NeuroMetrix, Inc.
Form S-3
January 08, 2016

As filed with the Securities and Exchange Commission on January 8, 2016

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	**(I.R.S. Employer**

incorporation or organization) Identification Number)

1000 Winter Street

Waltham, MA 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.

President and Chief Executive Officer

NeuroMetrix, Inc.

1000 Winter Street

Waltham, MA 02451

(781) 890-9989

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

With a copy to:

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

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

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. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) 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. ¨

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. ¨

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. ¨

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

Large accelerated filer¨ Accelerated filer ¨

Non-accelerated filer ¨ (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 Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $0.0001 par value per share	16,505,880 (3)	$ 1.565 (4)	$25,831,702.2	$ 2,601.25
Rights to purchase Series A Junior Participating Cumulative Preferred Stock, $0.001 par value(2)	(2)	(2)	(2)	(2)

(1) Pursuant to Rule 416 under the U.S. Securities Act of 1933, as amended (the "Securities Act"), this Registration Statement shall also cover any additional shares of common stock which become issuable by reason of any stock dividend, stock split or other similar transaction that results in an increase in the number of the outstanding shares of common stock of the Registrant.

(2) Pursuant to a shareholder rights agreement, dated as of March 7, 2007, between the Company and American Stock Transfer & Trust Company, as amended, each share of common stock has an attached right to purchase our Series A Junior Cumulative Preferred Stock, which rights are not currently exercisable.

(3) The number of shares of common stock includes 5,411,764 shares of common stock issuable upon conversion of the Company's outstanding shares of Series C Convertible Preferred Stock (the "Series C Preferred Stock") and 11,094,116 shares of common stock issuable upon exercise of certain of the Company's warrants (the "Warrants").

(4) In accordance with Rule 457(c) under the Securities Act, the aggregate offering price of the common stock is estimated solely for the calculation of the registration fees due for this filing. This estimate was based on the average of the high and low sales price of our stock reported by The NASDAQ Capital Market on January 7, 2016.

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

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE 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 WE ARE NOT SOLICITING OFFERS TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

Subject to Completion, Dated January 8, 2016

PROSPECTUS

NEUROMETRIX, INC.

16,505,880 Shares of Common Stock

This prospectus relates to the resale of up to 16,505,880 shares of our common stock, including 5,411,764 shares of our common stock issuable upon conversion of outstanding shares of Series C Preferred Stock and 11,094,116 shares of our common stock issuable upon exercise of certain outstanding Warrants.

These shares will be resold from time to time by the entities listed in the section titled “Selling Security Holders” beginning on page 18, which we refer to as the selling security holders or Selling Stockholders. The shares of common stock offered under this prospectus by the selling security holders have been issued, or are issuable upon conversion or exercise of securities issued, pursuant to the Securities Purchase Agreement by and among NeuroMetrix, Inc. and certain of the selling security holders, dated as of December 29, 2015 (the “Purchase Agreement”), and pursuant to an engagement letter, dated as of December 14, 2015, as amended on December 29, 2015, with H.C. Wainwright & Co., LLC, the placement agent for the offering made pursuant to the Purchase Agreement (the “Engagement Letter”). We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of securities by the selling security holders.

The selling security holders 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 a selling security holder may sell its shares of common stock in the section titled “Plan of Distribution” on page 21. We will pay the expenses incurred in registering the securities covered by the prospectus, including legal and accounting fees.

Our common stock is quoted on The NASDAQ Capital Market, or NASDAQ, under the symbol "NURO." On January 7, 2016, the last reported sale price of our common stock was $1.61 per share.

Investing in our securities involves risks. See "Risk Factors" beginning on page 6 of this prospectus.

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

THE DATE OF THIS PROSPECTUS IS JANUARY , 2016.

TABLE OF CONTENTS

INFORMATION CONTAINED IN THIS PROSPECTUS

You should rely only on the information contained or incorporated by reference into this prospectus. We have not, and the selling security holders have not, authorized anyone to provide you with additional or different information. These securities are not being offered in any jurisdiction where the offer is not permitted. You should assume that the information in this prospectus is accurate only as of the date on the front of the document and that any information we have incorporated by reference is accurate only as of the date of the documents incorporated by reference, regardless of the time of delivery of this prospectus or of any sale of our common stock. Unless the context otherwise requires, references to “we,” “our,” “us,” “NeuroMetrix ,” or the “Company” in this prospectus mean NeuroMetrix, Inc.

As previously disclosed on a Current Report on Form 8-K filed on December 1, 2015, we filed a Certificate of Amendment to our Restated Certificate of Incorporation to effect a 1-for-4 reverse stock split of our common stock as of December 1, 2015. As a result of the reverse stock split, every four shares of the our pre-reverse split common stock were combined and reclassified into one share of our common stock. No fractional shares were issued in connection with the reverse stock split. The par value and other terms of the common stock were not affected by the reverse stock split. All of the share and per share values discussed in this prospectus have been adjusted to reflect the effect of the reverse stock split.

PROSPECTUS SUMMARY

The following is only a summary. We urge you to read the entire prospectus, including the more detailed financial statements, notes to the financial statements and other information included herein or incorporated by reference from our other filings with the U.S. Securities and Exchange Commission (SEC). Investing in our securities involves risks. Therefore, please carefully consider the information provided under the heading "Risk Factors" beginning on page 6.

Our Business – An Overview

NeuroMetrix is an innovative health-care company that develops wearable medical technology and point-of-care tests that help patients and physicians better manage chronic pain, nerve diseases, and sleep disorders. Our business is fully integrated with in-house capabilities spanning product development, manufacturing, regulatory affairs and compliance, sales and marketing, and customer support. We derive revenues from the sale of medical devices and after-market consumable products and accessories. Our products are sold in the United States and selected overseas markets, and are cleared by the U.S. Food and Drug Administration, or FDA, and regulators in foreign jurisdictions where appropriate. We have two principal product lines:

- Wearable neuro-stimulation therapeutic devices
- Point-of-care neuropathy diagnostic tests

Our core expertise in biomedical engineering has been refined over nearly two decades of designing, building and marketing medical devices that stimulate nerves and analyze nerve response for diagnostic and therapeutic purposes. We created the market for point-of-care nerve testing and were first to market with sophisticated, wearable technology for management of chronic pain. We also have an experienced management team and Board of Directors.

Chronic pain is a significant public health problem. It is defined by the National Institutes of Health as any pain lasting more than 12 weeks in contrast to acute pain which is a normal bodily response to injury or trauma. Chronic pain conditions include painful diabetic neuropathy, or PDN, arthritis, fibromyalgia, sciatica, musculoskeletal pain, cancer pain and many others. Chronic pain may be triggered by an injury or there may be an ongoing cause such as disease or illness. There may also be no clear cause. Pain signals continue to be transmitted in the nervous system over extended periods of time often leading to other health problems. These can include fatigue, sleep disturbance, decreased appetite, and mood changes which cause difficulty in carrying out important activities and contributing to disability and despair. In general, chronic pain cannot be cured. Treatment of chronic pain is focused on reducing pain and improving function. The goal is effective pain management.

Chronic pain is widespread. It affects over 100 million adults in the United States and more than 1.5 billion people worldwide. The global market for pain management drugs and devices alone was valued at $35 billion in 2012. The estimated incremental impact of chronic pain on health care costs in the United States is over $250 billion per year and lost productivity is estimated to exceed $300 billion per year.

The most common approach to chronic pain is pain medication. This includes over-the-counter drugs (such as Advil and Motrin), and prescription drugs including anti-convulsants (such as Lyrica and Neurontin) and anti-depressants (such as Cymbalta and Elavil). Topical creams may also be used (such as Zostrix and Bengay). With severe pain, narcotic pain medications may be prescribed (such as codeine, fentanyl, morphine, and oxycodone). The approach to treatment is individualized, drug combinations may be employed, and the results are often hit or miss. Side effects and the potential for addiction are real and the risks are substantial.

Reflecting the difficulty in treating chronic pain, inadequate relief leads 25% to 50% of pain sufferers to turn to the over-the-counter market for supplements or alternatives to prescription pain medications. These include non-prescription medications, topical creams, lotions, electrical stimulators, dietary products, braces, sleeves, pads and other items. In total they account for over $4 billion in annual spending in the United States on pain relief products.

High frequency nerve stimulation is an established treatment for chronic pain supported by numerous clinical studies demonstrating efficacy. In simplified outline, the mechanism of action involves intensive nerve stimulation to activate the body’s central pain inhibition system resulting in widespread analgesia, or pain relief. The nerve stimulation activates brainstem pain centers leading to the release of endogenous opioids that act primarily through the delta opioid receptor to reduce pain signal transmission through the central nervous system. This therapeutic approach is available through deep brain stimulation and through implantable spinal cord stimulation, both of which require surgery and have attendant risks. Non-invasive approaches to neuro-stimulation (transcutaneous electrical nerve stimulation, or TENS) have achieved limited efficacy in practice due to device limitations, ineffective dosing and low patient compliance.

Our Strategy

There are large and important unmet medical needs in chronic pain treatment. Prescription pain medications and over-the-counter therapies are often inadequate and can lead to other health issues. We believe that controlled, personalized, neuro-stimulation to suppress pain provides an important complement to pain medications. As a medical device company with unique experience in designing devices to manage and alter peripheral nerve function, we believe we are well positioned to make neuro-stimulation widely available to chronic pain sufferers. We have direct experience with neuro-stimulation through our prescription SENSUS wearable pain management device which has been on the market for the past three years and Quell, our over-the-counter, or OTC, wearable device for pain relief which was launched in the second quarter of 2015 and builds upon the core SENSUS neuro-stimulation technology.

1

Our primary objective is revenue growth. We expect this to be led by the successful market adoption of Quell. We also expect an important contribution to revenue from DPNCheck, our rapid, accurate diagnostic test for diabetic peripheral neuropathy.

Our key business strategies include:

Driving Commercial Adoption of Key Proprietary Products.

- **Quell** , our OTC wearable device for pain relief, was unveiled at the January 2015 Consumer Electronics Show (CES) and made commercially available in the United States during the second quarter of 2015. Following commercial launch through the end of the third quarter of 2015, approximately 7,000 Quell devices plus electrodes and accessories were shipped to consumers with a total invoiced value of $1.6 million. Quell utilizes OptiTherapy, our proprietary non-invasive neuro-stimulation technology to provide relief from chronic intractable pain, such as nerve pain due to diabetes, fibromyalgia, arthritic pain, and lower back and leg pain. This advanced wearable device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic intractable pain without a doctor's prescription. Users of the device have the option of using their smartphones to automatically track and personalize their pain therapy. Quell was launched through two distribution channels: a professional channel using a direct sales force to target podiatrists, pain physicians, primary care physicians, and chiropractors who resell the product, and a direct-to-consumer channel using online marketing and lead generation. After establishing the professional and direct to consumer channels, we expanded distribution to include Amazon e-commerce sales and QVC direct response TV, or DRTV, sales. We are developing other distribution channels for broader access to the retail markets. We believe there are significant opportunities to market Quell outside of the United States, particularly in Western Europe, Japan and China; however, we do not intend to approach those markets until we have established a solid presence in the United States.

- **DPNCheck** , our diagnostic test for peripheral neuropathies, was made commercially available in the fourth quarter of 2011. DPNCheck revenues for the nine months ended September 30, 2015 were approximately $1.5 million. DPNCheck revenues for 2014 and 2013 were approximately $1.8 million and $1.3 million, respectively. Our US sales efforts focus on Medicare Advantage providers who assume financial responsibility and the associated risks for the health care costs of their patients. We believe that DPNCheck presents an attractive clinical case with early detection of neuropathy allowing for earlier clinical intervention to help mitigate the effects of neuropathy on both patient quality of life and cost of care. Also, the diagnosis and documentation of neuropathy provided by DPNCheck helps clarify the patient health profile which, in turn, may have a direct, positive effect on the Medicare Advantage premium received by the provider. We believe that attractive opportunities exist outside the United States, including Japan where we received regulatory approval and launched DPNCheck with our distribution partner Omron Healthcare in the third quarter of 2014; in China where we are also working with Omron Healthcare on the regulatory process and anticipate commercial launch in 2016; and in Mexico where our distributor Scienta Farma received regulatory approval and plans to launch in 2016.

Maintaining a High Level of Research and Development Productivity. As an indicator of productivity, new products commercialized over the previous three years made up nearly fifty percent of our 2014 revenues. That percentage will expand for 2015 with the addition of Quell. Our research and development, or R&D, team successfully delivered Quell, an FDA cleared, technologically sophisticated, smart phone integrated product with electrodes and other accessories. We believe that there are no comparable products on the market. Our R&D team is now charged with maintaining and expanding this competitive technological advantage, and enhancing our intellectual property position, through continuing innovation. We expect innovation to take the form of device and software enhancements to improve the user experience, expanded smart phone applications, and new electrode features to optimize therapy. Technological innovation will continue to be one of our top priorities.

Our Business Model

Our products consist of a medical device used in conjunction with a consumable electrode or biosensor. Other accessories and consumables are also available to customers. Our goal for these devices is to build an installed base of active customer accounts and distributors that regularly order aftermarket products to meet their needs. We successfully implemented this model when we started our business with the NC-stat system and applied it to subsequent product generations including the ADVANCE system. Our recently developed products, Quell, SENSUS and DPNCheck, conform to this model.

Marketed Products

Quell

Quell is a wearable device for relief of chronic intractable pain, such as nerve pain due to diabetes and lower back problems. It incorporates our OptiTherapy technology, a collection of proprietary approaches designed to optimize the clinical efficacy of nerve stimulation. These include high power electrical stimulation hardware with precise control, algorithms that automatically determine a therapeutic stimulation intensity and compensate for nerve desensitization, and automated detection of user sleep and appropriate adjustment of stimulation level. Quell is comprised of (1) an electronic device carried in a neoprene band that is worn on the upper calf and (2) an electrode that attaches to the device and is the interface between the device and the skin. The device is lightweight and can be worn during the day while active, and at night while sleeping. It has been cleared by the FDA for treatment of chronic intractable pain and will be available OTC. Users of the device have the option of using their smartphones to automatically track and personalize their pain therapy. The device was unveiled at the Consumer Electronics Show in January 2015 and was made commercially available in June 2015. In an independent post-market clinical study of Quell, initiated by NeuroMetrix, 81% of subjects reported an improvement in management of their chronic pain and health, and 67% reported a reduction in their use of pain medications. Quell is currently available at selected physician resellers including podiatrists, pain physicians, primary care physicians, and chiropractors, and also via e-commerce on our designated website at *(quellrelief.com)* and on Amazon.com, and via DRTV on QVC. We are developing other retail distribution channels to broaden access to consumers. Following commercial launch in 2015, approximately 7,000

devices and accessories were shipped to consumers. These devices along with electrodes and accessories had a total invoiced value of $1.6 million through September 30, 2015.

2

SENSUS

The SENSUS pain therapy device, the technological predecessor to Quell, is a prescription neuro-stimulation device based on TENS for relief of chronic, intractable pain. SENSUS, which was commercially launched in the first quarter of 2013, is a convenient and wearable device that offers physicians and their patients a non-narcotic pain relief option as a complement to medications. SENSUS is comprised of: (1) an electronic device with a strap that is worn on the upper calf and (2) an electrode which attaches to the device. We provide prescribing physicians with PC-based software that links to the device via a USB connection, thereby allowing them to download a record of the patient's use of the device. The SENSUS device and electrodes were cleared by the FDA for commercial distribution. When medically indicated and supported by proper documentation, TENS are generally reimbursed by Medicare and many commercial insurance companies under the DME benefit. We believe SENSUS will have a limited impact on future revenues. SENSUS customers have purchased approximately 9,200 devices from launch through September 30, 2015.

DPNCheck

DPNCheck is a fast, accurate, and quantitative nerve conduction test that is used to evaluate systemic neuropathies such as diabetic peripheral neuropathy, or DPN. It is designed to be used by primary care physicians, endocrinologists, podiatrists and other clinicians at the point-of-care to objectively detect, stage, and monitor DPN. The device measures nerve conduction velocity and response amplitude of the sural nerve, a nerve in the lower leg and ankle. These parameters are widely recognized as sensitive and specific biomarkers of DPN. DPNCheck is comprised of: (1) an electronic hand-held device and (2) a single patient use biosensor. In addition, we provide users with PC-based software that links to the device via a USB connection. This PC software allows physicians to generate reports and manage their sural nerve conduction data.

DPNCheck is a modified version of our previously marketed NC-stat nerve testing device that has the same clinical indications with respect to DPN. The modified device, which costs less than the original device, has the same functionality with respect to sural nerve testing. DPNCheck has been the subject of many published studies, including several studies specifically addressing the accuracy and clinical utility of the device in assessment of DPN. DPNCheck shipments commenced in late 2011 and approximately 2,600 devices had been placed with customers through September 30, 2015.

ADVANCE System

Our legacy neurodiagnostics business is based on the ADVANCE NCS/EMG System, or the ADVANCE System, which is a comprehensive platform for the performance of traditional nerve conduction studies. The ADVANCE

System is comprised of: (1) the ADVANCE device and related modules, (2) various types of electrodes and needles, and (3) a communication hub that enables the physician's office to network their device to their personal computers and our servers for data archiving, report generation, and other network services. The ADVANCE System is most commonly used with proprietary nerve specific electrode arrays. These electrode arrays combine multiple individual electrodes and embedded microelectronic components into a single patient-use disposable unit. We currently market seven different nerve specific electrode arrays.

Historically, the ADVANCE System has been marketed to a broad range of physician specialties including neurologists, orthopedic surgeons, primary care physicians, and endocrinologists, and utilized for a variety of different clinical indications including assessment of carpal tunnel syndrome, or CTS, low back and leg pain, and DPN. It is most commonly used in the assessment of CTS. Numerous papers have been published on the use of this technology in this clinical application. More than 1.8 million patient studies have been performed using our NC-stat technology (including the ADVANCE System) and there have been approximately 6.3 million nerve tests, including nearly 700,000 sural nerve tests. As of September 30, 2015, we had an installed base of approximately 500 active customers using our ADVANCE System.

Legacy Neurodiagnostics Business

We were founded in 1996 as a science-based health care company. Our focus had been the development of innovative products for the detection, diagnosis, and monitoring of peripheral nerve and spinal cord disorders, such as those associated with carpal tunnel syndrome, lumbosacral disc disease and spinal stenosis, and diabetes. Our NC-stat System for the performance of nerve conduction studies at the point-of-care was commercially launched in 1999. The second generation NC-stat was released in 2002. In 2008, we brought to market the more sophisticated ADVANCE System for nerve conduction testing and performance of invasive needle electromyography. These systems were general purpose with broad application in evaluating and diagnosing nerve disorders. Numerous studies demonstrating the clinical accuracy and utility of these devices have been conducted and published in high quality peer-reviewed journals. Furthermore, these devices have been used in FDA sanctioned clinical trials for pharmacological agents and large scale epidemiological studies sponsored by the NIH, Center for Disease Control, or CDC, and other governmental agencies. The products have been cleared by the FDA, field tested for over a decade and highly regarded for their ease of use, accuracy and reproducibility of results.

Following launch of NC-stat in 1999, we experienced rapid revenue growth, which led to our initial public offering in 2004. The health market, particularly the physician office segment, embraced the opportunity to perform nerve conduction tests which previously had always required referral to specialists. Point-of-care nerve testing was seen to provide a combination of improved patient care and patient convenience. The success of point-of-care nerve testing, a market which we created, was met with resistance in some sectors of the medical community, particularly by neurologists and physical medicine and rehabilitation physicians, both of which had traditionally provided nerve testing services. As a consequence of successful lobbying by these specialists, physicians using our technology experienced increased denials of coverage by third party payers resulting in their discontinuing usage and our difficulty in accruing new customer accounts. In late 2009 CMS included in the Physician Fee Schedule a new Category I CPT Code, CPT 95905, for nerve conduction studies performed using preconfigured electrode such as those employed with our products. During 2010 most Medicare fiscal intermediaries assumed coverage for CPT 95905 for some clinical indications; however, the health care environment has been such that we have been unable to secure broad coverage among private payers which is essential to the success of our ADVANCE System product. This experience was reflected in our revenues for the legacy Neurodiagnostics business, which peaked in 2006 at $55.3 million. We reported revenue for our legacy Neurodiagnostics business of $1.8 million for the nine months ended September 30, 2015 and $2.8 million, $3.8 million, and $6.1 million in 2014, 2013 and 2012, respectively. We currently manage this business to optimize cash flow.

Risks Affecting Us

Our business is subject to numerous risks, as discussed more fully in the section entitled “Risk Factors” immediately following this Prospectus Summary. At September 30, 2015 we had an accumulated deficit of $160.9 million and held cash and cash equivalents of $9.1 million. We believe that these resources, the cash to be generated from expected product sales and the net proceeds of $6.7 million from the sale of securities in connection with the issuance of the Series C Preferred Stock and Warrants in December 2015 will be sufficient to meet our projected operating requirements through the second quarter of 2016. See “Offering of Preferred Shares and Warrants” below. However, the amount of our future product sales is difficult to predict, especially in light of the limited nature of the recent commercialization of Quell, and actual sales may not be in line with our forecasts. We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected. Accordingly, we will need to raise additional funds to support our operating and capital needs for the third quarter of 2016 and beyond. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations.

Our Corporate Information

Our President and Chief Executive Officer, Shai N. Gozani, M.D., Ph.D. founded NeuroMetrix in June 1996. We are incorporated in Delaware. Our common stock is listed on The NASDAQ Capital Market under the ticker symbol

"NURO." Our principal offices are now located at 1000 Winter Street, Waltham, Massachusetts 02451. Our telephone number is (781) 890-9989. Our web site is *www.neurometrix.com*. We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this document. Our web site address is included in this document as an inactive textual reference only. The NeuroMetrix name and logo and the names of products and services offered by NeuroMetrix are trademarks, registered trademarks, service marks or registered service marks of NeuroMetrix.

Offering of Preferred Shares and Warrants

On December 31, 2015, we completed an offering of securities resulting in approximately $13.8 million in proceeds in connection with the issuance to investors of (i) 13,800 shares of Series C convertible preferred stock (the "Series C Preferred Stock") at a price of $1,000 per share, and (ii) warrants to purchase up to 10,823,528 shares of our common stock, par value $0.0001 per share (the "Warrants"). We used $6.3 million of the proceeds from this offering to redeem 63,000 shares of our outstanding Series B convertible preferred stock, or Series B Preferred Stock, held by Sabby, and will use the remainder for general working capital purposes. The issuance and sale of Series C Preferred Stock and Warrants was exempt from registration pursuant to Section 4(a)(2) of the Securities Act.

Each share of Series C Preferred Stock has a stated value of $1,000 and is convertible, at any time at the option of the holder thereof, into a number of shares of our common stock determined by dividing the stated value by the initial conversion price of $2.55, subject to the 4.99% ownership limitation described below. The Series C Preferred Stock has no dividend rights, liquidation preference or other preferences over our common stock and has no voting rights except as provided in the Certificates of Designation of Preferences, Rights and Limitations for the Convertible Preferred Stock, as filed with the Secretary of State of the State of Delaware, or as otherwise required by law. Shares of common stock underlying the Series C Preferred Stock are being registered for resale by the selling security holders pursuant to the Registration Statement of which this prospectus forms a part.

Warrants to purchase an aggregate of 11,094,116 shares of common stock are exercisable immediately after issuance. The Warrants include warrants to purchase 5,411,764 shares of our common stock, which expire twelve months from the effectiveness of the Registration Statement of which this prospectus forms a part, and warrants to purchase 5,411,764 shares of common stock, which expire five years from the effectiveness of the Registration Statement of which this prospectus forms a part. All of these Warrants have an exercise price of $2.30 per share, the consolidated closing bid price of our common stock as of December 28, 2015. The Warrants also include warrants issued to H.C. Wainwright & Co., LLC and related persons to purchase 270,588 shares of common stock, which are exercisable immediately after issuance, and have a five-year term from the effective date of the Registration Statement of which this prospectus forms a part and a per share exercise price of $3.19. Shares of common stock underlying the aggregate of 11,094,116 Warrants are being registered for resale by the selling security holders pursuant to the Registration Statement of which this prospectus forms a part. The Warrants are subject to certain ownership limitations as described below.

The Series C Preferred Stock and the Warrants contain limitations that prevent the holder of any Series C Preferred Stock or Warrants from acquiring shares upon conversion of the Series C Preferred Stock, or exercise of a Warrant, that would result in the number of shares beneficially owned by it and its affiliates exceeding 4.99% of the total number of shares of our common stock then issued and outstanding. In addition, upon certain changes in control of NeuroMetrix, the holder of shares of Series C Preferred Stock or Warrants can elect to receive, subject to certain limitations and assumptions, securities in a successor entity equal to the value of the Series C Preferred Stock or Warrants or if holders of common stock are given a choice of cash or property, then cash or property equal to the value of the outstanding Series C Preferred Stock or Warrants. The Series C Preferred Stock and Warrants were issued pursuant to the Purchase Agreement and the Engagement Letter (as both are defined on the cover of this prospectus).

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully review and consider the following risk factors and in the section entitled "Risk Factors" contained in our most recent annual report on Form 10-K, which has been filed with the SEC and is incorporated by reference in this prospectus, as well as any updates thereto contained in subsequent filings with the SEC or in any free writing prospectus and all other information contained in this prospectus and incorporated by reference into the prospectus before purchasing our securities. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of the following risks occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business

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

We have incurred significant cumulative net losses since our inception. Our net losses for the nine months ended September 30, 2015 and the years ended December 31, 2014, 2013, and 2012, were approximately $6.5 million, $7.8 million, $8.0 million, and $10.0 million, respectively. At September 30, 2015, we had an accumulated deficit of $160.9 million. The extent of our future operating income or losses is highly uncertain, and we cannot assure you that we will be able to achieve or maintain profitability.

Our future capital needs are uncertain and our independent auditor has expressed substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to raise additional capital and our operations could be curtailed if we are unable to obtain the required additional funding when needed. We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

We held cash and cash equivalents of $9.1 million as of September 30, 2015. We believe that these resources, the cash to be generated from future product sales and the net proceeds of $6.7 million from the issuance of the Series C Preferred Stock and Warrants on December 31, 2015 will be sufficient to meet our projected operating requirements through the second quarter of 2016. However, the amount of our future product sales is difficult to predict, especially in light of the recent commercialization of Quell, and actual sales may not be in line with our forecasts.

Our financial statements have been prepared assuming that we will continue as a going concern which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We expect to incur further losses as we aim to successfully commercialize Quell and DPNCheck and the operations of our business and will be dependent on funding our operations through additional public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. These circumstances raise substantial doubt about our ability to continue as a going concern. As a result of this uncertainty and the substantial doubt about our ability to continue as a going concern as of December 31, 2014, the report of our independent registered public accounting firm in our Annual Report on Form 10-K for the year ended December 31, 2014 includes a going concern explanatory paragraph. Management's plans include increasing revenue through the commercialization of Quell and DPNCheck. However, no assurance can be given at this time as to whether we will be able to achieve these objectives. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

We continue to face significant challenges and uncertainties and, as a result, our available capital resources may be consumed more rapidly than currently expected due to (a) decreases in sales of our products and the uncertainty of future revenues from new products; (b) changes we may make to the business that affect ongoing operating expenses; (c) changes we may make in our business strategy; (d) regulatory developments affecting our existing products and delays in the FDA approval process for products under development; (e) changes in our research and development spending plans; and (f) other items affecting our forecasted level of expenditures and use of cash resources. Accordingly, we will need to raise additional funds to support our future operating and capital needs for the third quarter of 2016 and beyond. We may attempt to obtain additional funding through public or private financing, collaborative arrangements with strategic partners, or through additional credit lines or other debt financing sources to increase the funds available to fund operations. However, we may not be able to secure such financing in a timely manner or on favorable terms, if 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. 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. Without additional funds, we may be forced to delay, scale back or eliminate some of our sales and marketing efforts, research and development activities, or other operations and potentially delay product development in an effort to provide sufficient funds to continue our operations. If any of these events occurs, our ability to achieve our development and commercialization goals would be adversely affected.

We are focused on commercialization of Quell, our over-the-counter, or OTC, wearable device for chronic pain. We cannot assure you that we will be successful in this field or that our current commercial product for peripheral neuropathy, DPNCheck, or the product candidates or product enhancements in our development pipeline, will be successful.

We are focused on the commercialization of Quell, our OTC wearable device for pain relief. Quell is based on our prescription product for pain relief, SENSUS. Quell has been on the market since June 2015 and we have shipped approximately 7,000 Quell devices since then. Additionally, DPNCheck, which was launched in 2011, is a quantitative nerve conduction test for systemic neuropathies, such as DPN. We also have other product candidates and product enhancements in our development pipeline. Our future prospects are closely tied to our success with Quell and DPNCheck, which, in turn, depend upon market acceptance and growth in future revenues. We cannot assure you that our commercialization strategy will be successful. If our strategy is not successful, it could materially affect our revenues and results of operations.

Our future success could be adversely affected by a number of factors, including:

- inability to create market demand for Quell through a direct sales force, through online marketing efforts, direct response television and other retail channels;
- manufacturing issues with Quell or our other products;
- inability to increase adoption of DPNCheck within the Medicare Advantage market;
- unfavorable market response to DPNCheck in Japan and other Asia markets;
- unfavorable changes to current Medicare, Medicare Advantage and commercial payer payment policies;
- changes to payor policies under the Patient Protection and Affordable Care Act;
- unfavorable experiences by patients and physicians using Quell and our other products; and,
- physicians' reluctance to alter their existing practices and adopt the use of our devices.

If we are unable to expand exposure and penetrate the market for Quell and/or DPNCheck, our ability to increase our revenues will be limited and our business prospects will be adversely affected.

We currently rely on sales of the products that comprise the ADVANCE System to generate a meaningful portion of our revenues. Any factors that negatively impact our sales of these products could significantly reduce our ability to

generate revenues. Our legacy neurodiagnostics business is based on the ADVANCE NCS/EMG System, or the ADVANCE System, which is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. For 2014 and 2013, 51% and 72%, respectively, of our total revenue was attributed to the ADVANCE System. While our revenue from the ADVANCE System has decreased in recent years and, we expect, will continue to decrease as we manage the business for cash flow and not growth, we continue to derive a portion of our revenues from sales of ADVANCE System electrodes. We expect that sales of ADVANCE System products will constitute approximately 15% to 20% of our total revenue during 2015. ADVANCE System electrode sales may be negatively impacted by many factors, including:

- changes in reimbursement rates or policies by third-party payers;
- manufacturing problems;
- claims that our products infringe on patent rights or other intellectual property rights owned by other parties;
- adverse regulatory or legal actions relating to our products; and
- clinical trial results relating to our products or our competitors' products.

If any of these events occurs, ADVANCE electrode sales could be significantly reduced which could materially affect our financial condition.

Our current and future revenue is dependent upon commercial acceptance of Quell by the market. The failure of such acceptance will materially and adversely affect our operations.

We anticipate that as revenue from our legacy neurodiagnostics business, the ADVANCE System, continues to decrease, we will rely more heavily on revenue from sales of Quell, our OTC wearable device. As a result, we will continue to incur operating losses until such time as sales of Quell and other products or product candidates gain market acceptance and we are able to generate sufficient revenue from their sale to meet our operating expenses. There can be no assurance that customers will adopt our technology and products, or that prospective customers will agree to pay for our products. In the event that we are not able to significantly increase the number of customers that purchase our products, or if we are unable to charge the necessary prices, our financial condition and results of operations will be materially and adversely affected.

If health care providers are unable to obtain sufficient reimbursement or other financial incentives from third-party health care payers related to the use of our products other than Quell, their adoption and our future product sales will be materially adversely affected.

Widespread adoption of our SENSUS and DPNCheck products by the medical community is unlikely to occur without a financial incentive from third-party payers for the use of these products. If health care providers are unable to obtain adequate reimbursement for procedures performed using these products, if managed care organizations do not receive improved capitated payments due to more accurate patient risk assessment using our products, and if DME suppliers are not adequately reimbursed for supplying our therapeutic products, we may be unable to sell our products at levels that are sufficient to allow us to achieve and maintain profitability, and our business would suffer significantly. Additionally, even if these products and procedures are adequately reimbursed by third-party payers today, adverse changes in payers future policies toward payment would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, private health insurers, workers' compensation programs and other organizations.

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 cover the procedures performed with our products or pay physicians an adequate amount for performing those procedures, if at all. Additionally, some private payers do not follow the Medicare 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. Importantly, we cannot predict the effects that implementation of the Patient Protection and Affordable Care Act will have on CMS, commercial insurers, health care providers, and ultimately on our business.

Healthcare reform legislation could adversely affect our future revenues.

Our future revenues from SENSUS will be impacted by the CMS Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program. Under this program, Medicare will no longer reimburse suppliers for certain products and services, including transcutaneous electrical nerve stimulation (TENS), based on the Medicare fee schedule amount. Instead CMS will provide reimbursement for those products and services based on a competitive bidding process. Our SENSUS pain management system is presently classified within TENS. The DMEPOS Competitive Bidding Program will likely require us to sell SENSUS devices and related consumables subject to Medicare reimbursement at significantly lower prices which would have a material adverse effect on SENSUS profitability. In those regions of the country where DMEPOS Competitive Bidding was implemented in January 2014, low Medicare pricing is restricting our ability to sell SENSUS. As the DMEPOS program is expanded to other regions, a similar effect will likely be seen

We are subject to extensive regulation by the FDA which could restrict the sales and marketing of the Quell, SENSUS and DPNCheck devices and the ADVANCE System as well as other products for which we may seek FDA clearance or approval, 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 with regard to manufacturing, labeling, sale, promotion, distribution, shipping and ongoing monitoring and follow-up. 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 be cleared or approved by the FDA. Medical devices may be marketed only for the indications for which they are approved or cleared. The regulatory review process can be expensive and lengthy. The FDA’s process for granting 510(k) clearance typically takes approximately three to six months, but it can be significantly longer. The process for obtaining a pre-market approval, or PMA, is much more costly and onerous. By law, the time period designated for the FDA’s review of a PMA is 180 days; however, this time is often extended and it is not uncommon for the PMA review process to take three years or longer from the time the application is filed with the FDA.

The FDA may remove our devices from the market or enjoin them from commercial distribution 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 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 occurs or if the FDA takes other enforcement actions, we may not be able to provide our customers with the products they require on a timely basis, our reputation could be harmed, and we could lose customers and suffer reduced revenues and increased costs.

We also are subject to numerous post-marketing regulatory requirements, including the FDA's 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. FDA enforcement actions relating to post-marketing regulatory requirements or other issues, including any issues arising from the not substantially equivalent letter described above, may include any of the following:

- warning letters, untitled letters, fines, injunctions, product seizures, consent decrees and civil penalties;
- requiring repair, replacement, refunds, customer notifications or recall of our products;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for 510(k) clearance or PMA approval of new products, new intended uses, or modifications to existing products;
- requesting voluntary rescission of 510(k) clearances or withdrawing PMA approvals 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. 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. The FDA has publicly stated that it is reevaluating its longstanding 510(k) review program. It is not clear when the program will be modified and what effect the modified review process will have on our ability to bring our product candidates to market.

We depend on several single source manufacturers to produce components of our products. Any material adverse changes in our 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 components of our Quell, DPNCheck and SENSUS systems, and to fully manufacture electrodes for the ADVANCE system. In the event that our manufacturers cease to manufacture sufficient quantities of our products or components 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 or components for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. We have a manufacturing and supply agreement with Parlex Polymer Flexible Circuits, Inc. for the manufacture of the ADVANCE electrodes for nerve conduction testing. Katecho, Inc. manufactures biosensors for use with our DPNCheck devices and manufactures electrodes for Quell and SENSUS, and Sunburst EMS, Inc. manufactures electronic boards and other components of our Quell, DPNCheck and SENSUS products which we assemble at our Massachusetts facility to produce completed devices. Moreover, due to the recent commercialization of Quell and the limited amount of our sales to date, other than Katecho, Inc., we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us.

We have experienced transient inventory shortages on new products, including Quell, during the initial production ramp-up phase. If any materially adverse changes in our relationships with these manufacturers occur, 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 product components 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 substantial quantities of components of our products 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.

If we or our manufacturers fail to comply with the FDA's quality system regulation, 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 regulation, or QSR, which is a complex regulation that governs the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces the QSR through periodic inspections. We cannot assure you that our facilities or the facilities of the manufacturers of our products would pass any future inspection. If our facilities or any of the facilities of the manufacturers of our products fail an 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 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 Federal Food, Drug and Cosmetic Act, or FDCA, caused by the device which may present a risk to health. In addition, the FDA and similar governmental agencies 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 and could have a material adverse effect on our financial condition and results of operations.

The success of our business depends upon our ability to advance our pipeline products to commercialization.

We commenced commercialization of Quell in June 2015. We have additional product candidates and enhancements of our existing products in our R&D pipeline. We expect that advancing our pipeline products will require significant time and resources. We may not be successful in our commercialization efforts for any of the product candidates or

product enhancements currently in our pipeline and we may not be successful in developing, acquiring, or in-licensing additional product candidates, to the extent we decide to do so. If we are not successful advancing new products through our development pipeline, the regulatory process and commercial launch, our business, financial condition, and results of operations will be adversely affected.