospectus is a part is not declared effective by November 8, 2009 (or, in the event that the registration statement is reviewed by the Securities and Exchange Commission, January 7, 2010), we may incur certain penalties as liquidated damages to the selling stockholders equal to 1% of the purchase price paid by the selling stockholders for each 30-day delay; provided that such damages shall not exceed, in the aggregate, 12% of the purchase price paid by the selling stockholders.

The table below, including the footnotes, presents information regarding the selling stockholders and the shares of our common stock (including shares that may be acquired upon exercise of the warrants) that were sold to the selling stockholders under the securities purchase agreement that the selling stockholders may offer and sell from time to time under this prospectus. Except as set forth below, none of the selling stockholders nor any of their respective affiliates, officers, directors or principal equity holders has held any position or office or had any other material relationship with us or our affiliates within the past three years.

The information in the following table for the selling stockholders is based upon information provided by each selling stockholder to us by or on behalf of the selling stockholders in a selling stockholder questionnaire. As used in this prospectus, the term selling stockholder includes each of the selling stockholders listed below, and any donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from a selling stockholder. The number of shares in the column Number of Shares Offered Hereby represents all of the shares of our common stock that a selling stockholder may offer under this prospectus. The table and footnotes assume that the selling stockholders will sell all of such shares. However, because the selling stockholders may sell all or some of their shares under this prospectus from time to time, or in another permitted manner (including pursuant to Rule 144 under the Securities Act), we cannot assure you as to the actual number of shares that will be sold by the selling stockholders or that will be held by the selling stockholders after completion of any sales. We do not know how

long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares. Information concerning the selling stockholders may change over time and changed information will be presented in a supplement to this prospectus only to the extent required under the Securities Act and the rules and regulations promulgated thereunder.

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Name	Number of Shares Beneficially Owned(1)	Number of Shares Offered Hereby(2)	Number of Shares to be Owned After Offering(3)	Percentage of Common Stock Owned After Offering(4)
Deerfield Special Situations Fund, L.P. (5), (6)	1,572,705	2,449,194		*
Deerfield Special Situations Fund International Limited (5), (7)	2,820,968	4,365,718		*
Growth Equity Opportunities Fund, LLC (8)	1,887,906	3,681,417		*
Delphi Ventures VIII, L.P. (9), (10)	1,869,650	3,645,818		*
Delphi BioInvestments VIII, L.P. (9), (11)	18,256	35,599		*
Biomedical Value Fund L.P. (12), (13)	1,090,265	2,126,017		*
Biomedical Offshore Value Fund, Ltd. (12), (14)	561,652	1,095,221		*
Lagunitas Partners LP (15), (16)	294,513	574,300		*
Gruber & McBaine International (15), (17)	73,628	143,575		*
Jon D. & Linda W. Gruber Trust (15), (18)	122,714	239,292		*
J. Patterson McBaine (15), (19)	1,298,797	239,292	1,176,083	5.12%
Symmetry Parallax Partners L.P. (20)	23,599	46,018		*
Daniel & Colette Hagen (21)	29,210	27,612	15,050	*
Cummings Bay Capital LP (22), (23)	125,000	243,750		*
Geneve Corp. (22), (24)	63,791	124,392		*
Total	11,852,654	19,037,215	1,191,133	

* Less than 1%

(1) Shares beneficially owned include shares of our common stock but do not include shares of common stock issuable upon exercise of the warrants, which cannot be exercised prior to March 8, 2010.

(2) The warrants are not exercisable prior to March 8, 2010. In addition, the warrants contain an exercise limitation providing that a holder thereof may not exercise to the extent that, if after giving effect to such exercise, the holder or any of its affiliates would beneficially own in excess of 9.99% or 19.99% (depending on the ownership level as of the date of closing of the private placement) of the outstanding shares of common stock immediately after giving effect to such exercise. In each case, the selling stockholder does not have beneficial ownership of the shares that may be acquired upon exercise of the warrant. Accordingly, the number of shares of common stock set forth in the table as being registered for a selling stockholder may exceed the number of shares of common stock that the selling stockholder could own beneficially as of the date of this prospectus or as at any time in the future through its exercise of the warrants.

(3) Assumes that the selling stockholder will sell all shares of common stock offered by it under this prospectus.

(4) Percentages are based on 22,907,234 shares of our common stock that were outstanding on September 29, 2009.

(5) James E. Flynn has the power to vote or dispose of the shares of common stock held by each of Deerfield Special Situations Fund, L.P. and Deerfield Special Situations Fund International Limited (collectively Deerfield). The address for Deerfield is Deerfield Management, 780 3rd Avenue, 37th Floor, New York, NY 10017.

(6) Number of shares being offered includes 876,489 shares of common stock issuable upon exercise of a warrant acquired in the private placement.

(7) Number of shares being offered includes 1,544,750 shares of common stock issuable upon exercise of a warrant acquired in the private placement.

(8) Number of shares being offered includes 1,793,511 shares of common stock issuable upon exercise of a warrant acquired in the private placement. The shares directly held by Growth Equity Opportunities Fund, LLC (GEO) are indirectly held by: New Enterprise Associates 12, Limited Partnership (NEA 12), which is the sole member of GEO; NEA Partners 12, Limited Partnership (NEA Partners 12), which is the sole general partner of NEA 12; NEA 12 GP, LLC (NEA 12 LLC), which is the sole general partner of NEA Partners 12; and each of the individual Managers of NEA 12 LLC. The individual Managers of NEA 12 LLC are M. James Barrett, Peter J. Barris, Forest Baskett, Ryan D. Drant, Patrick J. Kerins, Krishna Kittu Kolluri, C. Richard Kramlich, Charles M. Linehan, Charles W. Newhall III, Mark W. Perry, Scott D. Sandell and Eugene A. Trainor III. All indirect holders of such above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest therein. The address for GEO is 1119 St. Paul Street, Baltimore, MD 21202.

(9)

Each of Delphi Ventures VIII, L.P. and Delphi BioInvestments VIII, L.P. (collectively, (Delphi) shares voting and dispositive power over the shares of common stock of the Company held by the other fund. The address for Delphi is Delphi Ventures, 3000 Sand Hill Road, #1-135, Menlo Park, CA 94025.

(10) Number of shares being offered includes 1,776,168 shares of common stock issuable upon exercise of a warrant acquired in the private placement.

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(11) Number of shares being offered includes 17,343 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(12) Each of Great Point Partners, LLC, Dr. Jeffrey Jay and Mr. David Kroin share voting and dispositive power over the shares of common stock of the Company held by Biomedical Value Fund L.P. and Biomedical Offshore Value Fund, Ltd. (collectively, Biomedical). Each of Dr. Jeffrey Jay and Mr. David Kroin disclaim beneficial ownership of such shares. The address for Biomedical is Great Point Partners, 165 Mason Street, 3rd Floor, Greenwich, CT 06830.
(13) Number of shares being offered includes 1,035,752 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(14) Number of shares being offered includes 533,569 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(15) Each of Lagunitas Partners LP, Gruber & McBaine International, Jon D. & Linda W. Gruber Trust, and J. Patterson McBaine (collectively Gruber & McBaine) shares voting and dispositive power over the shares of common stock of the Company held by Gruber & McBaine. The address for each is Gruber & McBaine, 50 Osgood Place, San Francisco, CA 94133.
(16) Number of shares being offered includes 279,787 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(17) Number of shares being offered includes 69,947 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(18) Number of shares being offered includes 116,578 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(19) Number of shares being offered includes 116,578 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(20) Number of shares being offered includes 22,419 shares of common stock issuable upon exercise of a warrant acquired in the private placement. The address is Symmetry Capital, 2169 Folsom Street, #M305, San Francisco, CA 94110.
(21) Number of shares being offered includes 13,452 shares of common stock issuable upon exercise of a warrant acquired in the private placement. The address is Daniel Hagan, 1025 Ashland Avenue, St. Paul, MN 55104.
(22) Each of Cummings Bay Capital LP and Geneve Corp. (collectively, Cummings Bay Capital) shares voting and dispositive power over the shares of common stock of the Company held by the other fund. The address for each is Cummings Bay Capital, 96 Cummings Point Road, Stamford, CT 06902.
(23) Number of shares being offered includes 118,750 shares of common stock issuable upon exercise of a warrant acquired in the private placement.
(24) Number of shares being offered includes 60,601 shares of common stock issuable upon exercise of a warrant acquired in the private placement.

PLAN OF DISTRIBUTION

We are registering the shares covered by this prospectus to permit the selling stockholders to conduct public secondary trading of the shares from time to time after the date of this prospectus.

The selling stockholders, including their donees, pledgees, transferees or other successors-in-interest selling shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on the NASDAQ Global Market or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent any of the selling stockholders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that, if required under the Securities Act and the rules and regulations promulgated thereunder, this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act, to include the name of such transferee in the list of selling stockholders under this prospectus.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

- privately negotiated transactions;

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- at the market or through market makers or into an existing market for the shares;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal. Any such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with Financial Industry Regulatory Authority, or FINRA, Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

In connection with the sale of the shares of common stock, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the shares offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, or any other available exemption from registration under the Securities Act, provided that they meet the criteria and conform to the requirements of such rule or exemption.

The selling stockholders and any broker-dealers that act in connection with the sale of securities may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act in connection with such sales, and any discounts or commissions received by such broker-dealers and any profit on the resale of the securities sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. In the event that any selling stockholder is deemed to be an underwriter within the meaning of Section 2(11) of the Securities Act, the selling stockholder will be subject to the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act. To our knowledge and based upon information we received from the selling stockholders, each selling stockholder that is affiliated with a broker-dealer acquired the shares of common stock being registered hereunder in the ordinary course of business, and, at the time such selling stockholder acquired the shares being registered hereunder, such selling stockholder did not have any agreement or understanding, directly or indirectly, with any person to distribute such shares. To our knowledge, none of the selling stockholders received any shares as underwriting compensation.

To the extent, but only to the extent, required pursuant to the Securities Act and the rules and regulations promulgated thereunder, the number of shares of our common stock to be sold, the names of the selling stockholders, the

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respective purchase prices and public offering prices, the names of any agents, dealer or underwriter and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post effective amendment to the registration statement that includes this prospectus.

To comply with the securities laws of some states, if applicable, the shares may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the shares may not be sold unless such shares have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We will bear all of the costs, expenses and fees in connection with the registration of the shares of common stock, other than any commissions, discounts or other fees payable to broker-dealers in connection with any sale of shares, which will be borne by the selling stockholders selling such shares of common stock. We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration and sale of the shares offered by this prospectus.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

EXPERTS

The financial statements incorporated in this Prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2008 have been so incorporated in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

LEGAL MATTERS

Honigman Miller Schwartz and Cohn LLP, Kalamazoo, Michigan has issued a legal opinion as to the validity of the shares of our common stock offered by this prospectus.

INCORPORATION OF DOCUMENTS BY REFERENCE

The Securities and Exchange Commission allows us to incorporate by reference the information that we file with them. Incorporation by reference means that we can disclose important information to you by referring you to other documents that are legally considered to be part of this prospectus and later information that we file with the Securities and Exchange Commission will automatically update and supersede the information in this prospectus, any supplement and the documents listed below. Our Securities and Exchange Commission file number is 001-33351. We incorporate by reference the specific documents listed below (other than portions of current reports furnished under Item 2.02 or

Item 7.01 of Form 8-K or other portions of documents filed with the SEC which are furnished, but not filed, pursuant to applicable rules promulgated by the SEC).

- Annual Report on Form 10-K for the year ended December 31, 2008, which was filed on March 20, 2009;

- Quarterly Reports on Form 10-Q for the quarters ended June 30, 2009 and March 31, 2009;

- Current Reports on Form 8-K filed on September 15, 2009, September 14, 2009, May 22, 2009, March 18, 2009 and February 10, 2009;

- The description of our common stock contained in the Registration Statement on Form 8-A, which was filed on July 19, 2004, and all amendments and reports updating such description; and

- The description of our preferred stock purchase rights contained in the Registration Statement on Form 8-A, which was filed on March 8, 2007, and all amendments and reports updating such description.

We also incorporate by reference any future filings made with the Securities and Exchange Commission under Section 13(a), 13(c), 14, or 15(d) of the Exchange Act on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold by the selling stockholders or this registration statement has been withdrawn. Those documents will become a part of this prospectus from the date that the documents are filed with the Securities and Exchange Commission.

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Upon oral or written request and at no cost to the requester, we will provide to any person, including a beneficial owner, to whom a prospectus is delivered, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus. All requests should be made to: NeuroMetrix, Inc., 62 Fourth Avenue, Waltham, Massachusetts 02451, Attn: Corporate Secretary. Telephone requests may be directed to the Corporate Secretary at (781) 890-9989. You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone to provide you with different information. You should not assume that the information in this prospectus or the documents incorporated by reference is accurate as of any date other than the date on the front of this prospectus or those documents.

WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act, and we are required to file annual, quarterly and current reports and proxy statements and other information with the Securities and Exchange Commission. You may read and copy these reports, proxy statements and information at the Securities and Exchange Commission s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a web site that contains reports, proxy and information statements and other information regarding registrants, including NeuroMetrix, Inc., that file electronically with the Securities and Exchange Commission. You may access the Securities and Exchange Commission s web site at http://www.sec.gov.

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NEUROMETRIX, INC.

19,037,215 Shares

Common Stock

PROSPECTUS

, 2009

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Part II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The expenses in connection with the issuance and distribution of the securities being registered are set forth in the following table (all amounts except the registration fee are estimated):

Registration fee Securities and Exchange Commission	$	3,463.02
Accountants fees and expenses		10,000.00
Legal fees and expenses		15,000.00
Printing expenses		5,000.00
TOTAL	$	33,463.02

All expenses itemized above shall be borne by us.

Item 15. Indemnification of Directors and Officers.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the Delaware General Corporation Law, our Third Amended and Restated Certificate of Incorporation, or certificate of incorporation, includes a provision that eliminates the personal liability of our directors for monetary damages for breach of fiduciary duty as a director, except for liability (1) for any breach of the director s duty of loyalty to us or our stockholders, (2) for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, (3) under section 174 of the Delaware General Corporation Law (regarding unlawful dividends and stock purchases) or (4) for any transaction from which the director derived an improper personal benefit.

As permitted by the Delaware General Corporation Law, our Second Amended and Restated bylaws, as amended, or bylaws, provide that (1) we are required to indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very limited exceptions, (2) we may indemnify other employees as set forth in the Delaware General Corporation Law, (3) we are required to advance expenses, as incurred, to our directors and executive officers in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to certain very limited exceptions and (4) the rights conferred in our bylaws are not exclusive.

We have entered into indemnification agreements with each of our directors to give such directors additional contractual assurances regarding the scope of the indemnification set forth in our certificate of incorporation and to provide additional procedural protections. We also intend to enter into indemnification agreements with any new directors in the future.

The indemnification provisions in our certificate of incorporation, bylaws and the indemnification agreements entered into between us and each of our directors and our President and Chief Executive Officer may be sufficiently broad to permit indemnification of our directors and executive officers for liabilities arising under the Securities Act of 1933.

We have obtained liability insurance for our officers and directors.

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Item 16. Exhibits.

A list of exhibits filed with this registration statement on Form S-3 is set forth on the Exhibit Index and is incorporated herein by reference.

Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

4. That, for the purpose of determining liability under the Securities Act to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering

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thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to section 13(a) or section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Waltham, Commonwealth of Massachusetts, on October 2, 2009.

NEUROMETRIX, INC.

By: /s/ Shai N. Gozani, M.D., Ph.D.
Shai N. Gozani, M.D., Ph.D.
Chairman, President and Chief Executive Officer

KNOW ALL BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints each of Shai N. Gozani, M.D., Ph.D. and Thomas T. Higgins as such person s true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person s name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Shai N. Gozani, M.D., Ph.D. Shai N. Gozani, M.D., Ph.D.	Chairman, President and Chief Executive Officer (Principal Executive Officer)	October 2, 2009
/s/ Thomas T. Higgins Thomas T. Higgins	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	October 2, 2009
/s/ David E. Goodman, M.D. David E. Goodman, M.D.	Director	October 2, 2009
/s/ Allen J. Hinkle, M.D. Allen J. Hinkle, M.D.	Director	October 2, 2009
/s/ Charles R. LaMantia Charles R. LaMantia	Director	October 2, 2009

/s/ W. Mark Lortz W. Mark Lortz	Director	October 2, 2009
/s/ Timothy R. Surgenor Timothy R. Surgenor	Director	October 2, 2009

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EXHIBIT INDEX

Exhibit No.	Description
4.3	Form of Warrant (1)
*5.1	Opinion of Honigman Miller Schwartz and Cohn LLP
10.31	Form of Securities Purchase Agreement (1)
*23.1	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm
*23.2	Consent of Honigman Miller Schwartz and Cohn LLP (included in Exhibit 5.1)
*24.1	Power of Attorney (contained in signature page)

* Filed herewith.

(1) Filed as an exhibit to the registrant s Form 8-K (File No. 001-33351); as filed with the Securities and Exchange Commission on September 14, 2009, and incorporated by reference herein.