

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Table of Contents](#)

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2010

OR

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

For the transition period from            to

Commission File Number 001-33351

---

**NEUROMETRIX, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**04-3308180**

(I.R.S. Employer  
Identification No.)

**62 Fourth Avenue, Waltham, Massachusetts**

(Address of principal executive offices,  
including zip code)

**02451**

(Zip Code)

**(781) 890-9989**

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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 definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Smaller reporting company

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 23,098,331 shares of common stock, par value \$0.0001 per share, were outstanding as of November 1, 2010.

---

---

**NeuroMetrix, Inc.**  
**Form 10-Q**  
**Quarterly Period Ended September 30, 2010**

**TABLE OF CONTENTS**

**PART I—FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Financial Statements:</u>	
	<u>Balance Sheets (unaudited) as of September 30, 2010 and December 31, 2009</u>	<u>2</u>
	<u>Statements of Operations (unaudited) for the quarters and nine months ended September 30, 2010 and 2009</u>	<u>3</u>
	<u>Statements of Cash Flows (unaudited) for the nine months ended September 30, 2010 and 2009</u>	<u>4</u>
	<u>Notes to Unaudited Financial Statements</u>	<u>5</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>15</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>27</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>27</u>

**PART II—OTHER INFORMATION**

<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>28</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>28</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>31</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	<u>31</u>
<u>Item 4.</u>	<u>[Removed and Reserved.]</u>	<u>31</u>
<u>Item 5.</u>	<u>Other Information</u>	<u>31</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>31</u>
	<u>Signatures</u>	<u>32</u>

## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements

## NeuroMetrix, Inc.

## Balance Sheets

(Unaudited)

	September 30, 2010	December 31, 2009
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,924,073	\$ 22,937,410
Short-term investments	—	7,495,000
Accounts receivable, net	2,326,369	3,326,331
Inventories	4,500,750	4,559,607
Prepaid expenses and other current assets	745,794	404,716
Current portion of deferred costs	97,077	132,774
Total current assets	<u>26,594,063</u>	<u>38,855,838</u>
Restricted cash	408,000	408,000
Fixed assets, net	698,267	906,625
Intangible assets, net	227,500	280,000
Deferred costs and other long-term assets	56,942	116,057
Total assets	<u>\$ 27,984,772</u>	<u>\$ 40,566,520</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 647,525	\$ 1,086,946
Accrued compensation	959,313	1,369,257
Accrued expenses	1,508,891	1,295,577
Current portion of deferred revenue	521,359	699,775
Current portion of capital lease obligation	37,977	30,357
Total current liabilities	<u>3,675,065</u>	<u>4,481,912</u>
Deferred revenue, net of current portion	226,269	341,513
Capital lease obligation, net of current portion	3,707	33,224
Total liabilities	<u>3,905,041</u>	<u>4,856,649</u>
Commitments and contingencies (Notes 7 and 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, none outstanding	—	—
Common stock, \$0.0001 par value; 50,000,000 shares authorized; 23,098,331 and 22,969,670 shares issued and outstanding at September 30, 2010 and December 31, 2009, respectively	2,310	2,297
Additional paid-in capital	138,473,839	137,420,711
Accumulated deficit	(114,396,418)	(101,713,137)
Total stockholders' equity	<u>24,079,731</u>	<u>35,709,871</u>
Total liabilities and stockholders' equity	<u>\$ 27,984,772</u>	<u>\$ 40,566,520</u>

The accompanying notes are an integral part of these interim financial statements.

## NeuroMetrix, Inc.

## Statements of Operations

(Unaudited)

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
<b>Revenues:</b>				
Medical equipment	\$ 497,942	\$ 725,822	\$ 1,550,976	\$ 2,129,594
Consumables	2,916,393	5,600,129	9,282,228	17,782,354
Total revenues	3,414,335	6,325,951	10,833,204	19,911,948
Cost of revenues	1,347,816	1,826,599	4,049,178	5,701,907
Gross margin	2,066,519	4,499,352	6,784,026	14,210,041
<b>Operating expenses:</b>				
Research and development	1,475,640	1,511,528	4,808,171	4,241,964
Sales and marketing	2,535,810	2,787,942	8,919,631	8,229,550
General and administrative	1,589,723	2,123,845	5,905,376	6,816,078
Total operating expenses	5,601,173	6,423,315	19,633,178	19,287,592
Loss from operations	(3,534,654)	(1,923,963)	(12,849,152)	(5,077,551)
Interest income	13,983	52,217	45,381	188,534
Warrants fair value adjustment	—	(7,391,714)	—	(7,391,714)
Net loss before taxes	(3,520,671)	(9,263,460)	(12,803,771)	(12,280,731)
Income tax benefit	120,490	—	120,490	—
Net loss	\$ (3,400,181)	\$ (9,263,460)	\$ (12,683,281)	\$ (12,280,731)
<b>Per common share data, basic and diluted:</b>				
Net loss	\$ (0.15)	\$ (0.57)	\$ (0.55)	\$ (0.84)
<b>Weighted average number of common shares outstanding, basic and diluted</b>				
	23,038,106	16,223,033	23,028,270	14,700,425

The accompanying notes are an integral part of these interim financial statements.

**NeuroMetrix, Inc.**

**Statements of Cash Flows**

**(Unaudited)**

	Nine Months Ended September 30,	
	2010	2009
<b>Cash flows from operating activities:</b>		
Net loss	\$ (12,683,281)	\$ (12,280,731)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	396,645	444,289
Stock-based compensation	895,171	1,700,712
Warrants fair value adjustment	—	7,391,714
Changes in operating assets and liabilities:		
Accounts receivable	999,962	211,447
Inventories	58,857	713,648
Prepaid expenses and other current assets	(341,078)	(168,677)
Accounts payable	(439,421)	1,058,848
Legal settlement	—	(3,705,866)
Accrued expenses and compensation	(196,630)	104,692
Deferred revenue, deferred costs, and other	(198,848)	(163,046)
Net cash used in operating activities	(11,508,623)	(4,692,970)
<b>Cash flows from investing activities:</b>		
Purchases of investments	—	(7,495,000)
Maturities of investments	7,495,000	4,995,000
Purchases of fixed assets	(135,787)	(236,630)
Purchase of technological and intellectual property	—	(350,000)
Net cash provided by (used in) investing activities	7,359,213	(3,086,630)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock	157,970	17,530,608
Payments on capital lease	(21,897)	(16,246)
Net cash provided by financing activities	136,073	17,514,362
Net (decrease) increase in cash and cash equivalents	(4,013,337)	9,734,762
Cash and cash equivalents, beginning of period	22,937,410	12,302,284
Cash and cash equivalents, end of period	\$ 18,924,073	\$ 22,037,046
<b>Supplemental disclosure of noncash investing activities:</b>		
Warrants issued in securities purchase agreements recorded as a non-current liability (Note 12)	\$ —	\$ 14,496,627

The accompanying notes are an integral part of these interim financial statements.

**NeuroMetrix, Inc.**

**Notes to Unaudited Financial Statements**

**September 30, 2010**

**1. Business and Basis of Presentation**

**Business**

NeuroMetrix, Inc., or the Company, a Delaware corporation, was founded in June 1996. The Company is a science-based health care company transforming patient care through neurotechnology. To date the Company's 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. The Company markets systems for the performance of nerve conduction studies and needle electromyography procedures. The Company's product pipeline includes a rapid, low cost, point-of-care test for diabetic peripheral neuropathy, a nerve localization 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, and devices and pharmaceutical agents to treat peripheral nerve and spinal cord injuries.

The Company believes that its current cash, cash equivalents, and short-term investments, and the cash to be generated from expected product sales will be sufficient to meet its projected operating requirements through 2011. The Company is currently facing significant challenges and uncertainties and, as a result, the Company's available capital resources may be consumed more rapidly than currently expected due to (a) changes in future revenues; (b) changes the Company makes to its ongoing operating expenses; (c) changes in the Company's business strategy; (d) regulatory developments affecting the Company and its products; (e) decisions the Company makes regarding the size of its sales force and the magnitude of its sales and marketing programs; (f) changes the Company makes to research and development spending plans; (g) the outcome of the class action lawsuit against the Company; and (h) other items affecting the Company's forecasted level of expenditures and use of cash resources. Accordingly, the Company may need to raise additional funds to support its operating and capital needs. The Company 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 its operations. However, the Company may not be able to secure such financing on favorable terms, if at all. Without additional funds, the Company may be forced to delay, scale back or eliminate some of its 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 its operations.

**Unaudited Interim Financial Statements**

The accompanying unaudited balance sheet as of September 30, 2010, unaudited statements of operations for the quarters and nine months ended September 30, 2010 and 2009 and the unaudited statements of cash flows for the nine months ended September 30, 2010 and 2009 have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, the financial statements include all normal and recurring adjustments considered necessary for a fair presentation of the Company's financial position and operating results. Operating results for the quarter and nine months ended September 30, 2010 are not necessarily indicative of the

**NeuroMetrix, Inc.**

**Notes to Unaudited Financial Statements (Continued)**

**September 30, 2010**

**1. Business and Basis of Presentation (Continued)**

results that may be expected for the year ending December 31, 2010 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2009 included in the Company's Annual Report on Form 10-K, as filed with the Securities and Exchange Commission, or the SEC, on March 12, 2010 (File No. 001-33351). The accompanying balance sheet as of December 31, 2009 has been derived from audited financial statements prepared at that date, but does not include all disclosures required by accounting principles generally accepted in the United States of America.

**Financial Statements for the Quarter Ended March 31, 2010**

As reported in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2010, filed with the SEC on August 10, 2010, during the second quarter of 2010, the Company identified fraudulent sales transactions involving two sales representatives, resulting in a \$146,333 overstatement of revenues for the quarter ended March 31, 2010. The Company believes that these sales transactions, individually and in the aggregate, are not material to the financial results as reported in previously issued interim financial statements for the quarter ended March 31, 2010. As of and for the quarter ended March 31, 2010, these sales transactions affected the financial statements as follows: an overstatement of revenues of \$146,333; an overstatement of the associated cost of revenue and sales commissions of \$38,078 and \$30,937, respectively; an overstatement of accounts receivable of \$158,239, which includes an overstatement of sales tax payable of \$11,905; an understatement of inventory of \$31,673, net of inventory losses of \$6,405; and an understatement of other current assets of \$32,343 related to an insurance receivable for the associated loss claim less a \$5,000 deductible. There was no impact to total net cash used in operating activities within the statement of cash flows for the quarter ended March 31, 2010.

**Revenues**

Medical equipment revenues consist of sales of the NC-stat and ADVANCE Systems, related modules, and revenues from extended service agreements. Revenues associated with the sale of the NC-stat and ADVANCE devices are recognized upon shipment provided that the fee is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable, and no continuing obligations exist.

The revenues from the sale of an NC-stat docking station, as well as the ADVANCE communication hub together with access to NeuroMetrix information systems are considered one unit of accounting and are deferred and recognized on a straight-line basis over three years, the estimated period of time the Company provides the service associated with the information systems. The resulting deferred revenue and deferred costs are presented as separate line items on the accompanying balance sheet. Revenues related to extended service agreements for the devices are recognized ratably over the term of the extended service agreement.

Consumables revenues consist of sales of single use nerve specific electrodes, EMG needles, and other accessories. Consumables revenues are recognized upon shipment provided that the fee is fixed or determinable, persuasive evidence of an arrangement exists, collection of receivables is reasonably assured, and product returns are reasonably estimable.

**NeuroMetrix, Inc.**

**Notes to Unaudited Financial Statements (Continued)**

**September 30, 2010**

**1. Business and Basis of Presentation (Continued)**

The Company's payment terms extended to customers with traditional payment terms generally require payment within 30 days from invoice date. In addition, from the fourth quarter of 2009 through July 2010, the Company offered extended payment terms of up to one year for new customers placing large dollar value orders for a combination of medical equipment and consumables. Typically these sales involved installment payments in 12 equal monthly amounts. Revenues were recognized upon shipment provided the selling price was fixed or determinable, persuasive evidence of an arrangement existed, delivery had occurred and risk of loss had passed, collection of the resulting receivables was reasonably assured, and product returns were reasonably estimable. In developing parameters for revenue recognition, the Company relied on its historical experience for similar arrangements. During the three and nine months ended September 30, 2010, the Company recognized gross revenue of \$0 and \$1.2 million on sales with extended payment terms, respectively. As of September 30, 2010, accounts receivable, net included \$892,000 of amounts under extended payment terms.

Product sales are made with a 30-day right of return. Because the Company can reasonably estimate future returns, the Company recognizes revenues associated with product sales that contain a right of return upon shipment and at the same time reduces revenue and accounts receivable by the amount of estimated returns.

Proceeds received in advance of product shipment are recorded as deferred revenues.

**Use of Estimates**

The preparation of financial statements in conformity with United States generally accepted accounting principles requires management to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during reporting periods. Actual results could differ from those estimates.

**Recent Accounting Pronouncements**

In September 2009, the Emerging Issues Task Force, or EITF, issued new rules pertaining to the accounting for revenue arrangements with multiple deliverables. The new rules provide an alternative method for establishing fair value of a deliverable when vendor specific objective evidence cannot be determined. The guidance provides for the determination of the best estimate of selling price to separate deliverables and allows the allocation of arrangement consideration using this relative selling price model. The guidance supersedes the prior multiple element revenue arrangement accounting rules that are currently used by the Company. The new guidance can be prospectively applied by us beginning January 1, 2011 or can be early or retrospectively adopted. The Company is currently evaluating the impact of the new rules including the timing of adoption, but it does not believe adoption will have a material effect on its financial statements.

In September 2009, the EITF issued new rules to exclude (a) non-software components of tangible products and (b) software components of tangible products that are sold, licensed, or leased with tangible products when the software components and non-software components of the tangible product function together to deliver the tangible product's essential functionality. The new guidance can be prospectively applied by us beginning January 1, 2011 or can be early or retrospectively adopted. The



**NeuroMetrix, Inc.****Notes to Unaudited Financial Statements (Continued)****September 30, 2010****1. Business and Basis of Presentation (Continued)**

Company is currently evaluating the impact of the new rules including the timing of adoption, but it does not believe adoption will have a material effect on its financial statements.

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06, "Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements" ("ASU 2010-06"). ASU 2010-06 requires new disclosures regarding significant transfers in and out of Levels 1 and 2, as well as information about activity in Level 3 fair value measurements, including presenting information about purchases, sales, issuances, and settlements on a gross versus a net basis in the Level 3 activity roll forward. In addition, ASU 2010-06 also clarifies existing disclosures regarding input and valuation techniques, as well as the level of disaggregation for each class of assets and liabilities. ASU No. 2010-06 is effective for interim and annual periods beginning after December 15, 2009, except for the disclosures pertaining to purchases, sales, issuances, and settlements in the roll forward of Level 3 activity; those disclosures are effective for interim and annual periods beginning after December 15, 2010. The adoption of ASU 2010-06 had no current impact and is expected to have no subsequent impact on the Company's financial statements.

**2. Comprehensive Loss**

For the quarters and nine months ended September 30, 2010 and 2009, the Company had no components of other comprehensive income or loss other than net loss.

**3. Net Loss Per Common Share**

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Unvested restricted shares, although legally issued and outstanding, are not considered outstanding for purposes of calculating basic net income per share. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period plus the dilutive effect of outstanding instruments such as options, warrants, and restricted stock. Because the Company has reported a net loss attributable to common stockholders for all periods presented, diluted loss per common share is the same as basic loss per common share, as the effect of utilizing the fully diluted share count would have reduced the net loss per common share. Therefore, in calculating net loss per share amounts, shares underlying the following potentially dilutive common stock equivalents were excluded from the calculation of diluted net income per common share because their effect was anti-dilutive for each of the periods presented:

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Options	3,470,721	3,162,233	3,428,591	2,986,148
Warrants	8,375,694	2,002,883	8,375,694	674,964
Restricted stock	60,225	—	40,150	—
Total	<u>11,906,640</u>	<u>5,165,116</u>	<u>11,844,435</u>	<u>3,661,112</u>

**NeuroMetrix, Inc.****Notes to Unaudited Financial Statements (Continued)****September 30, 2010****4. Inventories**

Inventories consist of the following:

	<u>September 30,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
Purchased components	\$ 1,417,094	\$ 1,346,267
Finished goods	3,083,656	3,213,340
	<u>\$ 4,500,750</u>	<u>\$ 4,559,607</u>

**5. Intangible Assets**

In January 2009, the Company acquired certain technological and intellectual property assets from Cyberkinetics Neurotechnology Systems, Inc., or Cyberkinetics, and Andara Life Science, Inc., a wholly-owned subsidiary of Cyberkinetics, for \$350,000 in cash. The Company is amortizing these intangible assets using the straight-line method over their economic lives, which is estimated to be five years. Research and development expenses for the quarters ended September 30, 2010 and 2009 each included amortization of this technological and intellectual property of \$17,500. Research and development expenses for the nine months ended September 30, 2010 and 2009 each included \$52,500 of such amortization. Accumulated amortization on these intangible assets at September 30, 2010 was \$122,500.

The estimated future amortization expense for intangible assets as of September 30, 2010 is as follows:

	<u>Estimated</u> <u>Amortization</u> <u>Expense</u>
2010 (remaining three months)	\$ 17,500
2011	70,000
2012	70,000
2013	70,000
	<u>\$ 227,500</u>

## NeuroMetrix, Inc.

## Notes to Unaudited Financial Statements (Continued)

September 30, 2010

## 6. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2010	December 31, 2009
Customer credits, net	\$ 449,704	\$ 306,251
Professional services	369,646	488,191
License fee	187,500	—
Research and development purchase commitments	135,000	—
Travel and entertainment costs	77,500	77,550
Sales taxes	76,229	191,601
Other	213,312	231,984
	<u>\$ 1,508,891</u>	<u>\$ 1,295,577</u>

*Product Warranty Costs*

The Company accrues estimated product warranty costs at the time of sale which are included in cost of sales in the statements of operations. The amount of the accrued warranty liability is based on historical information such as past experience, product failure rates, number of units repaired, and estimated cost of material and labor. The liability for product warranty costs is included in accrued expenses in the balance sheet.

The following is a roll forward of the Company's accrued warranty liability for the quarters and nine months ended September 30, 2010 and 2009:

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
Balance at beginning of period	\$ 47,586	\$ 54,505	\$ 48,355	\$ 136,170
Accrual for warranties	1,638	2,560	4,209	7,322
Settlements made	(1,827)	(6,604)	(5,167)	(93,031)
Balance at end of period	<u>\$ 47,397</u>	<u>\$ 50,461</u>	<u>\$ 47,397</u>	<u>\$ 50,461</u>

## 7. Commitments and Contingencies

*Operating Lease*

The Company leases office and engineering laboratory space in Waltham, Massachusetts. The lease term extends through March 31, 2013. Base rent for the period April 2010 through March 2013 ranges from \$705,000 to \$765,000 on an annualized basis.

## NeuroMetrix, Inc.

## Notes to Unaudited Financial Statements (Continued)

September 30, 2010

## 7. Commitments and Contingencies (Continued)

Future minimum lease payments under noncancelable operating leases as of September 30, 2010 are as follows:

2010 (remaining three months)	\$ 176,250
2011	727,500
2012	757,500
2013	191,250
Total minimum lease payments	<u>\$ 1,852,500</u>

## 8. Fair Value Measurements

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis for the periods presented and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates, and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability.

	September 30, 2010	Fair Value Measurements at September 30, 2010 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 14,507,542	\$ 14,507,542	\$ —	\$ —
Total	<u>\$ 14,507,542</u>	<u>\$ 14,507,542</u>	<u>\$ —</u>	<u>\$ —</u>

	December 31, 2009	Fair Value Measurements at December 31, 2009 Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	\$ 22,223,503	\$ 22,223,503	\$ —	\$ —
Total	<u>\$ 22,223,503</u>	<u>\$ 22,223,503</u>	<u>\$ —</u>	<u>\$ —</u>

**NeuroMetrix, Inc.**

**Notes to Unaudited Financial Statements (Continued)**

**September 30, 2010**

**9. Legal Matters**

As previously disclosed in the Company's filings with the SEC, on March 17, 2008, a putative securities class action complaint was filed in the United States District Court for the District of Massachusetts against the Company and certain of its current and former officers. On March 27, 2008, a related putative securities class action complaint was filed in the same court, against the same defendants. These two actions were subsequently consolidated, and the court appointed a lead plaintiff. On November 10, 2008, a consolidated amended class action complaint was filed, which alleged, among other things, that between October 27, 2005 and February 12, 2008, the defendants violated the federal securities laws by allegedly making false and misleading statements and failing to disclose material information to the investing public. The plaintiffs sought unspecified damages. On January 30, 2009, the Company filed a motion to dismiss the consolidated amended complaint on the grounds, among others, that it failed to state a claim on which relief can be granted. On December 8, 2009, the Court entered an order granting defendants' motion to dismiss and dismissing the consolidated amended complaint in its entirety with prejudice. The plaintiffs filed a notice of appeal with the United States Court of Appeals for the First Circuit on January 6, 2010. Oral arguments on the plaintiffs' appeal were conducted on September 15, 2010. The appeal is currently pending.

The litigation process is inherently uncertain, and the Company cannot guarantee that the outcome of the above lawsuit will be favorable for the Company or that it will not be material to its business, results of operations, or financial position. However, the Company does not believe that a loss is probable related to this litigation. Accordingly, no accrual has been recorded relating to this matter at September 30, 2010.

As previously disclosed in the Company's filings with the SEC, on April 22, 2008, a shareholder derivative action was filed in the United States District Court for the District of Massachusetts against a number of the Company's current and former directors and officers. On December 10, 2008, a verified amended shareholder derivative complaint was filed, alleging, among other things, that, between August 2004 and the date the action was filed, the defendants breached various fiduciary duties to the Company based on conduct similar to that alleged in the putative securities class actions, including that the defendants caused the Company to make false and misleading statements, to fail to disclose material information to the public and to engage in improper business practices. The plaintiff sought various forms of monetary and non-monetary relief. The parties reached an agreement to resolve the shareholder derivative action, subject to Court approval, and executed a formal stipulation of settlement on December 21, 2009. On February 23, 2010, the Court entered an order approving the parties' settlement and entered a judgment dismissing the case in its entirety, with prejudice. In conjunction with the settlement, the Company's insurance carrier paid directly to third parties \$350,000 for the plaintiff's counsel's attorneys fees and reimbursement of expenses. No payment was required by the Company.

**10. Credit Facility**

On March 5, 2010, the Company entered into a Loan and Security Agreement, or the Credit Facility, with Comerica Bank, which permits it to borrow up to \$7.5 million on a revolving basis for a one-year term. Amounts borrowed under the Credit Facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the Credit Facility will be secured by the Company's cash, accounts receivable, inventory, and equipment. The Company had not borrowed any funds under the Credit

**NeuroMetrix, Inc.**

**Notes to Unaudited Financial Statements (Continued)**

**September 30, 2010**

**10. Credit Facility (Continued)**

Facility as of September 30, 2010 and is in compliance with the tangible net worth covenant of the Credit Facility.

**11. Workforce Reduction**

During the third quarter of 2010, the Company implemented a reduction in workforce that resulted in the elimination of 25 positions, representing approximately 25% of its workforce, as well as other cost savings initiatives. During the third quarter of 2010, the Company recorded a charge of \$172,000 in connection with this matter, primarily related to severance expenses. The full amount of the charge was paid as of September 30, 2010.

**12. Equity**

On September 8, 2009, the Company entered into securities purchase agreements in connection with a private placement of its securities to certain institutional and other accredited investors pursuant to which the Company agreed to sell and issue (i) an aggregate of 8,816,521 newly issued shares of its common stock, par value \$0.0001 per share and (ii) warrants to purchase an aggregate of 8,375,694 shares of common stock. The sale of securities resulted in aggregate gross proceeds of approximately \$18.7 million. The net proceeds, after deducting offering expenses (including fees to the placement agent and co-agent), were approximately \$17.3 million. In addition, the placement agents were issued warrants to purchase an aggregate of 207,188 shares of common stock. The placement agents' warrants are in the same form as those issued to participants in the private placement but the shares acquired upon exercise are not entitled to registration rights.

The common stock and warrants were sold as a unit for a price of \$2.12. Currently, the warrants are exercisable at any time 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. 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, to the extent the warrants are not assumed by the acquiring entity, the holder could elect to receive, subject to certain limitations and assumptions, cash equal to the Black-Scholes value of the outstanding warrants.

The warrants issued in connection with the private offering are within the scope of the Distinguishing Liabilities from Equity Topic of the Codification. This Codification topic requires issuers to classify as liabilities (or assets under certain circumstances) free-standing financial instruments which, at inception, require or may require an issuer to settle an obligation by transferring assets. Accordingly, the Company reflected these warrants as a liability in the Balance Sheet as of September 30, 2009. The fair value of the warrants at the issuance date was estimated using the Black-Scholes model. The

**NeuroMetrix, Inc.**

**Notes to Unaudited Financial Statements (Continued)**

**September 30, 2010**

**12. Equity (Continued)**

estimated fair value of the warrants, including the warrants issued to the placement agents, was \$14.5 million on the date of issuance and was recorded as a reduction of additional paid-in capital. In addition, the warrants were revalued at September 30, 2009 using the Black-Scholes model and the change in the fair value of the warrants was recognized in the warrants fair value adjustment line item in the Company's consolidated statement of operations.

At September 30, 2009, the estimated fair value of the warrants increased to \$21.9 million and was presented as a long term liability in the Company's balance sheet as of that date. The increase in the fair value of the warrants from the date of issuance to September 30, 2009 required the Company to record an increase in the value of the liability of \$7.4 million.

In October 2009, the Company executed addendums to the warrants issued in connection with the securities purchase agreements of September 8, 2009. The addendums revised the rights of warrant holders such that upon a change in control, as defined, the warrant holders will receive the Black-Scholes value of the warrants in the same currency and same proportions as will be received by the common stockholders of the Company, thereby removing the criteria in the agreements that required liability classification of the warrants. Following the addendums, the warrant liability was revalued at fair value resulting in a \$2.2 million credit to warrants fair value adjustment that was recorded in the Statement of Operations in October 2009. The remaining liability for common stock warrants of \$19.7 million was then reclassified to additional paid-in capital.

**13. Income Taxes**

The Company recorded a \$120,490 Federal income tax benefit in the quarter ended September 30, 2010 attributable to an election it made in the third quarter of 2010 under recent legislation that allowed net operating losses to offset 100% of alternative minimum tax ("AMT"). Prior to this legislation, only 90% of AMT could be offset by net operating losses. The Company received a full refund of \$120,490 in October 2010.

**14. Subsequent Event**

The Company had submitted a Federal grant proposal to fund costs related to a precision targeted therapeutic delivery system for peripheral nerve indications. On November 1, 2010, the Company received notification that it had been approved for a grant of \$244,479 from the Internal Revenue Service. The Company expects to receive the grant funding during November 2010.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and the accompanying notes to those financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. For a description of factors that may cause our actual results to differ materially from those anticipated in these forward-looking statements, please refer to the below section of this Quarterly Report on Form 10-Q titled "Cautionary Note Regarding Forward-Looking Statements." Unless the context otherwise requires, all references to "we", "us", the "Company", or "NeuroMetrix" in this Quarterly Report on Form 10-Q refer to NeuroMetrix, Inc.*

### Overview

NeuroMetrix was founded in June 1996. NeuroMetrix is a science-based health care company transforming patient care through neurotechnology. 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 rapid, low cost, point-of-care test for diabetic peripheral neuropathy, a nerve localization 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, and devices and pharmaceutical agents to treat peripheral nerve and spinal cord injuries.

We currently market and sell a medical device cleared by the United States Food and Drug Administration, or FDA, which is used for the assessment of neuropathies. Our ADVANCE™ NCS/EMG System, or the ADVANCE System, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. We are currently focusing our sales efforts for the ADVANCE System on physician offices and clinics, as well as specialist physicians with peripheral nerve expertise, including neurologists, physical medicine and rehabilitation physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians. Our ADVANCE System is comprised of: (1) various types of electrodes and needles, (2) our ADVANCE device and related modules, and (3) a communication hub that enables the physician's office to network their device to our servers for data archiving, report generation, and other network services. We sold a different device, the NC-stat System, to a broad group of physicians from its initial market launch in May 1999 through September 2010. Our NC-stat System is also a point-of-care device for the performance of nerve conduction studies. We replaced NC-stat in the physician office marketplace with the ADVANCE System in the fourth quarter of 2010. Our neurodiagnostic equipment is used in over 4,000 physicians' offices, clinics, and hospitals. Approximately 1.5 million patient studies have been performed with our neurodiagnostic devices since 1999.

We are continuing our efforts to bring clarity to physician reimbursement for medically appropriate nerve conduction studies using pre-configured electrodes. We believe that consistent and adequate physician reimbursement for nerve conduction studies performed using pre-configured electrodes is essential to our efforts to build our U.S. business and thereby deliver the significant clinical benefits of this technology to patients. A significant, positive step was taken on reimbursement in the fourth quarter of 2009 when the Centers for Medicare & Medicaid Services, or CMS published a new Category I CPT code (95905), or CPT code 95905, in the 2010 Physician's Fee Schedule for nerve conduction studies performed with preconfigured electrodes. Therefore, we believe that this CPT code may streamline Medicare reimbursement for medically appropriate nerve conduction studies performed using our pre-configured electrodes. This is an important development because we believe the assignment of this code reaffirms the clinical utility of our pre-configured electrodes and supports their use by physician offices and internal medicine specialists when medically appropriate. As for any new



CPT code, broad adoption by physicians will take time and may have some challenges. However, we believe that physicians using pre-configured electrodes will find this new code useful and supportive of their efforts to deliver optimal and efficient patient care.

Unlike pre-existing Medicare nerve conduction study codes, but similar to many other diagnostic procedures, CPT code 95905 is billed per limb tested as opposed to per nerve. Although practice patterns will vary, we believe that fewer units of CPT code 95905 will generally be billed per patient than under the pre-existing nerve conduction study codes. Lower physician reimbursement under CPT code 95905 can affect testing patterns, and has, and in the near term will continue to put downward pressure on our revenues and margins. It is difficult to predict adoption and utilization of this new CPT code in the near term as there are many factors in play. Over time, however, we believe the new CPT code may have a positive influence on reimbursement by commercial insurers. We believe that ultimately the effect of the CPT code on revenues will be positive and will allow us to increase revenues over time. In the meantime, we anticipate an ongoing period of readjustment that could span several quarters or perhaps longer.

We see a significant opportunity to expand utilization of our nerve testing technology in individuals with diabetes. Currently about 25 percent of the tests performed with our neurodiagnostic devices are targeted at diagnosis of large fiber diabetic peripheral neuropathy, or DPN, in patients exhibiting clinical symptoms of that condition. Nerve conduction studies, or NCS, are the gold standard for diagnosis of DPN; however, cost and limited access have prevented utilization of NCS for wide spread screening which is essential for early detection of DPN and prevention of its complications, such as foot ulcers. We believe that a rapid, low cost, point-of-care test for DPN represents an attractive U.S. and international market opportunity. We have made development of a low cost version of NC-stat and a low cost disposable electrode for this application, an R&D priority. Assuming that we reach our project milestones, we believe we have the capability to launch this product in the U.S. and several international markets in the second half of 2011.

ASCEND, another device under development, is being designed to precisely deliver pharmacologic agents such as anesthetics and corticosteroids in close proximity to nerves for regional anesthesia, pain control, and the treatment of focal neuropathies such as carpal tunnel syndrome will be de-emphasized in the near term which will postpone completion of its development and the regulatory process leading to product launch. We had submitted a Federal grant proposal to fund costs associated with the development of ASCEND. On November 1, 2010, we received notification that we had been approved for a grant of \$244,500 from the Internal Revenue Service. We expect to receive the grant funding during November 2010. At this time we are not able to forecast the timing for commercial launch of ASCEND.

Within our pipeline of pharmacologic compounds for neural conduction enhancement, we are developing our lead compound, NM101, for use in chronic spinal cord injury. We are presently performing the pre-clinical work required to file an investigational new drug application with the FDA and we plan to continue to advance the compound at a low level of funding through pre-clinical testing as we evaluate strategic options.

Andara is our implantable stimulator for spinal nerve repair. The FDA provided us with greater clarity on the clinical requirements for approval of this product. Our next step would be to design and conduct a clinical trial targeting the same safety and efficacy endpoints as the original study conducted by us but with a larger sample size. However, this project is currently on hold as we focus our resources on our other pipeline products.

## **Recent Developments**

In our nerve testing business, we recognize that our products need broader market exposure for growth. We have recently sold our nerve testing products to new customers in the U.S. physician office market through a direct sales force. We are in the process of supplementing our direct sales force with independent sales representatives. Our direct sales force is a core team of fifteen representatives assigned to key market areas, while the independent representatives are recruited to cover the remaining geography. In total, we plan to have about 40 sales territories. For the orthopedic and specialty markets now covered by our sales force, we are shifting our focus to regional distributors to expand coverage. We anticipate that this transition to a hybrid direct/distribution sales model will continue through the fourth quarter of 2010. Our goal is to have about 100 sales representatives handling our nerve testing products. After-sale support for all of our new and existing customers will continue to be provided by our team of field-based clinical educators.

We launched our ADVANCE System into the Physician Office market in October 2010. The ADVANCE System includes new customization features which we believe improve physician utility. We have introduced an equipment rental program to encourage adoption. Our field clinical educators and customer service representatives are offering incentives to our installed base of NC-stat System users to migrate to the ADVANCE System.

We continue to work with reimbursement experts to expand the number of commercial insurance companies providing reimbursement to physicians for nerve conduction testing with our technology. Our efforts to expand reimbursement have been met with resistance and our progress this year has been slow. We believe that commercial insurers are reluctant to add coverage for diagnostic testing, particularly by physician offices, in many medical areas. While we continue these efforts, the near-term prospects of a significant improvement in coverage by commercial insurers are not favorable. We are encouraging physicians to implement advance beneficiary notices (ABN) where they believe that nerve conduction study may not be covered by commercial carriers. The cost to patients under an ABN of a nerve conduction study using our technology may be less than outside referral for the study, even if reimbursed, due to co-pays and other ancillary expenses.

In order to resource our product and sales initiatives, and to conserve operating funds, we implemented a reduction in workforce in July 2010 that resulted in the elimination of approximately 25 percent of our workforce, as well as other cost savings initiatives. We estimate that this should reduce our annual spending by approximately \$2.5 million. During the third quarter of 2010, we recorded a charge of \$172,000 in connection with this matter, primarily related to severance expenses.

## **Overall Outlook**

We believe that today's health care environment continues to be characterized by uncertainty. Our customers face a range of challenges including changes in reimbursement, declining patient visits, and uncertainty arising from national health care reform. These factors have resulted in downward pressure on our revenues and margins. However, through our strategy of expanded product exposure through a hybrid direct/distributor sales model, targeted focus on the ADVANCE System, and our field based team of clinical educators, we have an opportunity to reinvigorate the business and expand our installed base of customers.

**Results of Operations****Comparison of Quarters Ended September 30, 2010 and 2009***Revenues*

The following table presents a historical view of our active customers and studies performed:

	Year Ended December 31, 2010			Year Ended December 31, 2009	
	Third Quarter	Second Quarter	First Quarter	Fourth Quarter	Third Quarter
Installed base (active testing accounts)	4,044	4,167	4,309	4,493	4,660
Patient studies	32,064	34,638	36,529	35,649	39,143

The following table summarizes our revenues from medical equipment and consumables:

	Quarter Ended September 30,		Change	% Change
	2010	2009		
	(\$ in thousands)			
Revenues:				
Medical equipment	\$ 497.9	\$ 725.8	\$ (227.9)	(31.4)%
Consumables	2,916.4	5,600.1	(2,683.7)	(47.9)
Total revenues	<u>\$ 3,414.3</u>	<u>\$ 6,325.9</u>	<u>\$ (2,911.6)</u>	(46.0)

Revenues in the quarter ended September 30, 2010 reflect the introduction of Medicare CPT code 95905, which was published by the CMS in the fourth quarter of 2009, as well as continued reimbursement uncertainty with commercial insurers. Medicare CPT code 95905 addresses nerve conduction studies performed with pre-configured electrode arrays such as those used with the NC-stat device. The new code both defines nerve test procedures and assigns values on a different basis than pre-existing codes. The net result is lower physician reimbursement per nerve study which has had a negative impact on our revenues.

Medical equipment revenues, consisting of sales of the NC-stat and ADVANCE devices, related modules, and revenues from extended service agreements, were \$497,900 and \$725,800 for the quarters ended September 30, 2010 and 2009, respectively, a decrease of \$227,900, or 31.4%. This decrease primarily reflects lower average selling price, or ASP, on system shipments in the third quarter of 2010 compared to the third quarter of 2009. We shipped 75 NC-stat and ADVANCE devices, net, to new customers during the third quarter of 2010 compared with 65 NC-stat and ADVANCE devices, net, shipped to new customers during the third quarter of 2009. In addition, during the third quarter of 2010, we shipped 10 ADVANCE devices to international distributors, compared to 32 ADVANCE devices shipped to international distributors in the third quarter of 2009. Medical equipment revenue reflects the proportional allocation of revenue among multiple products included on customer invoices. Excluding this proportional allocation, medical equipment ASP in the third quarter of 2010 was about \$1,900 compared to about \$3,500 in the third quarter of 2009.

Consumables revenues, consisting of single use nerve specific electrodes, which are used with our NC-stat System and our ADVANCE System, and EMG needles, which are used with our ADVANCE System, were \$2.9 million and \$5.6 million for the quarters ended September 30, 2010 and 2009, respectively, a decrease of \$2.7 million, or 47.9%. Three primary factors contributed to the decline between the third quarter of 2009 and the third quarter of 2010: our installed base of customers contracted by 13.2%; patient studies contracted by 18.1%; and our electrode ASP declined by 23.0% from \$35.41 in the quarter ended September 30, 2009 to \$27.26 during the same period in 2010.

*Cost of Revenues and Gross Margin*

The following table summarizes our cost of revenues and gross margin:

	Quarter Ended September 30,		Change	% Change
	2010	2009 (in thousands)		
Cost of revenues	\$ 1,347.8	\$ 1,826.6	\$ (478.8)	(26.2)%
Gross margin	\$ 2,066.5	\$ 4,499.4	\$ (2,432.9)	(54.1)

Our cost of revenues was \$1.3 million, or 39.5% of revenues, for the quarter ended September 30, 2010, compared to \$1.8 million, or 28.9% of revenues, for the same period in 2009. The decrease of \$478,800 in cost of revenues was due primarily to lower shipment volume, partially offset by \$187,000 in inventory obsolescence charges arising from the transition from the NC-stat System to the ADVANCE System in the physician office market. Our gross margin percentage of 60.5% of revenues for the quarter ended September 30, 2010 decreased from 71.1% of revenues for the same period in 2009. The lower gross margin percentage in the third quarter of 2010 resulted primarily from a 23.0% decline in electrode ASP compared with the third quarter of 2009 and the NC-stat inventory obsolescence charge of \$187,000.

We believe that our gross margin in the fourth quarter of 2010 should be in the range of 60-63%. In the first half of 2011, we anticipate that our gross margins will be reduced into the range of 55-60% due to higher purchased electrode costs flowing through cost of sales resulting from reduced electrode purchasing volumes as we work to better manage our electrode inventory and working capital.

*Operating Expenses*

The following table presents a breakdown of our operating expenses:

	Quarter Ended September 30,		Change	% Change
	2010	2009 (in thousands)		
Operating expenses:				
Research and development	\$ 1,475.7	\$ 1,511.5	\$ (35.8)	(2.4)%
Sales and marketing	2,535.8	2,787.9	(252.1)	(9.0)
General and administrative	1,589.7	2,123.9	(534.2)	(25.1)
Total operating expenses	\$ 5,601.2	\$ 6,423.3	\$ (822.1)	(12.8)

*Research and Development*

Research and development expenses decreased by \$36,000 in the quarter ended September 30, 2010 in comparison with the quarter ended September 30, 2009. The comparative results for the third quarter of 2010 included a \$174,000 decrease in consulting and outside services costs and a \$103,000 decrease in stock-based compensation, largely offset by \$251,000 in charges for expensed materials relating to the development of new products and other spending on supplies.

*Sales and Marketing*

Sales and marketing expenses decreased to \$2.5 million for the quarter ended September 30, 2010 from \$2.8 million for the quarter ended September 30, 2009. The decrease resulted largely from a \$106,000 decrease in personnel costs, largely attributable to the July 2010 reduction in workforce, a

\$98,000 decrease in stock-based compensation, and a \$74,000 decrease in consulting and outside services costs.

#### *General and Administrative*

General and administrative expenses decreased to \$1.6 million for the quarter ended September 30, 2010 from \$2.1 million for the quarter ended September 30, 2009. This decrease included a \$138,000 decrease in insurance costs, a \$128,000 decrease in consulting and outside services costs, a \$108,000 decrease in personnel costs, largely attributable to the July 2010 reduction in workforce, a \$57,000 decrease in recruiting costs, and a \$42,000 decrease in stock-based compensation.

Looking forward to the fourth quarter of 2010, we anticipate that total operating expenses may be slightly higher, into the range of \$5.8 to \$6.2 million, largely reflecting costs of development and marketing efforts associated with the NC-stat SL and increased year end general and administrative costs.

#### *Interest Income*

Interest income was \$14,000 and \$52,000 for the quarters ended September 30, 2010 and 2009, respectively. Interest income was earned from investments in cash equivalents and short-term investments. The decrease in interest income for the quarter ended September 30, 2010, as compared to the same period in 2009, reflects lower rates of return and a shift to higher quality, shorter duration, investments.

#### *Warrants Fair Value Adjustment*

Warrants fair value adjustment was a charge required to adjust the liability for outstanding warrants to fair value as of September 30, 2009. The fair value of the warrants issued in the September 2009 equity financing was \$14.5 million on the closing date and was recorded as a liability. At September 30, 2009, the warrant liability was revalued to a fair value of \$21.9 million. The \$7.4 million increase in the warrants liability was recorded in "warrant fair value adjustment" in the Statement of Operations for the quarter ended September 30, 2009.

In October 2009, the Company executed addendums to the warrants issued in connection with the securities purchase agreements of September 8, 2009. The addendums revised the rights of warrant holders such that upon a change in control the warrant holders will receive the Black-Scholes value of the warrants in the same currency and same proportions as will be received by the common stockholders of the Company. Following the addendums, the warrant obligation was revalued at fair value resulting in a \$2.2 million credit to warrants fair value adjustment that was recorded in the Statement of Operations in October 2009. The remaining liability for common stock warrants of \$19.7 million was then reclassified to additional paid-in capital.

**Comparison of Nine Months Ended September 30, 2010 and 2009***Revenues*

The following table summarizes our revenues from medical equipment and consumables:

	<b>Nine Months Ended September 30,</b>		<b>Change</b>	<b>% Change</b>
	<b>2010</b>	<b>2009</b>		
	(\$ in thousands)			
<b>Revenues:</b>				
Medical equipment	\$ 1,551.0	\$ 2,129.6	\$ (578.6)	(27.2)%
Consumables	9,282.2	17,782.3	(8,500.1)	(47.8)
Total revenues	<u>\$ 10,833.2</u>	<u>\$ 19,911.9</u>	<u>\$ (9,078.7)</u>	(45.6)

Revenues in the nine months ended September 30, 2010 reflect the introduction of Medicare CPT code 95905, which was published by the CMS in the fourth quarter of 2009, as well as continued reimbursement uncertainty with commercial insurers. Medicare CPT code 95905 addresses nerve conduction studies performed with pre-configured electrode arrays such as those used with the NC-stat device. The new code both defines nerve test procedures and assigns values on a different basis than pre-existing codes. The net result is lower physician reimbursement per nerve study which has had a negative impact on our revenues.

Medical equipment revenues, consisting of sales of the NC-stat and ADVANCE devices, related modules, and revenues from extended service agreements, were \$1.6 million and \$2.1 million for the nine months ended September 30, 2010 and 2009, respectively, a decrease of \$578,600, or 27.2%. This decrease reflects lower average selling price, or ASP, on system shipments in the first nine months of 2010 compared to the first nine months of 2009. We shipped 220 NC-stat and ADVANCE devices, net, to new customers during the first nine months of 2010 compared with 212 devices, net, shipped to new customers during the first nine months of 2009. In addition, during the first nine months of 2010, we sold 17 ADVANCE devices to international distributors, compared to 32 ADVANCE devices sold to international distributors in the first nine months of 2009. Medical equipment revenue reflects a proportional allocation of invoice amounts where there are multiple deliverables. Excluding this allocation, medical equipment ASP in the first nine months of 2010 was about \$2,300 compared to about \$4,200 in the first nine months of 2009.

Consumables revenues, consisting of single use nerve specific electrodes, which are used with our NC-stat System and our ADVANCE System, and EMG needles, which are used with our ADVANCE System, were \$9.3 million and \$17.8 million for the nine months ended September 30, 2010 and 2009, respectively, a decrease of \$8.5 million, or 47.8%. Three primary factors contributed to the decline between the first nine months of 2009 and the first nine months of 2010: our installed base of customers contracted by 13.2%; patient studies contracted by 17.8%; and our electrode ASP declined by 22.0% from \$35.44 for the nine months ended September 30, 2009 to \$27.63 for the nine months ended September 30, 2010.

*Cost of Revenues and Gross Margin*

The following table summarizes our cost of revenues and gross margin:

	Nine Months Ended September 30,		Change	% Change
	2010	2009 (in thousands)		
Cost of revenues	\$ 4,049.2	\$ 5,701.9	\$ (1,652.7)	(29.0)%
Gross margin	\$ 6,784.0	\$ 14,210.0	\$ (7,426.0)	(52.3)

Our cost of revenues was \$4.0 million, or 37.4% of revenues, for the nine months ended September 30, 2010, compared to \$5.7 million, or 28.6% of revenues for the same period in 2009. The decrease of \$1.7 million in cost of revenues was due to lower shipment volume. Our gross margin percentage of 62.6% of revenues for the nine months ended September 30, 2010 decreased from 71.4% of revenues for the same period in 2009. The lower gross margin percentage in the first nine months of 2010 resulted primarily from a 22.0% decline in electrode ASP compared with the first nine months of 2009.

We believe that our gross margin in the fourth quarter of 2010 should be in the range of 60-63%. In the first half of 2011, we anticipate that our gross margins will be reduced into the range of 55-60% due to higher purchased electrode costs flowing through cost of sales resulting from reduced electrode purchasing volumes as we work to better manage our electrode inventory and working capital.

*Operating Expenses*

The following table presents a breakdown of our operating expenses:

	Nine Months Ended September 30,		Change	% Change
	2010	2009 (in thousands)		
Operating expenses:				
Research and development	\$ 4,808.2	\$ 4,242.0	\$ 566.2	13.3%
Sales and marketing	8,919.6	8,229.5	690.1	8.4
General and administrative	5,905.4	6,816.1	(910.7)	(13.4)
Total operating expenses	\$ 19,633.2	\$ 19,287.6	\$ 345.6	1.8

*Research and Development*

Research and development expenses for the nine months ended September 30, 2010 and 2009 were \$4.8 million and \$4.2 million, respectively. The comparative results for the first nine months of 2010 included increases of \$455,000 in expensed materials relating to the development of new products, \$288,000 for license maintenance fees, and \$273,000 for personnel related costs, which were partially offset by a \$304,000 decrease in stock-based compensation, a \$70,000 decrease in professional fees, and a \$69,000 decrease in supplies cost.

*Sales and Marketing*

Sales and marketing expenses increased to \$8.9 million for the nine months ended September 30, 2010 from \$8.2 million for the nine months ended September 30, 2009. This increase mainly resulted from a \$745,000 increase in compensation and related costs resulting from the addition of international sales staff, which increased costs by \$424,000, and the addition of a team of field clinical educators

which increased costs by \$1.0 million, partially offset by reduced costs resulting from a reduction in the size of our direct sales force as we migrate to a hybrid direct/distributor sales model.

#### *General and Administrative*

General and administrative expenses decreased to \$5.9 million for the nine months ended September 30, 2010 from \$6.8 million for the nine months ended September 30, 2009. This decrease consisted of reductions of \$278,000 for consulting and outside services costs, \$216,000 for legal fees, \$177,000 for insurance costs, \$144,000 for personnel costs, and \$97,000 for credit payment fees, partially offset by an increase of \$97,000 in taxes, licenses, and fees and an increase of \$94,000 in bad debts expense.

#### *Interest Income*

Interest income was \$45,000 and \$189,000 for the nine months ended September 30, 2010 and 2009, respectively. Interest income was earned from investments in cash equivalents and short-term investments. The decrease in interest income for the nine months ended September 30, 2010, as compared to the same period a year ago reflects lower rates of return and a shift to higher quality, shorter duration investments.

#### *Warrants Fair Value Adjustment*

Warrants fair value adjustment was a charge required to adjust the liability for outstanding warrants to fair value as of September 30, 2009. The fair value of the warrants issued in the September 2009 equity financing was \$14.5 million on the closing date and was recorded as a liability. At September 30, 2009, the warrant liability was revalued to a fair value of \$21.9 million. The \$7.4 million increase in the warrants liability was recorded in "warrant fair value adjustment" in the Statement of Operations for the quarter ended September 30, 2009.

In October 2009, the Company executed addendums to the warrants issued in connection with the securities purchase agreements of September 8, 2009. The addendums revised the rights of warrant holders such that upon a change in control, as defined, the warrant holders will receive the Black-Scholes value of the warrants in the same currency and same proportions as will be received by the common stockholders of the Company. Following the addendums, the warrant obligation was revalued at fair value resulting in a \$2.2 million credit to warrants fair value adjustment that was recorded in the Statement of Operations in October 2009. The remaining liability for common stock warrants of \$19.7 million was then reclassified to additional paid-in capital.

#### **Liquidity and Capital Resources**

Our principal source of liquidity is our cash and cash equivalents, which we are investing in money market funds. As of September 30, 2010, these totaled \$18.9 million. Our ability to generate cash from operations is dependent upon our ability to generate revenue from sales of our products, as well as our ability to manage our operating costs and net assets. However, there is no assurance we will be successful in increasing our revenue. A further decrease in demand for our products or unanticipated increases in our operating costs would likely have an adverse effect on our liquidity and cash generated from operations.



We have filed with the SEC an equity shelf registration statement in the amount of \$50 million, which allows us to issue equity securities during a three year period through the first quarter of 2013, subject to limitations on smaller reporting companies regarding the amount of securities that may be sold in a given period. In addition, we have a Credit Facility under which we may borrow up to \$7.5 million on a revolving basis tied to cash and eligible accounts receivable. The credit facility has a one year term ending in the first quarter of 2011. The Credit Facility is discussed in more detail in the section below titled "Off-Balance Sheet Arrangements, Contractual Obligations and Contingent Liabilities and Commitments."

The following table sets forth information relating to our liquidity:

	<u>September 30,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>	<u>Change</u>	<u>% Change</u>
		(\$ in thousands)		
Cash and cash equivalents	\$ 18,924.1	\$ 22,937.4	\$ (4,013.3)	(17.5)%
Short-term held-to-maturity investments	—	7,495.0	(7,495.0)	(100.0)
Total cash, cash equivalents, and short-term held-to-maturity investments	<u>\$ 18,924.1</u>	<u>\$ 30,432.4</u>	<u>\$ (11,508.3)</u>	<u>(37.8)</u>

During the first nine months of 2010, our cash, cash equivalents, and short-term investments decreased by \$11.5 million, primarily due to net cash used in operating activities.

In managing our working capital, two of the financial measurements we monitor are days sales outstanding, or DSO, and inventory turnover rate, which are presented in the table below for the quarters ended September 30, 2010 and 2009, and the year ended December 31, 2009:

	<u>Quarter Ended</u> <u>September 30,</u>		<u>Year Ended</u> <u>December 31,</u>
	<u>2010</u>	<u>2009</u>	<u>2009</u>
Days sales outstanding (days)*	40	47	44
Inventory turnover rate (times per year)	1.2	1.5	1.5

\* Accounts with traditional payment terms.

In addition to receivables with traditional payment terms, we offered extended payment terms on initial, high value purchases by new customers from the fourth quarter of 2009 through July 2010. Typically these sales involved installment payments in 12 equal monthly amounts. As of September 30, 2010, there were net accounts receivable of \$892,000 with extended payment terms, which are excluded from the traditional DSO calculation. As of December 31, 2009, there were \$442,000 of such net accounts receivable.

Our inventory turnover rate for the quarter ended September 30, 2010 was 1.2 times per year, compared with 1.5 times per year for the year ended December 31, 2009. The decrease in the inventory turnover rate since December 31, 2009 reflected reduced sales compared with 2009 combined with near-static inventory levels. We are taking steps to reduce inventory purchases in order to better match our operating needs.

The following table sets forth information relating to the sources and uses of our cash:

	Nine Months Ended	
	September 30,	
	2010	2009
	(in thousands)	
Net cash used in operating activities	\$ (11,508.6)	\$ (4,693.0)
Net cash provided by (used in) investing activities	7,359.2	(3,086.6)
Net cash provided by financing activities	136.1	17,514.4

Our operating activities used \$11.5 million in the nine months ended September 30, 2010. This use of cash resulted largely from the net loss for the nine months of \$12.7 million. For the nine months ended September 30, 2009, our operating activities used \$4.7 million, which included legal settlement payments totaling \$3.7 million.

Our investing activities provided \$7.4 million in cash the nine months ended September 30, 2010. This source of cash resulted primarily from \$7.5 million provided by the maturities of investments. For the nine months ended September 30, 2010, our investing activities used \$3.1 million in cash. This use of cash included \$7.5 million to purchase short-term investments, \$350,000 to acquire certain technological and intellectual property assets, and \$237,000 to acquire fixed assets. These uses of cash in 2009 were partially offset by \$5.0 million provided by the maturity of certain investments.

Our financing activities provided \$136,000 in the nine months ended September 30, 2010, primarily from proceeds from the issuance of our common stock. In the nine months ended September 30, 2009, the net cash provided by financing activities, resulted mainly from an equity financing completed on September 8, 2009, under which we sold 8,816,521 shares of our common stock and warrants to purchase 8,375,694 shares of common stock. The sale of securities resulted in gross proceeds of approximately \$18.7 million. The net proceeds, after deducting offering expenses, were approximately \$17.3 million.

We expect to incur net losses and negative cash flows from operations for the foreseeable future. Based upon our current plans, we believe that our cash and cash equivalents, and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements through 2011. During the remainder of 2010, we expect to continue to hold our cash in money market funds.

#### *Off-Balance Sheet Arrangements, Contractual Obligations and Contingent Liabilities and Commitments*

As of September 30, 2010, we did not have any off-balance sheet financing arrangements.

We currently have a Credit Facility with Comerica Bank, which permits us to borrow up to \$7.5 million on a revolving basis for a one-year term. Amounts borrowed under the Credit Facility will bear interest equal to the prime rate plus 0.5%. Any borrowings under the Credit Facility will be secured by our cash, accounts receivable, inventory, and equipment. We have not borrowed any funds under the Credit Facility as of September 30, 2010 and we are in compliance with the financial covenant of the Credit Facility.

See notes 7 and 9 of the notes to unaudited financial statements for information regarding commitments and contingencies.

#### **Recent Accounting Pronouncements**

In September 2009, the Emerging Issues Task Force, or EITF, issued new rules pertaining to the accounting for revenue arrangements with multiple deliverables. The new rules provide an alternative method for establishing fair value of a deliverable when vendor specific objective evidence cannot be

determined. The guidance provides for the determination of the best estimate of selling price to separate deliverables and allows the allocation of arrangement consideration using this relative selling price model. The guidance supersedes the prior multiple element revenue arrangement accounting rules that are currently used by us. The new guidance can be prospectively applied by us beginning January 1, 2011 or can be early or retrospectively adopted. We are currently evaluating the impact of the new rules including the timing of adoption, but we do not believe adoption will have a material effect on our financial statements.

In September 2009, the EITF issued new rules to exclude (a) non-software components of tangible products and (b) software components of tangible products that are sold, licensed, or leased with tangible products when the software components and non-software components of the tangible product function together to deliver the tangible product's essential functionality. The new guidance can be prospectively applied by us beginning January 1, 2011 or can be early or retrospectively adopted. We are currently evaluating the impact of the new rules including the timing of adoption, but we do not believe adoption will have a material effect on our financial statements.

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update No. 2010-06, "*Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements*" ("ASU 2010-06"). ASU 2010-06 requires new disclosures regarding significant transfers in and out of Levels 1 and 2, as well as information about activity in Level 3 fair value measurements, including presenting information about purchases, sales, issuances, and settlements on a gross versus a net basis in the Level 3 activity roll forward. In addition, ASU 2010-06 also clarifies existing disclosures regarding input and valuation techniques, as well as the level of disaggregation for each class of assets and liabilities. ASU No. 2010-06 is effective for interim and annual periods beginning after December 15, 2009, except for the disclosures pertaining to purchases, sales, issuances, and settlements in the roll forward of Level 3 activity; those disclosures are effective for interim and annual periods beginning after December 15, 2010. The adoption of ASU 2010-06 had no current impact and is expected to have no subsequent impact on our financial statements.

### **Cautionary Note Regarding Forward-Looking Statements**

The statements contained in this Quarterly Report on Form 10-Q include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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, such as our estimates regarding anticipated operating losses, future revenues and projected expenses for the remainder of 2010 and beyond; our beliefs that the assignment of CPT code 95905 is essential to build our U.S. business, may streamline Medicare reimbursement for studies performed using our neurodiagnostic devices, reaffirms the clinical utility of our neurodiagnostic devices and supports its use by physician offices and internal medicine specialists and will over time positively influence reimbursement patterns by commercial insurers; our expectations regarding how physician reimbursement under CPT code 95905 could affect testing patterns and, in the short term, result in continued downward pressure on our revenues and margins, but in the longer term have a positive impact on our revenues; our beliefs that the new health care environment has resulted in significant uncertainty for customers and how this uncertainty will impact our business; our beliefs regarding potential liability or losses resulting from litigation; our expectations regarding the level of sales of our ADVANCE System and whether such system will be attractive for use in the physician office market; our expectations regarding the targeted timelines for commercialization of products in our development pipeline; our expectations that a rapid low cost point-of-care test for DPN represents a U.S. and international market opportunity, and our expectations surrounding the timeline by which this product could be developed and commercially launched; our effectiveness in implementing a hybrid direct/distribution sales model and the timeline in which we intend to do so; our beliefs regarding the

outcome of discussions with the FDA concerning its recent notice to us that certain reporting functions of the onCall Information System are not substantially equivalent to the cleared NC-stat System; our liquidity and our expectations regarding our needs for and ability to raise additional capital; and other factors discussed elsewhere in this Quarterly Report on Form 10-Q or any document incorporated by reference herein or therein. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this quarterly report 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. In particular, you should consider these forward-looking statements in light of the risk factors set forth in Item 1A. Risk Factors of our most recent Annual Report on Form 10-K, as supplemented by the risk factors set forth in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010 and June 30, 2010, and Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q, and factors described in our other public filings and in this report, as well as other factors that will be discussed in future reports filed with or furnished to the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary 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.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash, cash equivalents, short-term investments, accounts receivable, accounts payable, and accrued expenses. We consider investments that, when purchased, have a remaining maturity of 90 days or less to be cash equivalents. The primary objectives of our investment strategy are to preserve principal, maintain proper liquidity to meet operating needs, and maximize yields. To minimize our exposure to an adverse shift in interest rates, we invest mainly in cash equivalents and short-term investments with a maturity of twelve months or less and maintain an average maturity of twelve months or less. We do not believe that a notional or hypothetical 10% change in interest rate percentages would have a material impact on the fair value of our investment portfolio or our interest income.

### **Item 4. Controls and Procedures**

**(a) Evaluation of Disclosure Controls and Procedures.** Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of September 30, 2010, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

**(b) Changes in Internal Controls.** There were no changes in our internal control over financial reporting, identified in connection with the evaluation of such internal control that occurred during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

Please see Part I, Item 3. Legal Proceedings of our Annual Report on Form 10-K for the year ended December 31, 2009, as updated by or our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010 and June 30, 2010, as well as Note 9 "Legal Matters" of our Notes to Unaudited Financial Statements contained in this Quarterly Report on Form 10-Q for a description of legal proceedings involving us.

### Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the factors discussed in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2009 and Part II, Item 1A of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010 and June 30, 2010, which could materially affect our business, financial condition or results of operations. The risks described in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q are not the only risks that we face. In addition, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, and/or results of operations. Other than the addition of the following risk factors, the first of which replaces and supersedes the corresponding risk factor with the same title set forth in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, there have been no material changes in or additions to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2009 or our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2010 and June 30, 2010.

***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 with regard to 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 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 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.

In the second quarter of 2010, we were notified by the FDA that certain reporting functions of the onCall Information System ("onCall") that operates with the company's cleared NC-stat device and for which we submitted a 510(k) premarket notification in 2006 were deemed by the FDA to be not substantially equivalent to the cleared NC-stat System or other existing predicate devices. In its letter, the FDA indicated that we could submit another 510(k) with specific additional information identified in the letter. onCall has been in use since 1999, and continued in use with FDA's agreement after we voluntarily submitted a 510(k) in 2006 for these reporting functions, in order to resolve our differences of opinion with FDA as to whether such reporting functions had been covered by previous 510(k) premarket notifications. We submitted an administrative appeal of FDA's not substantially equivalent determination in July 2010. We have been in dialogue with the FDA's Center for Devices and Radiological Health ombudsman to better understand and address the FDA's concerns. In October 2010, we attended a meeting at the FDA to discuss our appeal with representatives of all relevant FDA departments. We are presently awaiting further guidance from the FDA following that meeting. It is possible that this dialogue or the appeal will lead to a determination of substantial equivalence for the current 510(k) premarket notification or our submitting a new 510(k) premarket notification for these reporting functions of onCall. We cannot currently predict the outcome of either the administrative appeal or the dialogue with the FDA staff.

With the evolution of our product line and launch of the ADVANCE System into the physician office market in October 2010, the NC-stat device with onCall is no longer being sold to new customers. Our installed base of NC-stat accounts built up over the past decade continues to perform nerve conduction testing using the NC-stat System including onCall. If the FDA does not clear these reporting functions and we are unable to offer onCall in its present configuration, we may be required to modify or remove these reporting functions, or transition these accounts to our ADVANCE System. We believe that we could manage the modifications in an orderly manner and in a way that the NC-stat System would retain its current utility for physicians. However, we are not able to predict the impact such modifications might have on our ability to generate revenues from the NC-stat System, particularly during a transition period, or the costs involved in transitioning these customers to the ADVANCE System. Either resolution, even if successful, could have a material adverse impact on our business.

We also are subject to numerous post-marketing regulatory requirements, including 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. 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. 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.

***If we fail to continue to meet all applicable NASDAQ Global Market requirements and The NASDAQ Stock Market determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, impair the value of your investment and harm our business.***

Our common stock is currently listed on the NASDAQ Global Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. On September 24, 2010, we received notice from the Listing Qualifications Department of the NASDAQ Stock Market, or NASDAQ, that our common stock had not met the \$1.00 per share minimum bid price requirement for the last 30 consecutive business days pursuant to NASDAQ Listing Rule 5450(a)(1) and that, if we were unable to demonstrate compliance with this requirement during the applicable grace periods, our common stock would be delisted after that time. The notification letter stated that pursuant to NASDAQ Listing Rule 5810(c)(3)(A) we would be afforded 180 calendar days, or until March 23, 2011, to regain compliance with the minimum bid price requirement. In order to regain compliance, shares of our common stock must maintain a minimum closing bid price of at least \$1.00 per share for a minimum of ten consecutive business days. If we do not regain compliance by March 23, 2011, NASDAQ will provide written notification to us that our common stock will be delisted. At that time, we may appeal NASDAQ's delisting determination to a NASDAQ Listing Qualifications Panel. Alternatively, we may be eligible for an additional 180 day grace period if we satisfy all of the requirements, other than the minimum bid price requirement, for listing on the NASDAQ Capital Market set forth in NASDAQ Listing Rule 5505. The closing bid price of our common stock on the NASDAQ Global Market was \$0.53 on November 1, 2010.

While we intend to engage in efforts to regain compliance, and thus maintain our listing, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above. If we fail to continue to meet all applicable NASDAQ Global Market requirements in the future and NASDAQ determines to delist our common stock, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock; adversely affect our ability to obtain financing on acceptable terms, if at all, for the continuation of our operations; and harm our business. Additionally, the market price of our common stock may decline further and stockholders may lose some or all of their investment.

***We have launched the ADVANCE System into the physician office market where previously we sold the NC-stat System. If our physician office customers do not adopt the ADVANCE System in sufficient numbers, it could have a material adverse effect on our business and results of operations.***

With the evolution of our product line and launch of the ADVANCE System into the physician office market in October 2010, we are no longer promoting the NC-stat System in that market. The NC-stat System has been sold into the physician office market since its initial launch in May 1999. The ADVANCE System has been sold into specialty markets such as neurology, orthopedic surgery, and pain management since 2008. If we are unable to encourage sufficient adoption and utilization of the ADVANCE System in the physician office market, our business will suffer.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. [Removed and Reserved.]**

**Item 5. Other Information**

None.

**Item 6. Exhibits**

See the Exhibit Index on the page immediately preceding the exhibits for a list of exhibits filed as part of this quarterly report, which Exhibit Index is incorporated herein by this reference.



**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**NEUROMETRIX, INC.**

Date: November 9, 2010

/s/ SHAI N. GOZANI, M.D., PH.D.

---

Shai N. Gozani, M.D., Ph.D.  
*Chairman, President and Chief Executive Officer*

Date: November 9, 2010

/s/ THOMAS T. HIGGINS

---

Thomas T. Higgins  
*Senior Vice President, Chief Financial Officer and Treasurer*

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
31.1	Certification of Principal Executive Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
31.2	Certification of Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
32	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350. Furnished herewith.

---



**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

I, Shai N. Gozani, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2010

/s/ SHAI N. GOZANI, M.D., PH.D.

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

*Chairman, President and Chief Executive Officer*

---

QuickLinks

[EXHIBIT 31.1](#)

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

I, Thomas T. Higgins, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2010

/s/ THOMAS T. HIGGINS

---

Thomas T. Higgins  
*Senior Vice President, Chief Financial Officer and Treasurer*

---

QuickLinks

[EXHIBIT 31.2](#)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of the undersigned officers of NeuroMetrix, Inc. (the "Company") hereby certifies to his knowledge that the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2010 to which this certification is attached (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 9, 2010

/s/ SHAI N. GOZANI, M.D., PH.D.

---

Shai N. Gozani, M.D., Ph.D.  
*Chairman, President and Chief Executive Officer*

/s/ THOMAS T. HIGGINS

---

Thomas T. Higgins  
*Senior Vice President, Chief Financial Officer and Treasurer*

This certification is being furnished and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated into any document for any purpose, under the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended.

---



QuickLinks

[EXHIBIT 32](#)