NeuroMetrix, Inc. Form 10-Q November 12, 2009

Use these links to rapidly review the document <u>TABLE OF CONTENTS</u>

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2009

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)

**62 Fourth Avenue, Waltham, Massachusetts** (Address of principal executive offices)

(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 twelve (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 ninety (90) days. Yes  $\circ$  No o

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 o No o

04-3308180 (I.R.S. Employer Identification No.)

> **02451** (Zip Code)

# Edgar Filing: NeuroMetrix, Inc. - Form 10-Q

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

Large accelerated filer o Accelerated filer o Non-accelerated filer o Smaller reporting company ý (Do not check if a 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 o No ý

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 22,963,234 shares of common stock, par value \$0.0001 per share, were outstanding as of November 2, 2009.

## NeuroMetrix, Inc. Form 10-Q Quarterly Period Ended September 30, 2009

# TABLE OF CONTENTS

## PART I FINANCIAL INFORMATION Item 1. Financial Statements:

<u>nem 1.</u>	Balance Sheets (unaudited) as of September 30, 2009 and December 31, 2008	
		<u>2</u>
	Statements of Operations (unaudited) for the quarters and nine months ended September 30, 2009 and 2008	<u>3</u>
	Statements of Cash Flows (unaudited) for the nine months ended September 30, 2009 and 2008	<u>4</u>
	Notes to Unaudited Financial Statements	
<u>Item 2.</u>	Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>5</u>
<u>Item 3.</u>	Quantitative and Qualitative Disclosures About Market Risk	<u>20</u>
Item 4T.	Controls and Procedures	<u>27</u>
		<u>27</u>
PART II O Item 1.	DTHER INFORMATION Legal Proceedings	
<u>Item 1A.</u>	Risk Factors	<u>29</u>
<u>Item 2.</u>	Unregistered Sales of Equity Securities and Use of Proceeds	<u>30</u>
<u>Item 3.</u>	Defaults Upon Senior Securities	<u>31</u>
Item 4.	Submission of Matters to a Vote of Security Holders	<u>31</u>
		<u>31</u>
<u>Item 5.</u>	Other Information	<u>31</u>
<u>Item 6.</u>	Exhibits	<u>31</u>
<u>Signatures</u>		
	1	<u>32</u>

## PART I FINANCIAL INFORMATION

## Item 1. Financial Statements

## NeuroMetrix, Inc.

## **Balance Sheets**

## (Unaudited)

	Se	eptember 30, 2009	D	ecember 31, 2008
Assets				
Current assets:				
Cash and cash equivalents	\$	22,037,046	\$	12,302,284
Short-term investments		9,995,000		7,495,000
Accounts receivable, net of allowance for				
doubtful accounts of \$450,000 and \$650,000 at				
September 30, 2009 and December 31, 2008,				
respectively		3,449,401		3,660,848
Inventories		4,893,159		5,606,807
Prepaid expenses and other current assets		482,472		313,795
Current portion of deferred costs		152,982		263,755
Total current assets		41,010,060		29,642,489
Restricted cash		408,000		408,000
Fixed assets, net		918,017		1,073,176
Intangible assets, net		297,500		
Deferred costs		79,890		116,972
Other long-term assets		59,385		137,705
C				
Total assets	\$	42,772,852	\$	31,378,342
	Ψ	,, / _,00 _	Ψ	01,070,012
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	1,260,123	\$	201,275
Accrued compensation	Ψ	1,435,736	Ψ	1,335,430
Accrued expenses		1,685,219		5,386,699
Current portion of deferred revenue		757,695		1,057,215
Current portion of capital lease obligation		28,173		29,748
Current portion of cupital lease congation		20,175		29,710
Total current liabilities		5,166,946		8,010,367
Deferred revenue, net of current portion		389,369		483,365
Capital lease obligation, net of current portion		41,683		52,059
Common stock warrants		21,888,341		52,059
Common stock warrants		21,000,341		
		07 496 222		0 5 4 5 70 1
Total liabilities		27,486,339		8,545,791
Commitments and contingencies (Notes 7, 9, and				
13)				
Stockholders' equity:				
Preferred stock, \$0.001 par value; 5,000,000				
shares authorized, none outstanding				
		2,296		1,386

# Edgar Filing: NeuroMetrix, Inc. - Form 10-Q

Common stock, \$0.0001 par value; 50,000,000 shares authorized; 22,963,234 and 13,858,797 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively		
Additional paid-in capital	117,360,585	112,626,802
Accumulated deficit	(102,076,368)	(89,795,637)
Total stockholders' equity	15,286,513	22,832,551
Total liabilities and stockholders' equity	\$ 42,772,852	\$ 31,378,342

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

# **Statements of Operations**

# (Unaudited)

		Quarter Ended September 30,				ine Months End	September 30,		
		2009		2008		2009	2008		
			(	Consolidated)			((	Consolidated)	
Revenues:			(-				( -		
Medical equipment	\$	725,822	\$	416,826	\$	2,129,594	\$	1,679,039	
Consumables	Ŧ	5,600,129	Ŧ	6,660,412	Ŧ	17,782,354	Ŧ	22,261,690	
consumations		0,000,123		0,000,112		1,,,02,00		22,201,070	
Total revenues		6,325,951		7,077,238		19,911,948		23,940,729	
Cost of revenues		1,826,599		2,082,805		5,701,907		6,701,373	
Cost of revenues		1,020,399		2,002,005		5,701,907		0,701,575	
		4 400 252		4 00 4 422		14 210 041		17.000.057	
Gross margin		4,499,352		4,994,433		14,210,041		17,239,356	
Operating expenses:		1 511 500		1 420 245		4 0 41 0 4 4		4 270 421	
Research and development		1,511,528		1,438,245		4,241,964		4,379,421	
Sales and marketing		2,787,942		2,706,403		8,229,550		12,166,535	
General and administrative		2,123,845		3,167,413		6,816,078		10,017,402	
Charge for impaired									
goodwill								5,833,464	
Total operating expenses		6,423,315		7,312,061		19,287,592		32,396,822	
Loss from operations		(1,923,963)		(2,317,628)		(5,077,551)		(15,157,466)	
Loss on available-for-sale		(1,725,705)		(2,317,020)		(5,077,551)		(15,157,100)	
investment				(169,289)				(2,226,454)	
Interest income		52,217		124,256		188,534		617,841	
Warrants fair value		52,217		124,230		100,554		017,041	
adjustment		(7,201,714)				(7,201,714)			
		(7,391,714)		52 500		(7,391,714)		121 250	
Other income				52,500				131,250	
Loss from continuing									
operations		(9,263,460)		(2,310,161)		(12,280,731)		(16,634,829)	
Loss from discontinued									
operations				(5,541,986)				(6,952,773)	
Net loss	\$	(9,263,460)	\$	(7,852,147)	\$	(12,280,731)	\$	(23,587,602)	
								,	
Per common share data, basic									
and diluted:									
Loss from continuing									
operations	\$	(0.57)	¢	(0.17)	¢	(0.84)	¢	(1.21)	
Loss from discontinued	φ	(0.57)	φ	(0.17)	φ	(0.84)	φ	(1.21)	
				(0.40)				(0.51)	
operations				(0.40)				(0.51)	
Net loss	\$	(0.57)	\$	(0.57)	\$	(0.84)	\$	(1.72)	
Weighted average number of									
common shares outstanding,									
basic and diluted		16,223,033		13,773,855		14,700,425		13,719,346	

# Edgar Filing: NeuroMetrix, Inc. - Form 10-Q

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

## **Statements of Cash Flows**

# (Unaudited)

	Ni	ine Months Endo 2009		2008
			((	Consolidated)
Cash flows from operating activities:				
Net loss	\$	(12,280,731)	\$	(23,587,602)
Adjustments to reconcile net loss to net cash used in operating				
activities:				
Depreciation and amortization		444,289		1,402,977
Stock-based compensation		1,700,712		1,889,531
Accretion of discount on investments				(38,159)
Loss on available-for-sale investment				2,226,454
Goodwill impairment				5,833,464
Asset impairment and restructuring charge				4,960,151
Warrants fair value adjustment		7,391,714		
Other income				(131,250)
Changes in operating assets and liabilities:				
Accounts receivable		211,447		1,916,182
Inventories		713,648		(956,867)
Prepaid expenses and other current assets		(168,677)		(245,680)
Other long-term assets		78,320		(96,393)
Accounts payable		1,058,848		(1,087,535)
Legal settlement		(3,705,866)		
Accrued expenses and compensation		104,692		(902,847)
Deferred revenue and deferred costs		(245,661)		(219,178)
Other liabilities		4,295		(14,546)
Net cash used in operating activities		(4,692,970)		(9,051,298)
Cash flows from investing activities:				
Purchases of investments		(7,495,000)		(1,050,598)
Maturities of investments		4,995,000		23,710,498
Purchases of fixed assets		(236,630)		(274,807)
Purchase of technological and intellectual property		(350,000)		
Release of restricted cash				1,070,598
Net cash (used in) provided by investing activities		(3,086,630)		23,455,691
Cash flows from financing activities:		(0,000,000)		20,000,001
Net proceeds from issuance of common stock and warrants		17,530,608		100,136
		(16,246)		(9,675)
Payments on capital lease		(10,240)		(9,073)
Net cash provided by financing activities		17,514,362		90,461
Net increase in cash and cash equivalents		9,734,762		14,494,854
Cash and cash equivalents, beginning of period		12,302,284		7,097,239
Cash and cash equivalents, end of period	\$	22,037,046	\$	21,592,093
	+	,,	~	,
Supplemental disclosure of noncash investing activities:				

# Edgar Filing: NeuroMetrix, Inc. - Form 10-Q

Contribution of intangible asset to joint venture by Cyberkinetics Neurotechnology Systems, Inc.	\$	\$ 2,100,000
Warrants issued in Securities Purchase Agreement recorded as		
a non-current liability	\$ 14,496,627	\$

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

#### Notes to Unaudited Financial Statements

#### September 30, 2009

## 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. The Company provides innovative products for preservation and restoration of nerve and spinal cord function, and pain control. 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 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. The Company is also developing devices and pharmaceutical agents to treat peripheral nerve and spinal cord injuries.

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. In addition, the placement agents were issued warrants to purchase an aggregate of 207,188 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, were approximately \$17.3 million. 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 into 2011 (See Note 13 Equity).

## **Unaudited Interim Financial Statements**

The accompanying unaudited balance sheet as of September 30, 2009, unaudited statements of operations for the quarters and nine months ended September 30, 2009 and 2008 (consolidated) and the unaudited statements of cash flows for the nine months ended September 30, 2009 and 2008 (consolidated) 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. Certain amounts previously reported have been reclassified in order to conform to the current period's presentation. Operating results for the quarter and nine months ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2008 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.



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

#### September 30, 2009

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

During the review of the Company's financial statements for the quarter ended March 31, 2009, the Company identified certain accounting errors in its prior period financial statements that individually and in the aggregate are not material to its financial statements taken as a whole for any related prior periods, the nine month period ended September 30, 2009, and the projected 2009 results. The correction of these errors, recorded in the quarter ended March 31, 2009, resulted in a \$234,000 decrease in operating expenses. If the errors were recorded in the periods during which they occurred, net loss from operations would have decreased by \$120,000 for the year ended December 31, 2008 and \$114,000 for the year ended December 31, 2007.

#### Revenues

Medical equipment revenues consist of the NC-stat and ADVANCE systems, related modules, and extended service agreement revenues. Revenues associated with the sale of the NC-stat and ADVANCE devices are recognized upon shipment provided that the fee is fixed or determinable, evidence of a persuasive arrangement exists, collection of receivables is reasonably assured, product returns are reasonably estimable, and no continuing obligations exist. The revenues from the sale of a 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 deferred and recognized on a straight line basis over the estimated period of time the Company provides the service associated with the information systems, which is the shorter of the estimated customer relationship period or the estimated useful life of the docking station or communication hub, currently three years. 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 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.

Certain product sales are made with a 30-day right of return. Since 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 by the amount of estimated returns.

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

#### **Principles of Consolidation**

The consolidated financial statements for the quarter and nine months ended September 30, 2008 reflect the Company's financial statements and those of PNIR (Peripheral Nerve Injury Repair) LLC, or PNIR, a joint venture with Cyberkinetics Neurotechnology Systems, Inc., or Cyberkinetics. The Company consolidates variable interest entities in which the Company is the primary beneficiary. All material intercompany balances and transactions have been eliminated in consolidation. The joint venture was dissolved in January 2009, effective as of December 31, 2008, and was deconsolidated from the Company's financial statements at that date.

## Notes to Unaudited Financial Statements (Continued)

#### September 30, 2009

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

#### Use of Estimates

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

## **Recent Accounting Pronouncements**

In April 2009, the Financial Accounting Standards Board, or FASB, issued guidance on providing interim disclosures about fair value of financial instruments. This new guidance requires the fair value disclosures that were previously disclosed only annually to be disclosed now on an interim basis. This guidance was effective for the Company in the second quarter of 2009 and the additional disclosures required have been made. Adoption did not have an impact on the Company's financial position, results of operations, or cash flows.

In April 2009, the FASB issued guidance amending the other-than-temporary impairment guidance for debt securities to make the guidance more operational and to improve the presentation and disclosure of other-than-temporary impairments on debt and equity securities in the financial statements. The new guidance does not amend existing recognition and measurement guidance related to other-than-temporary impairments of equity securities. The Company adopted this guidance in the second quarter of 2009. Adoption did not have an impact on the Company's financial position, results of operations, or cash flows.

In April 2009, the FASB issued guidance for estimating fair value when the volume and level of activity for the asset or liability have significantly decreased. This guidance also includes guidance on identifying circumstances that indicate a transaction is not orderly and emphasizes that even if there has been a significant decrease in the volume and level of activity for the asset or liability and regardless of the valuation technique(s) used, the objective of a fair value measurement remains the same. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. The Company adopted this guidance in the second quarter of 2009. Adoption did not have an impact on the Company's financial position, results of operations, or cash flows.

In May 2009, the FASB issued a pronouncement on subsequent event accounting. The guidance sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The pronouncement was effective for the Company's second quarter of 2009 and there was no effect from adoption. In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through November 12, 2009, the date the financial statements

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

#### September 30, 2009

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

were issued. In October 2009, the Company executed addendums to the warrants issued in connection with the securities purchase agreements of September 8, 2009 (See Note 14 Subsequent Event).

In June 2009, the FASB issued guidance on the FASB Accounting Standards Codification, or the Codification, and the hierarchy of generally accepted accounting principles. The Codification is the single source of authoritative nongovernmental generally accepted accounting principles in the U.S. (GAAP). The Codification was effective for interim and annual periods ending after September 15, 2009. Adoption did not have an impact on the Company's financial position, results of operations, or cash flows.

In August 2009, the FASB issued additional guidance on the fair value measurement of liabilities. The guidance provides clarification that in circumstances in which a quoted price in an active market for the identical liability is not available, a reporting entity is required to measure fair value using one or more of the following methods: 1) a valuation technique that uses a) the quoted price of the identical liability when traded as an asset or b) quoted prices for similar liabilities or similar liabilities when traded as assets and/or 2) a valuation technique that is consistent with the principles of the guidance (e.g. an income approach or market approach). The guidance also clarifies that when estimating the fair value of a liability, a reporting entity is not required to adjust to include inputs relating to the existence of transfer restrictions on that liability. This guidance will be effective for the Company's fourth quarter of 2009. Adoption of this guidance is not expected to have a significant impact on the Company's financial position, results of operations, or cash flows.

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 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 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 functionally. The new guidance can be prospectively applied 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 does not believe adoption will have a material effect on its financial statements.

#### 2. Comprehensive Loss

In November 2007, the Company made an investment of \$2.5 million in shares of Cyberkinetics common stock and accounted for this investment as an available-for-sale security. At December 31, 2007, the Company had recognized a temporary loss of \$1.4 million within other comprehensive

## Notes to Unaudited Financial Statements (Continued)

#### September 30, 2009

#### 2. Comprehensive Loss (Continued)

income. For the quarter and nine months ended September 30, 2008, the Company reassessed its investment in Cyberkinetics and, based on the outlook for Cyberkinetics and the period of time that the common stock of Cyberkinetics had traded below the price paid by the Company for its investment, recognized losses of \$169,000 and \$2.2 million, respectively, in the statement of operations due to an impairment in the value of the investment that the Company determined was other-than-temporary.

	Quarter Septem			Nine Mont Septem		
	2009		2008	2009		2008
		(C	onsolidated)		(0	Consolidated)
Comprehensive loss:						
Net loss	\$ (9,263,460)	\$	(7,852,147) \$	(12,280,731)	\$	(23,587,602)
Other comprehensive income:						
Realized loss on available-for-sale investment						1,441,745
Other comprehensive income						1,441,745
Comprehensive loss	\$ (9,263,460)	\$	(7,852,147) \$	(12,280,731)	\$	(22,145,857)

## 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. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding plus the dilutive effect of outstanding convertible instruments such as warrants and options. Because we have reported a net loss attributable to common stockholders for all annual 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 for 2009, shares underlying the 8,582,882 warrants outstanding and the 3,332,359 outstanding options as of September 30, 2009 are not included in the calculation of diluted net loss per common share. In calculating net loss per share amounts for 2008, shares underlying 2,260,590 outstanding options as of September 30, 2008 were not included in the calculation of diluted net loss per common share.

#### 4. Inventories

Inventories consist of the following:

	Sep	tember 30, 2009	De	ecember 31, 2008
Purchased components	\$	1,484,393	\$	1,640,967
Finished goods		3,408,766		3,965,840
	\$	4,893,159	\$	5,606,807

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

September 30, 2009

#### 5. Goodwill and Intangible Assets

Goodwill

As a result of the December 2007 acquisition of substantially all of the assets of EyeTel Imaging, Inc., or EyeTel, and their product, the DigiScope, a product used for the detection of eye disorders such as diabetic retinopathy, an eye disease prevalent in patients with diabetes, the Company recorded approximately \$5.8 million of goodwill on its balance sheet at December 31, 2007. In accordance with the provisions of the Intangibles Goodwill and Other Topic of the Codification, the Company is required to assess the realizability of goodwill annually, and whenever events or changes in circumstances suggest that the carrying amount may not be recoverable. The operations of EyeTel were incorporated into the Company's one segment and the Company determined that it was comprised of a single reporting unit for goodwill impairment testing. Subsequent to the American Medical Association CPT Panel meeting in February 2008, the Company's common stock price declined significantly such that as of March 31, 2008, the Company's publicly traded market value was below its net book value. Based on this, the Company determined that an interim goodwill impairment test in which it assessed the fair value of all recorded and unrecorded tangible and intangible assets and liabilities, including its recently acquired EyeTel and PNIR (described below) intangible assets. The Company determined that no assets were impaired and determined that there was no residual value of goodwill. Accordingly, the Company recorded a charge of \$5.8 million to write off goodwill during the quarter ended March 31, 2008.

#### Intangible Assets

In February 2008, the Company formed PNIR, a joint venture with Cyberkinetics with initial ownership of 50% by the Company and 50% by Cyberkinetics. Cyberkinetics contributed \$2.1 million of technology and intellectual property when the joint venture was formed. Research and development expenses for the quarter and nine months ended September 30, 2008 included amortization of this intellectual property of \$105,000 and \$262,500, respectively. The joint venture was dissolved in January 2009, effective as of December 31, 2008, and was deconsolidated from the Company's financial statements at that date.

In January 2009, the Company acquired certain technological and intellectual property assets from Cyberkinetics and Andara Life Science, Inc., a wholly-owned subsidiary of Cyberkinetics, for \$350,000 in cash. The assets acquired in January 2009 include all of Cyberkinetics' rights and regulatory filings for the Andara Oscillating Field Stimulator (OFS) technology for treatment of acute spinal cord injury, an investigational device designed to stimulate spinal cord repair and restore sensation; the rights to develop and commercialize a therapeutic product for peripheral nerve injury based on the Andara OFS neurostimulation technology; development and commercialization rights to certain derivatives of the pharmacological agent 4-aminopyridine that may have an alternative future use in central and peripheral nervous system injury and disease; and certain other intellectual property and technology, which has been capitalized. The Company had previously pursued some of these product development efforts through the PNIR joint venture. Research and development expenses for the quarter and nine months ended September 30, 2009 included amortization of this technological and intellectual property of \$17,500 and \$52,500, respectively. Accumulated amortization on these intangible assets at September 30, 2009 was \$52,500.

The Company amortizes its intangible assets using the straight-line method over their economic lives, which is estimated to be five years.

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

## September 30, 2009

## 5. Goodwill and Intangible Assets (Continued)

The estimated future amortization expense for intangible assets as of September 30, 2009 is as follows:

	Estimated Amortization Expense
2009 (remaining three months)	\$ 17,500
2010	70,000
2011	70,000
2012	70,000
2013	70,000

## 6. Other Balance Sheet Items

Accrued expenses consist of the following:

Sep	tember 30, 2009	De	cember 31, 2008
\$	590,553	\$	470,857
	188,259		325,847
			3,705,866
	906,407		884,129
\$	1,685,219	\$	5,386,699
	\$	<b>2009</b> \$ 590,553 188,259 906,407	2009 \$ 590,553 \$ 188,259 906,407

## 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 rollforward of the Company's accrued warranty liability for the quarters and nine months ended September 30, 2009 and 2008:

•				1 (1110)	Bildea	
2009		2008		2009		2008
\$ 54,505	\$	231,292	\$	136,170	\$	251,948
2,560		117,837		7,322		451,097
(6,604)		(150,867)		(93,031)		(504,783)
\$ 50,461	\$	198,262	\$	50,461	\$	198,262
	Septer 2009 \$ 54,505 2,560 (6,604)	September   2009   \$ 54,505 \$   2,560   (6,604)	\$ 54,505 \$ 231,292 2,560 117,837 (6,604) (150,867)	September 30,   2009 2008   \$ 54,505 \$ 231,292 \$   2,560 117,837   (6,604) (150,867)   \$ 50,461 \$ 198,262 \$	September 30, Septem   2009 2008 2009   \$ 54,505 \$ 231,292 \$ 136,170   2,560 117,837 7,322   (6,604) (150,867) (93,031)	September 30, September   2009 2008 2009   \$ 54,505 \$ 231,292 \$ 136,170 \$   2,560 117,837 7,322 (6,604) (150,867) (93,031)   \$ 50,461 \$ 198,262 \$ 50,461 \$

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

#### September 30, 2009

## 7. Commitments and Contingencies

#### **Operating Lease**

In February 2008, the Company amended the Lease Agreement dated October 18, 2000 between Fourth Avenue LLC and the Company for office and engineering laboratory space. The amendment extended the term of the lease through March 31, 2013. Base rent for the period April 2009 through March 2013 was reduced from \$930,000 annually to a range of \$675,000 to \$765,000 annually.

Future minimum lease payments under noncancelable operating leases as of September 30, 2009 are as follows:

2009 (remaining three months)	\$ 168,750
2010	697,500
2011	727,500
2012	757,500
2013	191,250
Total minimum lease payments	\$ 2,542,500

#### 8. Fair Value Measurements

The Company adopted the requirements of the Fair Value Measurements and Disclosures Topic of the Codification effective January 1, 2008 for its financial assets and liabilities that are remeasured and reported at fair value at each reporting period. The adoption of this Codification topic did not have a material impact on the Company's financial position, results of operations, or cash flows.

In accordance with the provisions of this Codification topic, the Company elected to defer implementation of this Codification topic as it related to its non-financial assets and liabilities that are recognized and disclosed at fair value in the financial statements on a non-recurring basis until January 1, 2009. Effective for the quarter ended March 31, 2009, the Company implemented this Codification topic for its non-financial assets and liabilities that are remeasured at fair value on a non-recurring basis. The adoption of this Codification topic for the Company's non-financial assets and liabilities that are remeasured at fair value on a non-recurring basis did not impact its financial position, results of operations, or cash flows.

This Codification topic could impact future periods. In addition, the Company may have additional disclosure requirements in the event the Company completes an acquisition or incurs an impairment of its assets in future periods.

This Codification topic defines fair value, establishes a framework for measuring fair value in applying generally accepted accounting principles, and expands disclosures about fair value measurements. This Codification topic identifies two kinds of inputs that are used to determine the fair value of assets and liabilities: observable and unobservable. Observable inputs are based on market data or independent sources while unobservable inputs are based on the Company's own market assumptions. Once inputs have been characterized, this Codification topic requires companies to prioritize the inputs used to measure fair value into one of three broad levels. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values identified by Level 2 inputs utilize observable inputs other than Level 1 prices, such as

## Notes to Unaudited Financial Statements (Continued)

## September 30, 2009

## 8. Fair Value Measurements (Continued)

quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities. Fair values identified by Level 3 inputs are unobservable data points and are used to measure fair value to the extent that observable inputs are not available. Unobservable inputs reflect the Company's own assumptions about the assumptions that market participants would use at pricing the asset or liability.

The following tables present information about our 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 we 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:

			Fair Value Measurements at September 30, 2009 Using						
	Se	eptember 30, 2009	Quoted Prices in Active Markets for Identical Assets (Level 1)		urkets Other tical Observable s Inputs		Significant Inobservable Inputs (Level 3)		
Assets:									
Cash equivalents	\$	21,188,655	\$	21,188,655	\$	\$			
Total	\$	21,188,655	\$	21,188,655	\$	\$			
Liabilities:									
Common stock warrants	\$	21,888,341	\$		\$	\$	21,888,341		
Total	\$	21,888,341	\$		\$	\$	21,888,341		

			Fair Value Measurements at December 31, 2008 Using						
	De	December 31, 2008		oted Prices in tive Markets or Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)			
Assets:									
Cash equivalents	\$	8,992,107	\$	8,992,107	\$	\$			
Total	\$	8,992,107	\$	8,992,107	\$	\$			

Due to the lack of market quotes relating to our common stock warrants, the fair value of the common stock warrants was determined at September 30, 2009 using the Black-Scholes model, which is based on Level 3 inputs. As of September 30, 2009, inputs used in the Black Scholes model include our stock price as of that date of \$3.21, a risk-free interest rate of 2.31%, a dividend yield of 0%, an

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

#### September 30, 2009

#### 8. Fair Value Measurements (Continued)

expected life of approximately 4.9 years, and expected volatility of 100%. The assumptions used may change as the underlying sources of these assumptions and market conditions change. As a result of this calculation, the Company recorded a loss of \$7.4 million during the quarter ended September 30, 2009. The Company did not have any financial liabilities carried at fair value as of December 31, 2008.

The following table provides a summary of changes in the fair value of the Company's Level 3 financial liabilities for the nine month period ended September 30, 2009:

Balance at December 31, 2008	\$
Initial fair value of warrants	14,496,627
Warrants fair value adjustment	7,391,714
Balance at September 30, 2009	\$ 21,888,341

#### 9. Legal Matters

As previously disclosed in the Company's filings with the Securities and Exchange Commission, or 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 alleges, among other things, that between October 27, 2005 and February 12, 2008, 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 are seeking 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. In March 2009, the parties mutually agreed to participate in mediation to attempt to resolve the litigation, and the court entered an order staying the proceedings. The mediation did not resolve the litigation, and plaintiffs opposed defendants' motion to dismiss on July 20, 2009. The defendants filed their reply brief in further support of their motion to dismiss the amended complaint on July 31, 2009.

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.

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 plaintiffs are seeking various forms of monetary and non-monetary relief. In March 2009, the parties agreed to participate in mediation to attempt to resolve the litigation. The parties have reached an agreement in

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

#### September 30, 2009

#### 9. Legal Matters (Continued)

principle to resolve the shareholder derivative action, subject to court approval, among other conditions, and on October 30, 2009 filed a joint motion with the court to stay all proceedings pending finalization of the settlement. The proposed settlement amount is within the coverage limits of the Company's insurance program.

As previously disclosed in the Company's filings with the SEC, on February 9, 2009, the Company announced that it had reached a resolution with the United States Department of Justice, or DOJ, and the Office of Inspector General, or OIG, of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of the Company's past sales and marketing practices relating to its NC-stat System.

As part of the resolution, the Company entered into a Deferred Prosecution Agreement, or the Deferred Prosecution Agreement, dated February 5, 2009, with the DOJ related to its operation of marketing referral programs. Pursuant to the Deferred Prosecution Agreement, the Company agreed to a \$1.2 million payment, and the DOJ has agreed not to prosecute the Company in return for compliance with the terms of the three-year Deferred Prosecution Agreement.

In addition, the Company entered into a civil Settlement Agreement with the DOJ and OIG, or the Settlement Agreement, dated February 9, 2009. The Settlement Agreement involves the referral programs and allegations that, where physicians performed a nerve conduction study using the NC-stat System and did not obtain an F-wave measurement, in limited circumstances, the Company caused physicians to seek reimbursement using the slightly higher valued 95903 CPT code payable for nerve conduction studies where an F-wave measurement is obtained, rather than the 95900 CPT code. While the Company did not admit to the allegations with respect to the F-wave coding issue, the Company agreed to pay \$2.5 million to settle this dispute and enter into a five-year Corporate Integrity Agreement with OIG. The Company remains fully eligible to participate in all federal health care programs.

The settlement payments discussed above in the total amount of \$3.7 million were paid in the first quarter of 2009.

#### 10. Joint Venture with Cyberkinetics

In February 2008, the Company and Cyberkinetics formed PNIR and entered into a Collaboration Agreement and Operating Agreement to develop and commercialize products for the treatment of peripheral nerve injury. The joint venture was initially 50% owned by the Company and 50% owned by Cyberkinetics. Under the terms of the joint venture, the Company had agreed to fund the initial \$2.0 million in product development costs and the Company and Cyberkinetics were to share equally in all costs in excess of the initial \$2.0 million. Cyberkinetics had contributed technology, know-how and intellectual property, primarily relating to their Andara OFS technology, to the joint venture (See Note 5 Goodwill and Intangible Assets).

The joint venture was considered to be a variable interest entity under the provisions of the Consolidation Topic of the Codification. The Company had determined that it was the primary beneficiary based on a review of the relative economic risks of the two parties to the joint venture. As a result, the Company had consolidated the joint venture and recorded the \$2.1 million contribution of technology and intellectual property by Cyberkinetics to intangible assets. The joint venture was

## Notes to Unaudited Financial Statements (Continued)

#### September 30, 2009

# 10. Joint Venture with Cyberkinetics (Continued)

dissolved in January 2009, effective as of December 31, 2008, and was deconsolidated from the Company's financial statements at that date.

Cyberkinetics had agreed to nominate and recommend to their stockholders for election to their board of directors a representative designated by the Company. Dr. Shai Gozani M.D. Ph.D., our Chief Executive Officer and President, had been named as our initial designee. The former president of Cyberkinetics joined the Company's Board of Directors in April 2009.

## **11. Discontinued Operations**

On September 30, 2008, as part of the Company's ongoing focus on cost-efficiencies in all areas of its business, and its refocused efforts towards its core business, which is the sale of the ADVANCE System and support for its existing NC-stat System customers, the Company approved a plan for the closure of its facility in Columbia, Maryland and to discontinue sales and support of DigiScopes and DigiScope related services, effective November 1, 2008. On November 7, 2008, the Company sold substantially all of the assets related to the DigiScope business to Advanced Diagnostics, LLC in exchange for assuming certain identified commitments of approximately \$400,000 and a cash payment of \$50,000. The CEO and President of Advanced Diagnostics, LLC is a former executive of the Company who continued to receive payments under a separation agreement with the Company through February 2009.

The Company has classified the results of operations of the DigiScope activity as discontinued operations in the accompanying financial statements, for all periods presented. The loss from discontinued operations for the quarter and nine months ended September 30, 2008 consisted of the following:

	Quarter Ended September 30, 2008			line Months Ended eptember 30, 2008
Net revenue	\$	203,315	\$	930,951
Cost of goods sold		(176,956)		(545,788)
Research and development		(138,218)		(531,354)
Sales and marketing				(166,841)
General and administrative		(329,976)		(1,259,590)
Asset impairment and restructuring charge		(4,960,151)		(4,960,151)
Amortization of intangibles		(140,000)		(420,000)
Net loss from discontinued operations	\$	(5,541,986)	\$	(6,952,773)

There was no activity for DigiScope for the quarter and nine months ended September 30, 2009.

#### 12. Restructuring Related Activity

In May 2008, the Company implemented a plan to reduce the size of its direct sales force and to take certain other actions to reduce its operating expenses, largely as a result of a decline in revenues.

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

#### September 30, 2009

#### 12. Restructuring Related Activity (Continued)

These actions affected 24 positions, substantially all of which were in sales. The total cost associated with these actions, including severance and benefit costs, was \$318,981.

Effective May 31, 2008, the Chief Operating Officer of the Company entered into a separation agreement with the Company. Under the terms of the separation agreement, he received continuation of his salary, car allowance, and health benefits for nine months following the effectiveness of his resignation, equal to \$217,970, which was recorded during the quarter ended March 31, 2008 under the provisions of the Compensation-Nonretirement Postemployment Benefits Topic of the Codification. In addition, he received a lump sum payment equal to three months salary and car allowance totaling \$69,810, which we recorded during the quarter ended June 30, 2008 under the provisions of Exit or Disposal Cost Obligations Topic of the Codification.

The following table provides a rollforward of the liability balance for the action taken, substantially all of which was recorded as sales and marketing expense on the Company's Consolidated Statement of Operations, the balance of which was paid out in semi-monthly installments through February 28, 2009.

	Quarter Ended September 30, 2008			ine Months Ended ptember 30, 2008
Balance at beginning of period	\$	229,621	\$	
Accrual for severance(1)				606,761
Severance payments made(1)		(108,526)		(485,666)
Other exit costs(2)		111,083		111,083
Balance at end of period	\$	232,178	\$	232,178

(1)

Direct sales force reduction.

#### (2)

DigiScope

#### 13. 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. The warrants are exercisable at any time six months after the closing date through the fifth anniversary of the closing date. The warrants have an exercise price of \$2.20 per share, reflecting a 10% premium over the

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

#### September 30, 2009

## 13. Equity (Continued)

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 (See Note 14 Subsequent Event).

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 has reflected these warrants as a liability in the Balance Sheet. The fair value of the warrants at the issuance date was estimated using the Black-Scholes model. The 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 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 is presented as a long term liability in the accompanying 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. The Company will revalue unexercised warrants at each reporting period over the life of the warrants using the Black-Scholes model and the changes in the fair value of the warrants will be recognized in the Company's statement of operations (See Note 14 Subsequent Event).

As part of the offering, the Company entered into a registration payment arrangement, which is a contingent obligation to make future payments or otherwise transfer consideration that should be separately recognized and measured in accordance with the Contingencies Topic of the Codification. The Company agreed to register the shares of common stock issued in the offering, the shares of common stock underlying the warrants issued to the investors, and certain shares currently owned by two of the Company's significant stockholders who invested in the private placement with the SEC within a contractually specified time period and the Company has filed a registration statement covering all required shares. The Company has also agreed to use its best efforts to keep the registration statement continuously effective. If the Company fails to have a registration statement(s) declared effective within the timeframes specified in the securities purchase agreements or is unable to keep the registration statement(s) continuously effective in accordance with the terms of the securities purchase agreements, it is subject to liquidated damages of up to a maximum of 12% of the purchase

## Notes to Unaudited Financial Statements (Continued)

## September 30, 2009

## 13. Equity (Continued)

price of shares issued under the offering. The Company has ascribed no value to the registration payment arrangement as of September 30, 2009 because they are not deemed to be probable of payment.

### 14. Subsequent Event

In October 2009, the Company executed addendums to the warrants issued in connection with the securities purchase agreements of September 8, 2009 (See Note 13 Equity). The addendums revise 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.

## 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 refers to NeuroMetrix, Inc.

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

This Quarterly Report on Form 10-Q contains "forward-looking statements" intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. You can identify these statements by the fact that they do not relate strictly to historical or current facts. They contain words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "may," "could," "might," and other words or phrases of similar meaning and include, without limitation, discussions of future actions or objectives, development and acquisition plans, strategies, future performance, the outcome of contingencies such as legal proceedings, and future financial results. Although these forward-looking statements reflect our good-faith belief and reasonable judgment based on current information, these statements involve a number of risks and uncertainties, many of which are beyond our control, which could cause our actual results to differ materially from those suggested by the 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, 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, or SEC. Given these risks and uncertainties, you should not place undue reliance on any such forward-looking statements in this Quarterly Report on Form 10-Q, which speak only as of the date hereof. Except as required by law, we assume no obligation to update these forward-looking statements, even though our situation may change in the future. All future written and verbal forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to and in our reports filed with or furnished to the SEC.

#### Overview

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

We have two medical devices cleared by the United States Food and Drug Administration, or FDA, which are used for the assessment of neuropathies. The NC-stat System is a point-of-care device for the performance of nerve conduction studies. The NC-stat System, our initial product for the assessment of neuropathies, has been sold historically to a broad group of physicians, including primary care physicians and specialists since its initial market launch in May 1999. The NC-stat System is



comprised of: (1) single use nerve-specific electrodes, (2) the NC-stat device and related components, and (3) the NC-stat docking station, an optional device that enables the physician's office to transmit data to our onCall Information System. The ADVANCE NCS/EMG System, or the ADVANCE System, is a comprehensive platform for the performance of traditional nerve conduction studies and invasive electromyography procedures. This system is used primarily by neurologists, physical medicine and rehabilitation, or PM&R physicians, neurosurgeons, orthopedic and hand surgeons, and pain medicine physicians. The ADVANCE System is comprised of: (1) various types of electrodes and needles, (2) the ADVANCE device and related modules, and (3) a communication hub that enables the physician's office to network their device to our servers for data archiving, report generation, and other network services. Our neurodiagnostic equipment is used in approximately 5,000 physicians' offices, clinics, and hospitals. Over one and a half million patients have been tested with our neurodiagnostic equipment since 1999.

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

## **Business Developments**

On September 8, 2009, we completed an equity financing under which we sold 8,816,521 shares of our common stock and warrants to purchase 8,375,694 shares of common stock. In addition, the placement agents were issued warrants to purchase an aggregate of 207,188 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. This financing strengthened our balance sheet and provided us greater operating flexibility. See Note 13 Equity and Note 14 Subsequent Event of the Notes to Unaudited Financial Statements for additional information regarding the warrants.

On October 30, 2009 the Centers for Medicare and Medicaid Services, or CMS, published the Physicians Fee Schedule for 2010 which included a new Category I code for nerve conduction studies performed with pre-configured electrode arrays such as are utilized with the NC-stat device. We believe that physicians using the NC-stat device will find the new code useful and supportive of their efforts to deliver optimal patient care.

We advanced our new product pipeline during the quarter ended September 30, 2009. "Vantage", our successor to NC-stat, continued forward in the development process toward a target commercial launch in 2010 following certain development and regulatory milestones. Vantage is designed to facilitate nerve conduction studies by primary care physicians and other non-specialists. It will be backwards compatible with our current pre-configured electrodes and will include additional productivity enhancing features.

"ASCEND", another device under development is 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 CTS. During the quarter ended September 30, 2009, we received 510(k) clearance on the ASCEND stimulator. Commercial launch is targeted for the second half of 2010 pending certain regulatory milestones.

"Andara" is our implantable stimulator for spinal nerve repair. The FDA recently provided greater clarity on the clinical requirements for approval. Our next step would be to design and conduct a clinical trial targeting the same safety and efficacy endpoints as the original study but with a larger sample size.



Regarding our pharmacologic compounds for neural conduction enhancement, we are developing our lead compound NM101 for use in chronic spinal cord injury. Our plan is to move the compound through a Phase 1 clinical trial and then evaluate strategic options. We are presently performing the pre-clinical work required to file an investigational new drug application with the FDA.

Reimbursement from third-party payers is an important element of success for medical device companies. Over the last several years, physicians using NC-stat have experienced and may continue to experience challenges from third-party payers and governmental agencies regarding the reimbursement of nerve conduction studies performed using this device. A number of third-party payers, including commercial payers, have taken and may continue to take the position of not reimbursing our customers for procedures performed using the NC-stat System. We believe that the 2010 Physicians Fee Schedule published by CMS on October 30, 2009, which included a new Category I code for nerve conduction studies performed with pre-configured electrode arrays could improve reimbursement clarity for physicians using our NC-stat Systems. However, it will likely take time to achieve broad physician awareness of the code, for uniform implementation of the code throughout the Medicare system, and for the reimbursement effects, if any, of the Medicare code to be realized among third party payers. While we are unable to predict either the timing of these events or the ultimate effects on third party payers, we believe that the new code is a benefit to our business and that physicians using NC-stat will find the code useful and supportive of their efforts to deliver optimal patient care.

#### **Discontinued** Operations

On September 30, 2008, we approved a plan for the closure of our facility in Columbia, Maryland and to discontinue sales and support of DigiScopes and DigiScope related services, effective November 1, 2008. On November 7, 2008, we sold substantially all of the assets related to the DigiScope business to Advanced Diagnostics, LLC in exchange for assuming certain identified commitments of approximately \$400,000 and a cash payment of \$50,000. Total revenues of discontinued operations and loss from discontinued operations for the quarter ended September 30, 2008 were \$203,000 and \$5.5 million, respectively. Total revenues of discontinued operations and loss from discontinued operations for the nine months ended September 30, 2008 were \$931,000 and \$7.0 million, respectively.

## **Results of Operations**

## Comparison of Quarters Ended September 30, 2009 and 2008

#### Revenues:

Medical equipment revenues consisting of the NC-stat and ADVANCE systems, related modules, and extended service agreement revenues, were \$726,000 and \$417,000 for the quarters ended September 30, 2009 and 2008, respectively, an increase of \$309,000. This reflects an increase in sales of higher priced ADVANCE units, including a large order of \$280,000 for ADVANCE Systems, including consumables, to our distributor in the United Kingdom. We have additional interest from other European sources which we are pursuing. Currently, revenue on sales to distributors is recorded on a "sell in" basis, wherein revenue is recorded when product is shipped to the distributor.

Consumables revenues, consisting of single use nerve specific electrodes, EMG needles, and other accessories were \$5.6 million and \$6.7 million for the quarters ended September 30, 2009 and 2008, respectively, a decrease of \$1.1 million. This decrease primarily reflects a decline in patient studies performed with NC-stat Systems, and a corresponding decline in electrodes used and sold. Factors contributing to the decline include the overall state of the economy resulting in an overall reduction in health care purchasing and higher unemployment levels and loss of insurance coverage contributing to fewer patient visits, as well as continued uncertainty surrounding reimbursement.



## Cost of revenues

Our overall cost of revenues decreased to \$1.8 million, or 28.9% of revenues, for the quarter ended September 30, 2009, compared to \$2.1 million, or 29.4% for the same period in 2008. This decrease in cost of revenues is a result of lower volume and manufacturing efficiencies, while product mix has remained consistent. Overall gross margin of 71.1% in the third quarter of 2009 was consistent with the prior year quarter overall gross margin of 70.6%.

## Research and Development

Our research and development expenses include expenses associated with our research, product development, clinical, regulatory, and quality assurance departments.

Research and development expenses of \$1.5 million for the quarter ended September 30, 2009 were up slightly from \$1.4 million for the same period in 2008. The increase was primarily attributable to spending on our pharmacologic compounds for neural conduction enhancement.

## Sales and Marketing

Our sales and marketing expenses include expenses from the marketing, field sales, sales administration, and inside sales departments.

Sales and marketing expenses were up slightly at \$2.8 million for the quarter ended September 30, 2009 versus \$2.7 million for the same period in 2008. The increase was primarily due to \$234,000 in additional employee compensation reflecting a revision to the sales staff compensation structure to place an increased emphasis on base salary, and recruiting costs partially offset by a \$67,000 decrease in travel and entertainment costs.

## General and Administrative

Our general and administrative expenses include expenses from the executive, finance, administrative, customer service, and information technology departments.

General and administrative expenses decreased \$1.1 million to \$2.1 million for the quarter ended September 30, 2009 from \$3.2 million for the same period in 2008. The decrease reflected a drop of \$560,000 for legal fees following resolution of the DOJ and the OIG cases and a \$157,000 reduction in bad debt expense.

## Loss on available-for-sale investment

In November 2007, we purchased approximately 5.4 million shares of common stock of Cyberkinetics, representing approximately 13% of Cyberkinetics' issued and outstanding shares at the time of the investment, at a price of \$0.46 per share. We marked this investment to market as of September 30, 2008 and recorded a \$169,000 charge during the third quarter of 2008 because we believed the investment had experienced a decline in value that was other-than-temporary. The investment was fully impaired as of December 31, 2008.

#### Interest Income

Interest income was \$52,000 and \$124,000 for the quarters ended September 30, 2009 and 2008, respectively. Interest income was earned from investments in cash equivalents and short-term investments. The decrease reflects lower average invested balances as well as lower interest rates.



#### Warrants fair value adjustment

Warrants fair value adjustment is the charge required to adjust the liability for outstanding warrants to fair value. 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 has executed addendums to the warrants issued in connection with the securities purchase agreements of September 8, 2009 (See Note 14 Subsequent Event). The addendums revise 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.

## Comparison of Nine Months Ended September 30, 2009 and 2008

## Revenues:

Medical equipment revenues consisting of the NC-stat and ADVANCE devices, related modules, and extended service agreement revenues, were \$2.1 million and \$1.7 million for the nine months ended September 30, 2009 and 2008, respectively, an increase of \$400,000, or 26.8%. This reflects increased sales of higher priced ADVANCE units and international sales.

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 \$17.8 million and \$22.3 million for the nine months ended September 30, 2009 and 2008, respectively, a decrease of \$4.5 million. This decrease reflects a decline in patient studies performed with NC-stat and ADVANCE, and a corresponding decline in electrodes used and sold. Factors contributing to the decline include the overall state of the economy resulting in an overall reduction in health care purchasing and higher unemployment levels contributing to fewer patient visits, as well as continued uncertainty surrounding reimbursement.

## Cost of revenues

Our overall cost of revenues decreased to \$5.7 million, or 28.6% of revenues, for the nine months ended September 30, 2009, compared to \$6.7 million, or 28.0% of revenues for the same period in 2008. Gross margin declined to 71.4% of revenues in 2009 from 72.0% of revenues in 2008. The 2009 gross margin was adversely affected by a total of \$251,000 of inventory obsolescence charges during 2009.

## Research and Development

Research and development expenses decreased \$137,000 to \$4.2 million for the nine months ended September 30, 2009 from \$4.4 million for the same period in 2008. The decrease reflected lower employee compensation of \$117,000 and a \$210,000 decrease in the amortization of intangible assets, partially offset by a \$161,000 increase in development spending on our pharmacologic compounds.



#### Sales and Marketing

Sales and marketing expenses decreased \$3.9 million to \$8.2 million for the nine months ended September 30, 2009 from \$12.2 million for the same period in 2008. The decrease reflected savings of \$2.8 million in employee compensation due to the reduction of the size of our direct sales force in May 2008 and further savings of \$455,000 in travel and entertainment, \$221,000 in advertising and promotion, \$212,000 in consulting, and \$156,000 in shipping. These decreases were partially offset by a \$298,000 increase in recruiting fees.

#### General and Administrative

General and administrative expenses decreased \$3.2 million to \$6.8 million for the nine months ended September 30, 2009 from \$10.0 million for the same period in 2008. The decrease was due to \$1.7 million in reduced legal fees largely related to the DOJ and OIG cases which were settled in the first quarter of 2009, \$304,000 in lower taxes, licenses, and fees, \$327,000 in lower employee compensation, \$266,000 in lower bad debt expense, and \$122,000 in reduced insurance costs.

#### Charge for impaired goodwill

As of March 31, 2008, our publicly traded market value was significantly below our net book value. Therefore, we determined that an interim goodwill impairment test was required. As the net book value of our assets exceeded the enterprise value, we performed step two of the impairment test pursuant to the Intangibles Goodwill and Other Topic of the Financial Accounting Standards Board Accounting Standards Codification impairment test in which we assessed the fair value of all recorded and unrecorded tangible and intangible assets and liabilities, including EyeTel Imaging, Inc. and PNIR (Peripheral Nerve Injury Repair) LLC, or PNIR, intangibles. We determined that no assets were impaired and determined that there was no residual value of goodwill. Accordingly, we recorded a charge of \$5.8 million to write off goodwill during the quarter ended March 31, 2008.

## Loss on available-for-sale investment

In November 2007, we purchased approximately 5.4 million shares of common stock of Cyberkinetics, representing approximately 13% of Cyberkinetics' issued and outstanding shares at the time of the investment, at a price of \$0.46 per share. We marked this investment to market as of September 30, 2008 and recorded year to date charges of \$2.2 million for the nine months ended September 30, 2008 because we believed the investment had experienced a decline in value that was other-than-temporary. The investment was fully impaired as of December 31, 2008.

#### Interest Income

Interest income was \$189,000 and \$618,000 for the nine months ended September 30, 2009 and 2008, respectively. Interest income was earned from investments in cash equivalents and short-term investments. The decrease is primarily due to lower average invested balances, as well as lower interest rates.

#### Warrants fair value adjustment

Warrants fair value adjustment is the charge required to adjust the liability for outstanding warrants to fair value. The fair value of the warrants issued in the September 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.



# Edgar Filing: NeuroMetrix, Inc. - Form 10-Q

## Table of Contents

In October 2009, the Company has executed addendums to the warrants issued in connection with the securities purchase agreements of September 8, 2009 (See Note 14 Subsequent Event). The addendums revise 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 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.

## Liquidity and Capital Resources

On September 8, 2009, we completed an equity financing 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.

Our principal source of liquidity is our current cash, cash equivalents, and short-term investments. As of September 30, 2009, these totaled \$32 million. The weighted average maturity of our short-term investments was 190 days. 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. A 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. The following sets forth information relating to our liquidity:

	2009			December 31, 2008 (\$ in thousands)		Change	% Change	
Cash and cash equivalents	\$	22,037.0	\$	12,302.3	\$	9,734.7	79.1%	
Short-term investments		9,995.0		7,495.0		2,500.0	33.4	
Total cash, cash equivalents, and short-term investments	\$	32,032.0	\$	19,797.3	\$	12,234.7	61.8%	

During the first nine months of 2009, our cash, cash equivalents, and short-term investments increased by \$12.2 million, primarily due to the equity financing net proceeds of \$17.3 million, partially offset by net cash used in operating activities of \$4.7 million (which included a one-time legal settlement with DOJ and OIG of \$3.7 million). In addition, we invested \$350,000 to acquire certain technology assets from Cyberkinetics and we acquired \$237,000 of fixed assets.

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, 2009 and 2008, and the year ended December 31, 2008:

	Quarter Septem		Year Ended December 31,
	2009	2008	2008
Days sales outstanding	49	55	54
Inventory turnover rate (times per year)	1.5	1.3	1.6

Payment terms extended to our customers generally require payment within 30 days from invoice date. The improvement in DSO from December 31, 2008 to September 30, 2009 is a reflection of increased collection efforts. Accounts payable are normally paid within 30 to 40 days from receipt of a vendor's invoice.



Our inventory turnover rate improved for the quarter ended September 30, 2009 to 1.5 times per year compared with 1.3 times per year in the comparable 2008 quarter.

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

	Nine Months Ended September 30,					
	2009 2008			2008		
		(\$ in thousands)				
Net cash used in operating activities	\$	(4,693.0)	\$	(9,051.3)		
Net cash (used in) provided by investing activities		(3,086.6)		23,455.7		
Net cash provided by financing activities		17,514.4		90.5		

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 current cash, cash equivalents, and short-term investments, and the cash to be generated from expected product sales will be sufficient to meet our projected operating requirements into 2011.

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

As of September 30, 2009, we did not have any off-balance sheet financing arrangements.

#### **Recent Accounting Pronouncements**

See Note 1 "Business and Basis of Presentation" of the Notes to Unaudited Financial Statements for a discussion of recent accounting pronouncements.

#### 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 4T. Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

Our management carried out an evaluation, with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of September 30, 2009. Our disclosure controls and procedures are designed to provide reasonable assurance 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 that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, to allow timely decisions regarding required disclosures.

# Edgar Filing: NeuroMetrix, Inc. - Form 10-Q

## Table of Contents

Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer have concluded that they believe the disclosure controls and procedures were effective, as of the end of the period covered by this report, in providing reasonable assurance 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 financial officers, as appropriate to allow timely decisions regarding required disclosures. We continue to review and document our disclosure controls and procedures, including our internal controls over financial reporting, and may periodically make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II OTHER INFORMATION

## Item 1. Legal Proceedings

As previously disclosed in our filings with the Securities and Exchange Commission, or 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 us and certain of our 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 alleges, among other things, that between October 27, 2005 and February 12, 2008, 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 are seeking unspecified damages. On January 30, 2009, we 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. In March 2009, the parties mutually agreed to participate in mediation to attempt to resolve the litigation, and the court entered an order staying the proceedings. The mediation did not resolve the litigation, and plaintiffs opposed defendants' motion to dismiss on July 20, 2009. The defendants filed their reply brief in further support of their motion to dismiss the amended complaint on July 31, 2009.

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.

As previously disclosed in our 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 our 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 plaintiffs are seeking various forms of monetary and non-monetary relief. In March 2009, the parties agreed to participate in mediation to attempt to resolve the litigation. The parties have reached an agreement in principle to resolve the shareholder derivative action, subject to court approval, among other conditions, and on October 30, 2009 filed a joint motion with the court to stay all proceedings pending finalization of the settlement. The proposed settlement amount is within the coverage limits of the Company's insurance program.

As previously disclosed in the Company's filings with the SEC, on February 9, 2009, the Company announced that it had reached a resolution with the United States Department of Justice, or DOJ, and the Office of Inspector General, or OIG, of the United States Department of Health and Human Services regarding the previously-disclosed investigation into certain of the Company's past sales and marketing practices relating to its NC-stat System.

As part of the resolution, the Company entered into a Deferred Prosecution Agreement, or the Deferred Prosecution Agreement, dated February 5, 2009, with the DOJ related to its operation of marketing referral programs. Pursuant to the Deferred Prosecution Agreement, the Company agreed to a \$1.2 million payment, and the DOJ has agreed not to prosecute the Company in return for compliance with the terms of the three-year Deferred Prosecution Agreement.

In addition, the Company entered into a civil Settlement Agreement with the DOJ and OIG, or the Settlement Agreement, dated February 9, 2009. The Settlement Agreement involves the referral programs and allegations that, where physicians performed a nerve conduction study using the NC-stat System and did not obtain an F-wave measurement, in limited circumstances, the Company caused

physicians to seek reimbursement using the slightly higher valued 95903 CPT code payable for nerve conduction studies where an F-wave measurement is obtained, rather than the 95900 CPT code. While the Company did not admit to the allegations with respect to the F-wave coding issue, the Company agreed to pay \$2.5 million to settle this dispute and enter into a five-year Corporate Integrity Agreement with OIG. The Company remains fully eligible to participate in all federal health care programs.

The settlement payments discussed above in the total amount of \$3.7 million were paid in the first quarter of 2009.

## Item 1A. Risk Factors

Other than the additional risk factor detailed below, there have been no material changes in the risk factors described in "Item 1A Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2008 and factors described in our other public filings, except to the extent additional factual information disclosed elsewhere in this Quarterly Report on Form 10-Q relates to such risk factors.

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

Widespread adoption of our products by the medical community is unlikely to occur if physicians do not receive sufficient reimbursement from third-party payers for performing procedures using our products. If physicians are unable to obtain adequate reimbursement for procedures performed using our products, we may be unable to sell our products and our business would suffer significantly. Additionally, even if these procedures are reimbursed by third-party payers, adverse changes in payers' policies toward reimbursement for the procedures would harm our ability to market and sell our products. Third-party payers include those governmental programs such as Medicare and Medicaid, workers' compensation programs, private health insurers and other organizations. These organizations may deny coverage if they determine that a procedure was not reasonable or necessary, for example, if its use was not considered medically appropriate, or was experimental, or was performed for an unapproved indication. In addition, some health care systems are moving towards managed care arrangements in which they contract to provide comprehensive health care for a fixed cost per person, irrespective of the amount of care actually provided. These providers, in an effort to control health care costs, are increasingly challenging the prices charged for medical products and services and, in some instances, have pressured medical suppliers to lower their prices. If we are pressured to lower our prices, our revenues may decline and our profitability could be harmed. The Centers for Medicare & Medicaid Services, or CMS, guidelines set the reimbursement rates for procedures covered by Medicare. Future regulatory action by CMS or other governmental agencies or negative clinical results may diminish reimbursement payments to physicians for performing procedures using our products. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not reimburse physicians for performing procedures using our products in an adequate amount, if at all. Additionally, some private payers do not follow the CMS and Medicaid guidelines and may reimburse for only a portion of these procedures or not at all. We are unable to predict what changes will be made in the reimbursement methods used by private or governmental third-party payers.

On October 30, 2009 the Physician Fee Schedule for 2010 was published by the CMS and included a new category I CPT code for nerve conduction studies performed with preconfigured electrode arrays such as are utilized with the NC-stat System. It will likely take time to achieve broad physician awareness of the code, for uniform implementation of the code throughout the Medicare system, and for the reimbursement effects, if any, of the Medicare code to be realized among third party payers. We are unable to predict either the timing of these events or their ultimate effects on third party payers.



# Edgar Filing: NeuroMetrix, Inc. - Form 10-Q

## Table of Contents

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

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

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.

Proceeds from the transaction are expected to be used to expand the Company's direct U.S. sales force, increase its international presence, fund certain clinical outcome studies, advance its lead potassium channel blocker compound to a Phase I milestone, as well as for other general working capital purposes.

## Item 3. Defaults Upon Senior Securities

None.

## Item 4. Submission of Matters to a Vote of Security Holders.

None.

## 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.

/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

Date: November 12, 2009

## EXHIBIT INDEX

## Exhibit No.

Description

- 4.1 First Amendment to Shareholder Rights Plan, dated September 8, 2009. Filed as Exhibit 4.1 to our Current Report on Form 8-K (File No. 001-33351) dated September 8, 2009 and incorporated herein by reference.
- 4.2 Form of warrant to purchase shares of common stock. Filed as Exhibit 4.2 to our Current Report on Form 8-K (File No. 001-33351) dated September 8, 2009 and incorporated herein by reference.
- 10.1<sup>+</sup> Third Amended and Restated 2004 Stock Option and Incentive Plan(1)
- 10.2 Form of Securities Purchase Agreement. Filed as Exhibit 10.1 to our Current Report on Form 8-K (File No. 001-33351) dated September 8, 2009 and incorporated herein by reference.
- 10.3 Form of First Addendum to Stock Purchase Warrant. Filed herewith.
- 31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
- 31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Filed herewith.
- 32 Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. Furnished herewith.

+

(1)

Incorporated herein by reference to Appendix A to NeuroMetrix, Inc.'s Proxy Statement on Schedule 14A filed April 24, 2009 (File No. 001-33351).

Indicates a management contract or any compensatory plan, contract, or arrangement.