UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2004

Commission file number 000-50856

NEUROMETRIX, INC.

(Exact name of registrant as specified in its charter)

Delaware 04-3308180

(State or other jurisdiction of incorporation or organization)

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

62 Fourth Avenue, Waltham, Massachusetts

Controls and Procedures

Item 4.

02451 (Zip Code)

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(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 ⊠ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes o No ⊠

APPLICABLE ONLY TO CORPORATE ISSUERS

Indicate the number of shares outstanding of each of the issuer's classes of common stock as of the latest practicable date:

12,025,119 shares of common stock, par value \$0.0001 per share, were outstanding as of November 9, 2004

NEUROMETRIX, INC. FORM 10-Q INDEX

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NeuroMetrix, Inc. Balance Sheets

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	September 30, 2004			December 31, 2003
		(Unaudited)		
Assets				
Current assets:	ф	20 642 642	ф	4 CDD E4C
Cash and cash equivalents	\$	30,642,612	\$	1,622,516
Accounts receivable, net of allowance for doubtful accounts of \$300,000 at September 30, 2004 and		2.025.040		4 054 000
December 31, 2003		2,927,840		1,851,983
Inventory		1,323,915		1,078,390
Prepaid expenses and other current assets		307,988		217,165
Current portion of deferred costs		125,561		115,978
Total current assets		35,327,916		4,886,032
Restricted cash		1 007 200		1 907 200
		1,897,200		1,897,200
Fixed assets, net		697,085		339,224
Deferred costs	ф	121,476	Φ.	95,325
Total assets	\$	38,043,677	\$	7,217,781
Liabilities, Warrants for Redeemable Convertible Preferred Stock, Redeemable Convertible Preferred				
Stock and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	\$	978,261	\$	434,385
Accrued expenses	Ψ	1,408,373	Ψ	937,075
Current portion of long-term debt		1,400,575		515,236
Current portion of deferred revenue		329,258		245,447
Total current liabilities		2,715,892		2,132,143
Total Current natimities		2,713,032		2,132,143
Long-term debt		_		2,046,986
Deferred revenue		370,751		211,676
Other long-term liabilities		188,182		185,454
Total liabilities		3,274,825	_	4,576,259
Commitments and contingencies (Note 7)				
Warrants for redeemable convertible preferred stock		_		450,100
Redeemable convertible preferred stock (liquidation preference of \$55,675,459 at December 31, 2003)				47,693,742
Constitution, and the Addition				
Stockholders' equity (deficit):				
Common stock, \$0.0001 par value; 50,000,000 and 30,000,000 shares authorized at September 30, 2004 and				
December 31, 2003 respectively, 12,025,119 and 1,042,990 shares issued and outstanding at September 30,		4.000		10.1
2004 and December 31, 2003, respectively		1,203		104
Additional paid-in capital		92,234,428		(2.442)
Subscriptions receivable		(022.55.4)		(2,143)
Deferred compensation		(823,774)		(598,933)
Accumulated deficit		(56,643,005)		(44,901,348)
Total stockholders' equity (deficit)		34,768,852		(45,502,320)
Total liabilities, warrants for redeemable convertible preferred stock, redeemable convertible preferred stock and	ď	20.042.655	¢	7 247 704
stockholders' equity (deficit)	\$	38,043,677	\$	7,217,781

The accompanying notes are integral part of these financial statements.

NeuroMetrix, Inc. Statements of Operations (Unaudited)

	Three Months Ended			Nine Months Ended				
	S	eptember 30, 2004	September 30, 2003		5	September 30, 2004	9	September 30, 2003
		2004	_	2003		2004		2003
Revenues:								
Diagnostic device	\$	614,565	\$	349,592	\$	1,502,482	\$	1,002,082
Biosensor		4,204,753		2,237,102		10,643,118		5,295,144
Total revenues		4,819,318		2,586,694		12,145,600		6,297,226
Cost of revenues		1,290,243		759,089		3,287,873		1,874,077
Gross margins		3,529,075		1,827,605		8,857,727		4,423,149
Operating expenses:								
Research and development (1)		942,913		592,989		2,434,792		1,666,600
Sales and marketing (1)		2,037,840		1,227,682		5,634,389		3,441,899
General and administrative (1)		1,306,172		762,179		3,347,124		2,010,057
Total operating expenses		4,286,925		2,582,850		11,416,305		7,118,556
Loss from operations		(757,850)		(755,245)		(2,558,578)		(2,695,407)
Interest income		51,629		2,779		70,166		19,637
Interest expense		(666,674)		(28,792)		(960,404)		(38,850)
Net loss		(1,372,895)		(781,258)		(3,448,816)		(2,714,620)
Accretion of redeemable convertible preferred stock		(190,874)		(502,361)		(1,386,301)		(1,507,083)
Deemed dividend on redeemable convertible preferred stock		_		_		(787,885)		_
Beneficial conversion feature associated with redeemable convertible						(= 0=0 == t)		
preferred stock			_			(7,050,771)		<u> </u>
Net loss attributable to common stockholders	\$	(1,563,769)	\$	(1,283,619)	\$	(12,673,773)	\$	(4,221,703)
The 1000 didibation to common discinistration		(1,000,700)		(1,200,010)	<u> </u>	(12,075,775)	<u> </u>	(1,==1,7 00)
Net loss per common share (basic and diluted)	\$	(0.18)	\$	(1.24)	\$	(3.46)	\$	(4.07)
Weighted average shares used to compute basic and diluted net loss		8,819,558		1 020 615		3,660,515		1 027 040
per common share		0,019,550		1,038,615		3,000,515		1,037,940
(1) Non-cash stock-based compensation expense incl	uded i	n these amounts	are	as follows:				
Research and development	\$	21,549	\$	8,258	\$	227,814	\$	17,758
Sales and marketing		48,939	•	9,575		320,020		23,942
General and administrative		69,140		6,591		402,074		12,220
Total non-cash stock based compensation	\$	139,628	\$	24,424	\$	949,908	\$	53,920
	_	_						_

The accompanying notes are integral part of these financial statements.

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NeuroMetrix, Inc. Statements of Cash Flows (Unaudited)

	Nine Months Ended			
	September 30, 2004		S	September 30, 2003
Cash flow for operating activities:				
Net loss	\$	(3,448,816)	\$	(2,714,620)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		145,219		165,987
Compensation expense associated with stock options		949,908		53,920
Accrued payments on long-term debt		_		1,528
Accretion of debt issuance discount		437,778		_
Changes in operating assets and liabilities:				
Accounts receivable		(1,075,857)		(1,169,130)
Inventory		(245,525)		(248)
Prepaid expenses and other current assets		(90,823)		(35,196)
Accounts payable		543,876		378,200
Accrued expenses		470,049		215,423

Other long-term liabilities	2,728	46,364
Deferred revenue and costs	 207,152	 7,539
Net cash used in operating activities	(2,104,311)	(3,050,233)
Cash flows for investing activities		
Purchases of fixed assets	 (503,080)	 (108,021)
Net cash used in investing activities	(503,080)	(108,021)
Cash flows from financing activities		
Proceeds from exercise of stock options	46,911	2,815
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	10,553,484	_
Proceeds from initial public offering, net of offering costs of \$3,572,908	24,027,092	_
Proceeds from long-term debt	_	1,000,000
Repayments of long-term debt	 (3,000,000)	(7,139)
Net cash provided by financing activities	31,627,487	995,676
Net increase (decrease) in cash and cash equivalents	29,020,096	(2,162,578)
Cash and cash equivalents, beginning of period	1,622,516	2,700,659
Cash and cash equivalents, end of period	\$ 30,642,612	\$ 538,081
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 493,752	\$ 37,322
Relative fair value of warrant issued in connection with note payable	\$ _	\$ 450,100
Accretion of redeemable convertible preferred stock	\$ 1,386,301	\$ 1,507,088
Deemed dividend on redeemable convertible preferred stock	\$ 787,885	\$ _
Beneficial conversion feature associated with redeemable convertible preferred stock	\$ 7,050,771	\$ _

The accompanying notes are integral part of these financial statements.

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NeuroMetrix, Inc. Notes to Financial Statements

1. Nature of the Business and Basis of Presentation

NeuroMetrix, Inc. (the "Company"), a Massachusetts corporation, was formed in June 1996 to utilize proprietary or licensed biomedical engineering and neurophysiology technology developed in the Harvard-M.I.T. Division of Health Sciences and Technology. In May 2001, the Company reincorporated in Delaware.

The Company designs, develops and sells proprietary medical devices used to diagnose neuropathies. Neuropathies are diseases of the peripheral nerves and parts of the spine that frequently are caused by or associated with diabetes, low back pain and carpal tunnel syndrome, as well as other clinical disorders. The Company operates in one business segment.

On July 27, 2004, the Company completed an Initial Public Offering ("IPO") of 3,000,000 shares of its common stock at \$8.00 per share, for gross consideration of \$24 million. All of the shares were sold by the Company. The Company granted the underwriters a 30-day option to purchase up to an additional 450,000 shares of common stock from the Company which the underwriters exercised in full on August 17, 2004. The total net proceeds to the Company of approximately \$24.0 million, after expenses, will be used for the expansion of our sales and marketing activities, research and development activities relating to potential new products, capital expenditures, repayment of our outstanding debt obligations to Lighthouse Capital Partners IV, L.P. and other general corporate purposes. The Company's shares trade on The Nasdaq National Market System under the symbol "NURO."

On July 27, 2004, upon completion of the Company's IPO, all shares of the Company's redeemable convertible preferred stock outstanding on that date converted into 7,488,758 shares of common stock and the outstanding warrant to purchase redeemable convertible preferred stock converted into a warrant to purchase common stock.

The accompanying unaudited balance sheet as of September 30, 2004 and unaudited statements of operations for the three and nine month periods ended September 30, 2004 and 2003 and the unaudited statements of cash flows for the nine month periods ended September 30, 2004 and 2003 have been prepared in accordance with accounting principles generally accepted in the United States 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 for complete financial statements. In the opinion of management, all adjustments (consisting only of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the nine month period ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2003 included in the Company's Registration Statement on Form S-1 (Registration No. 333-115440), as amended (the "Form S-1"). The accompanying balance sheet as of December 31, 2003 has been derived from audited financial statements prepared at that date.

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.

Reverse Stock Split

On June 2, 2004, the Company's Board of Directors approved a 1-for-4 reverse stock split of the Company's issued common stock, subject to stockholder approval, to be effected prior to the IPO. On June 18, 2004, the Company's stockholders approved this reverse stock split. This reverse stock split became effective on July 15, 2004 upon the filing by the Company of an amended and restated certificate of incorporation with the Delaware Secretary of State giving effect to this reverse stock split. Common share and common share-equivalents have been restated to reflect this reverse stock split for all periods presented.

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Recent Accounting Pronouncements

In January 2003, the FASB issued FIN No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51* ("FIN No. 46"). The primary objectives of FIN No. 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights (variable interest entities) and to determine when and which business enterprise should consolidate the variable interest entities. The new model for consolidation applies to an entity which either (1) the equity investors (if any) do not have a controlling financial interest or (2) the equity investment at risk is insufficient to finance the entity's activities without receiving additional subordinated financial support from the other parties. FIN No. 46 also requires enhanced disclosures for variable interest entities. FIN No. 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. The standard as amended by FIN 46R, applies to the first fiscal year or interim period beginning after March 15, 2004 to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. The adoption of FIN No. 46 on April 1, 2004 did not have a material impact on the Company's financial position, results of operations, or cash flows.

In March 2004, the Emerging Issues Task Force ("EITF") reached a consensus on EITF No. 03-06, *Participating Securities and Two-Class Method under FASB Statement No. 128, Earning per Share.* EITF No. 03-06 addresses a number of questions regarding the computation of earnings per share ("EPS") by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the company when, and if, it declares dividends on its common stock. The issue also provides further guidance in applying the two-class method of calculating EPS. It clarifies what constitutes a participating security and how to apply the two-class method of computing EPS once it is determined that a security is participating, including how to allocate undistributed earnings to such a security. The consensuses reached on EITF No. 03-06 is effective for fiscal periods beginning after March 31, 2004. Prior period earnings per share amounts will be restated to conform to the consensuses to ensure comparability year over year. There was no impact resulting from the Company's adoption of EITF No. 03-06 on April 1, 2004.

2. Accounting for Stock-Based Compensation

Employee stock awards granted under the Company's compensation plans are accounted for in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"), and related interpretations. The Company has not adopted the fair value method of accounting for stock-based compensation. Accordingly, compensation expense is recorded for options issued to employees to the extent that the fair value of the Company's common stock exceeds the exercise price of the option at the date granted and all other criteria for fixed accounting have been met. All stock-based awards granted to non-employees are accounted for at their fair value in accordance with SFAS No. 123, as amended, and EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, under which compensation expense is generally recognized over the vesting period of the award.

The Company provides the disclosure requirements of SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure, an amendment of FASB Statement No.* 123 ("SFAS No. 148"). If compensation expense for the Company's stock-based compensation plan had been determined based on the fair value at the grant dates as calculated in accordance with SFAS No. 123, the Company's net loss attributable to common stockholders and net loss per common share would approximate the pro forma amounts below:

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	Three Months Ended					Ended			
	S	September 30, September 30,		September 30, 2003				September 30, 2003	
Net loss attributable to common stockholders, as reported	\$	(1,563,769)	\$	(1,283,619)	\$	(12,673,773)	\$	(4,221,703)	
Add stock-based compensation expense included in reported net									
loss attributable to common stockholders		139,628		24,424		949,908		53,920	
Less stock-based compensation expense determined under fair									
value method		(265,160)		(35,884)		(1,229,163)		(72,752)	
Net loss attributable to common stockholders – pro forma		(1,689,301)		(1,295,079)		(12,953,028)		(4,240,535)	
Net loss per common share (basic and diluted)									
As reported	\$	(0.18)	\$	(1.24)	\$	(3.46)	\$	(4.07)	
Pro forma	\$	(0.19)	\$	(1.25)	\$	(3.54)	\$	(4.09)	

The Company has estimated the fair value of its granted stock options using the following weighted average assumptions:

	Three months	s ended	Nine month	s ended
	ember 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003
Risk-free interest rate	3.6%	3.0%	3.1%-3.9%	3.0%
Expected dividend yield	_	_	_	_
Expected option term	5 years	5 years	5 years	5 years
Volatility	65.0%	0.0%	0%-65.0%	0.0%
Weighted average fair value of options granted	\$ 5.40 \$	1.66 \$	7.01	1.35

Prior to May 13, 2004, the Company applied the minimum value method and did not consider expected volatility of the underlying stock. Subsequent to this date, the Company assumed volatility to be 65%.

The Company amortizes employee stock compensation on a straight line basis over the applicable vesting period, generally four years.

Since options vest over several years and additional option grants are expected to be made in future years, the pro forma effects of applying the fair value method may be material to reported net income or loss in future years.

2. Net Loss Per Common Share

The Company accounts for and discloses net loss per common share in accordance with SFAS No. 128, *Earnings Per Share* ("SFAS No. 128"). Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants (using the treasury stock method) and the weighted average conversion of the redeemable convertible preferred stock into shares of common stock (using the if-converted method).

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The following potentially dilutive, common share equivalents were excluded from the calculation of diluted net loss per common share because their effect was antidilutive for each of the periods presented:

	Three Mont	hs Ended	Nine Month	ıs Ended
	September 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003
Options	1,024,871	483,349	1,024,871	483,349
Warrants	100,000	100,000	100,000	100,000
Redeemable convertible preferred stock	_	5,647,289	_	5,647,289

3. Inventories

Inventory consists of the following:

	Se	eptember 30, 2004	 December 31, 2003
Purchased components	\$	338,370	\$ 238,757
Finished goods		985,545	839,633
Total inventories	\$	1,323,915	\$ 1,078,390

4. Fixed Assets

Fixed assets consist of the following:

	S	eptember 30, 2004	 December 31, 2003	
Computer and laboratory equipment	\$	1,153,738	\$ 847,027	
Furniture and equipment		188,859	186,664	
Production equipment		620,511	352,814	
Construction in progress		7,546	81,069	
Leasehold improvements		19,443	19,443	
		1,990,097	1,487,017	
Less: accumulated depreciation		(1,293,012)	(1,147,793)	
	\$	697,085	\$ 339,224	

5. Other Balance Sheet Items

Accrued expenses consist of the following:

	Sep	ptember 30, 2004	 December 31, 2003
Compensation	\$	790,030	\$ 492,481
Licenses		125,000	100,000
Professional services		117,750	79,866
Other		375,593	264,728
	\$	1,408,373	\$ 937,075

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Estimated product warranty costs are accrued at the time of sale and are included in cost of sales in the statements of operations. The amount of the accrued warranty liability is based on historical information including past experience, user error, variability in physiology and anatomy of customers' patients, product failure rates, number of units repaired and estimated cost of material and labor. Accrued warranty accrual is included in Accrued Expenses.

The following is a rollforward of the Company's accrued warranty liability for the three and nine month periods ended September 30, 2004 and 2003:

	Three Mo	nths Ended	Nine Months Ended			
	September 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003		
Balance at beginning of period	\$ 38,761	9,233	\$ 22,15	1 \$ 2,711		
Accrual for warranties	49,135	33,169	130,43	82,806		
Settlements made	(39,025)	(27,506)	(103,71)	6) (70,621)		
Balance at end of period	\$ 48,871	\$ 14,896	\$ 48,87	1 \$ 14,896		

6. Long-Term Debt

On May 21, 2003, the Company entered into an agreement with Lighthouse Capital Partners IV, L.P. ("Lighthouse") to establish a line of credit for \$3,000,000 ("Line of Credit"). The Company had the ability to draw down amounts under the Line of Credit through December 31, 2003, upon adherence to certain conditions. Upon the final maturity date or the earlier prepayment of each advance, the Company was required to pay, in addition to the paid principal and interest, an additional amount equal to 11% of the original principal, or \$330,000. This additional amount was being accreted over the applicable borrowing period as additional interest expense.

In connection with the Line of Credit, the Company issued Lighthouse a warrant to purchase up to 400,000 shares of Series E-1 preferred stock at an exercise price of \$1.50 per share, for a term of seven years. Upon completion of the Company's IPO, this warrant converted into a warrant to purchase common stock.

On July 29, 2004, the Company paid \$3,123,521 to Lighthouse. This amount represented payment in full of all outstanding obligations under the line of credit with Lighthouse.

7. Commitments and Contingencies Operating Leases

In September 2000, the Company entered into a noncancelable operating lease, commencing January 1, 2001, for new office and laboratory space. The lease expires on March 31, 2009.

Future minimum lease payments under noncancelable operating leases as of September 30, 2004 are as follows:

2004	\$ 202,500
2005	930,000
2006	930,000
2007	930,000
2008	930,000
Thereafter	232,500
Total minimum lease payments	\$ 4,155,000

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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 condensed 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. As a result of many factors, such as those set forth under the section of this Quarterly Report on Form 10-Q titled "Management's Discussion and Analysis of Financial Condition and Results of Operations-Important Factors that May Affect Future Operating Results", our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

NeuroMetrix was founded in September 1996. We design, develop and sell proprietary medical devices that allow all physicians to diagnose neuropathies at the point of service, that is, in the physician's office at the time the patient is examined. Our proprietary technology provides physicians with an in-office diagnostic system, the NC-stat System, which enables physicians to make rapid and accurate diagnoses of neuropathies. The NC-stat System is comprised of: (1) disposable NC-stat biosensors that are placed on the patient's body, used once, and inactivated after use; (2) the NC-stat monitor 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 which formulates the data it receives for each test into a detailed report that is provided to the customer through facsimile or e-mail. Each component of the NC-stat System is also sold separately. The sensitivity of the nervous system to metabolic and mechanical damage, compounded by its limited regenerative ability, creates a robust market opportunity for a medical device that can assist in point-of-service diagnoses of neuropathies in a manner that is cost-effective for the patient and third-party payer. We believe the ease of use, accuracy and convenience provided by the NC-stat System position it to become a standard of care for the assessment of neuropathies at the point of service.

We derive our revenues from the sale of NC-stat biosensors, monitors and docking stations directly to end users, which are generally physicians. Diagnostic device revenues include revenues derived from the sale of our NC-stat monitors and NC-stat docking stations. Biosensor revenues include revenues derived from the sale of various types of disposable biosensors used to perform nerve conduction studies with the NC-stat monitor.

Reimbursement from third-party payers is an important element of success for medical products companies. To date, we believe, that with a few specific exceptions, nearly all of the nerve conduction studies performed by our customers with the NC-stat System have been satisfactorily covered by third-party

payers. However, widespread adoption of the NC-stat System by the medical community is unlikely to occur if physicians do not continue to receive satisfactory reimbursement from third-party payers for procedures performed with the NC-stat System.

One of the primary challenges we face in our business is successfully expanding the market for nerve conduction studies. A successful market expansion will depend upon, in part, our targeting of primary care physicians who traditionally have not been targeted by companies selling equipment used to perform nerve conduction studies and our ability to alter physicians' practices relating to the diagnosis of neuropathies. In order to successfully implement this growth strategy, we are increasing our sales force significantly and our total headcount, and we are participating in various industry conferences in order to accelerate the market awareness and adoption of our products. These efforts, as well as the overall expansion of our business, provide challenges to our organization and may strain our management and operations. We are focused on monitoring our business as it grows and appropriately acquiring and allocating resources to address these issues, with a goal of achieving and sustaining profitability.

Our financial objective is to achieve and sustain profitable growth. Our efforts in 2004 will continue to be focused primarily on expanding our sales and marketing for the NC-stat System and continuing our ongoing program of making enhancements and improvements to the NC-stat System, including the introduction of new biosensors. During the third quarter of 2004, we received FDA 510(k) marketing clearance for our sural nerve biosensor. We expect this disposable biosensor to be a key component of our diabetes and low back pain product offerings. We are also in the early stages of designing a drug delivery system for the minimally invasive treatment of neuropathies by both primary care and

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specialist physicians. We are also focusing our efforts on the management of accounts receivable and control of inventory balances.

Results of Operations

The following table presents certain statement of operations information stated as a percentage of total revenues:

	Three Months September 3		Nine Months I September 2	
	2004	2003	2004	2003
Revenues:				
Diagnostic device	12.8%	13.5%	12.4%	15.9%
Biosensor	87.2	86.5	87.6	84.1
Total revenues	100.0	100.0	100.0	100.0
Cost of revenues	26.8	29.3	27.1	29.8
Gross Margins	73.2	70.7	72.9	70.2
Operating Expenses:				
Research and development	19.6	22.9	20.0	26.5
Sales and marketing	42.3	47.5	46.4	54.7
General and administrative	27.1	29.5	27.6	31.9
Total operating expenses	89.0	99.9	94.0	113.0
Loss from operations	-15.7	-29.2	-21.1	-42.8
Interest income (expense), net	12.8	-1.0	-7.3	0.3
Net Loss	-28.5%	-30.2%	-28.4%	-43.1%

Comparison of Three Months Ended September 30, 2004 and September 30, 2003

Revenues

The following tables present a breakdown of our customers, biosensor units used and revenues:

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	_	12-Month Period <u>Ended September 30,</u> 2004 2003				Change	% Change	
Customers		2,064		1,668		396	23.7%	
		Three Mo EndedSep 2004				Change	% Change	
Biosensor units		96,790		56,374		40,416	71.7	
Revenues:			(in	thousands)				
Diagnostic device	\$	614.6	\$	349.6	\$	265.0	75.8	
Biosensor		4,204.7		2,237.1		1,967.6	88.0	
Total revenues	\$	4,819.3	\$	2,586.7	\$	2,232.6	86.3%	

Diagnostic device revenues were \$614,600 and \$349,600 for the three months ended September 30, 2004 and September 30, 2003, respectively, representing a year-over-year increase of \$265,000, or 75.8%. This increase is primarily attributable to an increase in the list price of our NC-stat monitors and docking stations, which resulted in a higher average aggregate sales price and contributed approximately \$138,500 of the increase while higher volume of unit sales contributed approximately \$123,700 of the increase during the three months ended September 30, 2004 as compared to the same period in 2003. Diagnostic device revenues accounted for 12.8% and 13.5% of our total revenues for the three months ended September 30, 2004 and September 30, 2003, respectively.

Biosensor revenues were \$4.2 million and \$2.2 million for the three months ended September 30, 2004 and September 30, 2003, respectively, representing a year-over-year increase of \$2.0 million, or 88.0%. The increase was primarily due to an increased customer base for our biosensors, increased frequency of testing by our customers, and the introduction in March 2004 of a new biosensor to test the ulnar nerve at the elbow. Biosensor revenues accounted for 87.2% and 86.5% of our total revenues for the three months ended September 30, 2004 and September 30, 2003, respectively.

Our customers used 96,790 biosensor units in the three months ended September 30, 2004, compared to 56,374 units for the same period in 2003, an increase of 40,416 units, or 71.7%.

Our total revenues were \$4.8 million and \$2.6 million for the three months ended September 30, 2004 and September 30, 2003, respectively, representing a year-over-year increase of \$2.2 million, or 86.3%. During the 12-month period ending September 30, 2004, a total of 2,064 customers used our NC-stat System compared to 1,668 customers for the same period ending September 30, 2003. This represents a 23.7% year-over-year increase in the number of customers that used our NC-stat System.

We expect revenues in the remainder of 2004 to continue to increase compared to the comparable period in 2003 as we continue to expand our sales and marketing efforts and our customer base and make enhancements and improvements to our NC-stat System, including the introduction of new biosensors. In January 2004, we increased the list price of our NC-stat monitor and docking station by approximately 40%, which we expect to contribute to an increase in diagnostic device revenues for the remainder of 2004 as compared to the comparable period of 2003. Our revenues could be negatively impacted by a variety of factors, including the level of demand for nerve conduction studies, potential for changes in third-party reimbursement for nerve conduction studies, the overall economy and competitive factors.

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Costs and expenses

The following table presents our costs and expenses and net loss:

		Three Moi Septem					
		2004		2003	Change	% Change	
			(ir	n thousands)			
Cost of revenues:	ф	100.4	ф	4.CT D	20.2	45.60/	
Diagnostic device	\$	193.4	\$	167.2 \$	26.2	15.6%	
Biosensor		1,096.9		591.9	505.0	85.3	
Total costs of revenues		1,290.2		759.1	531.2	70.0	
Gross Margin:							
Diagnostic device		421.2		182.4	238.8	131.0	
Biosensor		3,107.9		1,645.2	1,462.6	88.9	
Total gross margin		3,529.1		1,827.6	1,701.5	93.1	
Gross Margin%:							
Diagnostic device		68.5%	6	52.2%			
Biosensor		73.9		73.5			
Total gross margin%		73.2		70.7			
Operating Expenses:							
Research and development (1)		942.9		593.0	349.9	59.0	
Sales and marketing (1)		2,037.8		1,227.7	810.2	66.0	
General and administrative (1)		1,306.2		762.2	544.0	71.4	
Total operating expenses		4,286.9		2,582.8	1,704.0	66.0	
Loss from operations		(757.8)		(755.2)	(2.6)	.3	
Interest income		51.6		2.8	48.9	1757.8	
Interest expense		(666.7)		(28.8)	(637.9)	2215.5	
Net loss		(1,372.9)		(781.3)	(591.6)	75.7	
Accretion of dividend on preferred stock		(190.9)	_	(502.4)	311.5	-62.0	
Net loss available to common stockholders	\$	(1,563.7)	\$	(1,283.6) \$	(903.1)	70.4	
(1) Includes non-cash stock-based compensation of:							
Research and development	\$	21.5	\$	8.2			

Sales and marketing
48.9
General and administrative
69.1

9.6

Gross Margin

Diagnostic device gross margin percentage was 68.5% and 52.2% for the three months ended September 30, 2004 and September 30, 2003, respectively. The increase in the gross margin percentage in the third quarter of 2004 compared with the same period in 2003 is primarily attributable to an increase in the list price of our NC-stat monitor and docking station.

Biosensor gross margin percentage increased to 73.9% for the three months ended September 30, 2004 from 73.5% for the same period in 2003. The small increase in biosensor gross margin percentage is primarily due to a slightly more favorable mix toward our higher margin biosensors in third quarter of 2004 when compared to the third quarter of 2003.

Our overall gross margin percentage was 73.2% for the three months ended September 30, 2004 compared with 70.7% for the same period in 2003.

Research and Development

Our research and development, or R&D, expenses include expenses from research, product development, clinical, regulatory and quality assurance departments.

R&D expenses increased \$349,900, or 59.0%, to \$942,900 for the three months ended September 30, 2004 from \$593,000 for the same period in 2003. As a percentage of revenues, R&D expenses were 19.6% and 22.9% for the three months ended September 30, 2004 and September 30, 2003, respectively. The increase in expenses was primarily due to an increase of \$168,000 in employee compensation and benefit costs resulting from the net addition of five employees in our R&D department, as well as, an increase in recruiting costs of \$29,700 related to the hiring of new employees. Also contributing to the increase in R&D expense was an increase in the cost of clinical studies and prototype testing of \$117,000 and an increase in consulting services of \$32,200.

For the remainder of 2004, we expect our spending on R&D will increase over the comparable period in 2003 due to the hiring of additional employees. We expect R&D expenses, as a percentage of total revenues, to remain fairly level with the first nine months of 2004. This percentage may vary, however, depending primarily on our revenues for the remainder of 2004.

Sales and Marketing

Sales and marketing expenses increased \$810,200, or 66.0%, to \$2.0 million for the three months ended September 30, 2004 from \$1.2 million for the same period in 2003. As a percentage of revenues, sales and marketing expenses were 42.3% and 47.5% for the three months ended September 30, 2004 and September 30, 2003, respectively. The increase in expenses was primarily due to increases of \$284,400 in employee compensation and benefit costs and \$122,600 in travel expense that resulted from the addition of nine employees in our sales and marketing department; \$291,000 in sales commissions paid to our independent regional sales agencies that were directly related to our higher revenues in the third quarter of 2004; an increase of \$70,600 in outside consulting service expense and \$39,400 in non-cash stock-based compensation related to employee stock options. Because our independent regional sales agencies are compensated exclusively on a commission basis, their compensation is linked directly to our revenues. The compensation of our internal sales force is predominately based upon meeting internal performance goals and is, therefore, also linked to our revenues.

We expect to hire additional sales and marketing personnel during the remainder of 2004. For 2004, we expect sales and marketing expenses, as a percentage of total revenues, to increase over the level for the third quarter of 2003. This percentage may vary, however, depending primarily on our revenues for the remainder of 2004.

General and Administrative

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

General and administrative expenses increased \$544,000, or 71.4%, to \$1.3 million for the three months ended September 30, 2004 from \$762,200 for the same period in 2003. As a percentage of revenues, general and

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administrative expenses were 27.1% and 29.5% for the three months ended September 30, 2004 and September 30, 2003, respectively. The increase in expenses was primarily due to an increase of \$137,900 in employee compensation and benefit costs resulting partially from the hiring of two additional employees, an increase of \$62,500 in non-cash stock-based compensation related to employee stock options, an increase of \$93,900 in outside consulting services expense partially used to aid our recent initial public offering, and a charge of \$30,400 for doubtful account receivables in the third quarter of 2004. Also contributing to the increase in G&A expense were increases of \$148,800 in our insurance costs, \$94,500 increase in our legal and accounting costs, and financial printing costs and filing fees of \$31,800, all related to fulfilling the requirements of a publicly traded company. Partially offsetting these increases in G&A expense was a decrease in recruiting costs of \$86,400 resulting from an executive search in the third quarter of 2003 that did not recur in 2004.

We expect our general and administrative expenses to increase during the remainder of 2004 as a result of our expected growth and the additional requirements that we will need to fulfill as a publicly traded company, although these expenses, as a percentage of total revenues, are likely to decrease gradually as revenues increase. This percentage may vary, however, depending primarily on our revenues for the remainder of 2004.

Interest Income

Interest income was \$51,600 and \$2,800 during the three months ended September 30, 2004 and September 30, 2003, respectively. Interest income was earned from investments in cash equivalents and short-term investments. Interest income increased during the three months ended September 30, 2004, compared with the same period of 2003, because of higher average cash balances available for investment resulting from proceeds received of approximately \$24.0 million from our initial public offering at the end of July 2004 and in August 2004 and approximately \$10.6 million from our sale of Series E-1 redeemable convertible preferred stock in March 2004.

Interest Expense

Interest expense was \$666,700 and \$28,800 during the three months ended September 30, 2004 and 2003, respectively. The increase in interest expense in 2004 was primarily the result of the full repayment of our borrowing under our credit line entered into in May 2003 with Lighthouse Capital Partners. The early repayment of this debt resulted in a charge of approximately \$375,000 related to unamortized deferred issuance costs and approximately \$263,000 of balloon interest charges.

Comparison of Nine Months Ended September 30, 2004 and September 30, 2003

Revenues

The following table presents a breakdown of our customers, biosensor units used and revenues:

	Nine Months Ended September 30,					
	2	004	2003		Change	% Change
Customers		2,064	1,668		396	23.7%
Biosensor units		248,700	146,600		102,100	69.6
			(in thousands)			
Revenues:			, ,		_	
Diagnostic device	\$	1,502.5	\$ 1,002.1	\$	500.4	49.9
Biosensor		10,643.1	5,295.1		5,348.0	101.0
Total revenues	\$	12,145.6	\$ 6,297.2	\$	5,848.4	92.9
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Diagnostic device revenues were \$1.5 million and \$1.0 million for the nine months ended September 30, 2004 and September 30, 2003, respectively, representing a year-over-year increase of \$500,400, or 49.9%. This increase is primarily attributable to an increase in the list price of our NC-stat monitors and docking stations in January 2004, which resulted in a higher average sale price during the nine months ended September 30, 2004 as compared with the same period in 2003. Diagnostic device revenues accounted for 12.4% and 15.9% of our total revenues for the nine months ended September 30, 2004 and September 30, 2003, respectively.

Biosensor revenues were \$10.6 million and \$5.3 million for the nine months ended September 30, 2004 and September 30, 2003, respectively, representing a year-over-year increase of \$5.3 million, or 101.0%. The increase was primarily due to an increased customer base for our biosensors and increased frequency of testing by our customers. In addition, the introduction of new biosensors in May 2003 and March 2004 contributed to the increase in revenues for the nine months ended September 30, 2004 compared with the same period in 2003. Biosensor revenues accounted for 87.6% and 84.1% of our total revenues for the nine months ended September 30, 2004 and September 30, 2003, respectively.

Our customers used 248,700 biosensor units in the nine months ended September 30, 2004, compared with 146,600 units for the same period in 2003, an increase of 102,100 units, or 69.6%.

Our total revenues were \$12.1 million and \$6.3 million for the nine months ended September 30, 2004 and September 30, 2003, respectively, representing a year-over-year increase of \$5.8 million, or 92.9%. During the 12-month period ending September 30, 2004, a total of 2,064 customers used our NC-stat System compared with 1,668 customers for the same period ending September 30, 2003. This represents a 23.7% year-over-year increase in the number of customers that used our NC-stat System.

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Costs and expenses

The following table presents our costs and expenses and net loss:

	Nine Months Ended September 30,							
		2004		2003 in thousands)	_	\$ Change	% Change	
Cost of revenues:								
Diagnostic device	\$	515.3	\$	498.7	\$	16.6	3.3%	
Biosensor		2,772.5		1,375.4		1,397.2	101.6	
Total costs of revenues		3,287.9		1,874.1		1,413.8	75.4	
Gross Margin:								
Diagnostic device		987.1		503.4		483.8	96.1	
Biosensor		7,870.6		3,919.8		3,950.8	100.8	
Total gross margin		8,857.7		4,423.2		4,434.6	100.3	
Gross Margin%:								
Diagnostic device		65.7%	6	50.29	6			
Biosensor		73.9		74.0				
Total gross margin		72.9		70.2				
Operating Expenses:								
Research and development (1)		2,434.8		1,666.6		768.2	46.1	

Sales and marketing (1)	5,634.4	3,441.9	2,192.5	63.7
General and administrative (1)	3,347.1	2,010.1	1,337.0	66.5
Total operating expenses	 11,416.3	7,118.6	4,297.7	60.4
Loss from operations	(2,558.5)	(2,695.4)	136.9	5.1
Interest income	70.2	19.6	50.5	257.3
Interest expense	(960.4)	(38.9)	(921.6)	2372.1
Net loss	 (3,448.8)	(2,714.6)	(734.2)	27.0
Accretion of dividend on preferred stock	(1,386.3)	(1,507.1)	120.8	8.0
Deemed dividend on redeemable convertible preferred stock	(787.9)	0.0	(787.9)	_
Beneficial conversion feature	(7,050.8)	0.0	(7,050.8)	
Net loss available to common stockholders	\$ (12,673.8) \$	(4,221.7) \$	(8,452.1)	200.2

(1) Includes non-cash stock-based compensation of:

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Research and development	\$	227.9	\$ 17.7
Sales and marketing		320.0	24.0
General and administrative		402.0	12.2
Total non-cash stock based compensation	S	949 9	\$ 53.9

Gross Margin

Diagnostic device gross margin percentage was 65.7% and 50.2% for the nine months ended September 30, 2004 and September 30, 2003, respectively. The increase in the gross margin percentage in the first nine months of 2004, as compared with the same period in 2003, is attributable partially to an increase in the list price of our NC-stat monitor and docking station, and partially to a decrease in the price we paid for our diagnostic devices as a result of a change in our third-party manufacturer.

Biosensor gross margin percentage decreased to 73.9% for the nine months ended September 30, 2004 from 74.0% for the same period in 2003. The small decrease in biosensor gross margin percentage is primarily due to the introductory sales of the ulnar nerve at the elbow biosensor, which yielded a temporary lower margin resulting from initial production start up costs.

Our overall gross margin percentage was 72.9% for the nine months ended September 30, 2004, compared with 70.2% for the same period in 2003. The increase in our overall gross margin was primarily due to the significant increase in our diagnostic device gross margin, as discussed above.

Research and Development

R&D expenses increased \$768,200, or 46.1%, to \$2.4 million for the nine months ended September 30, 2004, from \$1.7 million for the same period in 2003. As a percentage of revenues, R&D expenses were 20.0% and 26.5% for the nine months ended September 30, 2004 and September 30, 2003, respectively. The increase in expenses was primarily due to an increase of \$434,900 in employee compensation and benefit costs resulting from the hiring of five additional employees in our R&D department, an increase in non-cash stock-based compensation of \$210,100 related to employee stock options, an increase of \$88,600 resulting from clinical studies and prototype testing and an increase of \$44,900 in outside consulting services.

Sales and Marketing

Sales and marketing expenses increased \$2.2 million, or 63.7%, to \$5.6 million for the nine months ended September 30, 2004 from \$3.4 million for the same period in 2003. As a percentage of revenues, sales and marketing expenses were 46.4% and 54.7% for the nine months ended September 30, 2004 and September 30, 2003, respectively. The increase in expenses was primarily due to: an increase of \$755,100 in sales commissions paid to our independent regional sales agencies, which were directly related to our higher revenues in the first nine months of 2004; increases of \$748,600 in employee compensation and benefit costs and \$248,000 in travel expense which resulted from the addition of nine employees in our sales and marketing department; an increase of \$296,100 in non-cash stock-based compensation related to employee stock options; and an increase of \$157,800 in outside consulting service expense.

General and Administrative

General and administrative expenses increased \$1.3 million, or 66.5%, to \$3.3 million for the nine months ended September 30, 2004 from \$2.0 million for the same period in 2003. As a percentage of revenues, general and administrative expenses were 27.6% and 31.9% for the nine months ended September 30, 2004 and September 30, 2003, respectively. The increase in expenses was primarily due to: an increase of \$388,300 in non-cash stock-based compensation related to employee stock options; an increase of \$224,500 in outside consulting services expense partially used to aid our recent initial public offering efforts; an increase of \$225,400 in our insurance costs; an increase of \$217,200 in employee compensation and benefit costs, resulting from the hiring of two additional employees;

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charges for doubtful accounts receivable of \$167,400; \$92,900 increase in our legal and accounting costs, and financial printing costs and filing fees of \$34,100 all related to fulfilling the requirements of a public traded company. Partially offsetting these increases in G&A expense was a decrease in recruiting costs of \$65,400 resulting from an executive search in the third quarter of 2003 that did not recur in 2004.

Interest income was \$70,200 and \$19,600 during the nine months ended September 30, 2004 and September 30, 2003, respectively. Interest income was earned from investments in cash equivalents and short-term investments. Interest income increased during the nine months ended September 30, 2004, compared with the same period of 2003, because of higher average cash balances available for investment resulting from proceeds received of approximately \$24.0 million from our initial public offering at the end of July 2004 and in August 2004 and approximately \$10.6 million from our sale of Series E-1 redeemable convertible preferred stock in March 2004.

Interest Expense

Interest expense was \$960,400 and \$38,900 during the nine months ended September 30, 2004 and September 30, 2003, respectively, representing an increase of \$921,600. The increase in interest expense in 2004 was primarily the result of the full repayment of our borrowing under our credit line entered into in May 2003 with Lighthouse Capital Partners. The early repayment of this debt resulted in a charge of approximately \$375,000 related to unamortized deferred issuance costs and approximately \$263,000 of balloon interest charges.

Deemed Dividend and Beneficial Conversion Feature on Redeemable Convertible Preferred Stock

In the first nine months of 2004, we recorded a \$787,900 deemed dividend as a result of the March 2004 Series E-1 redeemable convertible preferred stock financing. The deemed dividend resulted from an adjustment to the conversion ratios as a result of anti-dilution protection associated with the Series D redeemable convertible preferred stock. We also recorded a charge of \$7.1 million for a beneficial conversion feature embedded within the Series E-1 redeemable convertible preferred stock issued in March 2004. There was no deemed dividend or beneficial conversion charge in the first nine months of 2003.

Liquidity and Capital Resources

We commenced operations in September 1996 and prior to our initial public offering in July 2004, have financed our operations since inception through the private placement of equity and debt. As of September 30, 2004, we have received aggregate net proceeds of \$43.5 million from the issuance of redeemable convertible preferred stock. On July 27, 2004 we closed the initial public offering of our common stock selling 3.0 million shares at \$8.00 per share. On August 19, 2004 we sold a 450,000 common share over-allotment to our underwriters at \$8.00 per share. Our initial public offering including the over-allotment shares provided net proceeds of approximately \$24.0 million. Also, upon the completion of our initial public offering, all outstanding shares of redeemable convertible preferred stock were automatically converted into common stock. We repaid approximately \$2.9 million of secured debt which was outstanding at the beginning of the quarter in July 2004 using a portion of the proceeds of our initial public offering. As of September 30, 2004, we had \$30.6 million in cash and cash equivalents.

In managing our working capital, two of the financial measurements that we monitor are days' sales outstanding, or DSO, and inventory turnover rate, which are presented in the table below for the year ended December 31, 2003 and the three months ended September 30, 2004 and September 30, 2003:

		Year Ended December 31,	Three Months September	30,
		2003	2004	2003
Days' sales outstanding (days)		53	53	62
Inventory turnover rate (times per year)		2.8	4.3	4.2
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Our customer payment terms are generally 30 days from invoice date. At September 30, 2004, our DSO was at 53 days, the same number of days as compared to December 31, 2003. We continue to focus our efforts on reducing our accounts receivable balances over 60 days old.

Accounts payable are normally paid within 30 days from receipt of a vendor's invoice.

Our inventory turnover in the third quarter of 2004 was 4.3 times per year, an increase of 1.5 times per year when compared to the 2.8 inventory turnover rate for the year ended December 31, 2003. This increase was primarily due to the significant increase in the order rate in the third quarter of 2004. We continue to monitor inventory turnover as we adjust our inventory levels in anticipation of the expansion of our sales distribution channels.

Cash and cash equivalents were \$30.6 million at September 30, 2004 and \$1.6 million at December 31, 2003.

Cash used in operating activities was \$2.1 million during the nine months ended September 30, 2004. The major use of cash in the nine months ended September 30, 2004 was to fund net losses of \$3.4 million which included non-cash stock-based compensation of \$949,900 and non-cash accretion of debt issuance discount related to outstanding warrants of \$437,800. Cash was also used to fund an increase of \$1.1 million in accounts receivable resulting from the significant growth in revenues and an increase in our inventory balance of \$245,500, partially offset by increases in accounts payable and accrued expenses of \$543,900 and \$470,000, respectively, and an increase in deferred revenue and costs of \$207,200.

Cash used in investing activities was \$503,100 in the nine months ended September 30, 2004. Cash was used for the purchase of fixed assets, primarily representing tooling equipment for new products in the amount of \$194,175 and computer systems used in sales and administration in the amount of \$278,700.

Cash provided by financing activities was \$31.6 million in the nine months ended September 30, 2004, and primarily represented proceeds received from the issuance of preferred stock of \$10.6 and the net proceeds of \$24.0 million realized from our initial public offering including the over-allotment shares. These proceeds received were offset by

\$3.0 million of repayments of long-term debt to Lighthouse Capital Partners.

In May 2003, we entered into a loan and security agreement with Lighthouse Capital Partners that provided us with a secured line of credit of up to \$3.0 million. This line of credit was secured by all of our tangible and intangible assets and was available to us through December 31, 2003. On June 30, 2004, we had a total outstanding principal balance of \$2.9 million under this secured line of credit. We used a portion of the proceeds from our initial public offering completed in July 2004 to prepay all amounts (principal and interest) under this secured credit line, or \$3.1 million.

In connection with our lease that we entered into with a term beginning January 1, 2001, we are required to maintain, for the benefit of the lessor, an irrevocable standby letter of credit stating the lessor as the beneficiary in the amount of \$1.9 million over the term of the lease, which is secured by a certificate of deposit in an amount equal to 102% of the letter of credit. The certificate of deposit is renewable in 30-day increments. The amount is classified as restricted cash in the balance sheet.

During the remainder of 2004, we will be expending funds in connection with our efforts to expand our sales and marketing for the NC-stat System and continue our ongoing program of making enhancements and improvements to the NC-stat System, including the introduction of new biosensors. We will also expend funds on the design of a drug delivery system, which is in its early stages, for the minimally invasive treatment of neuropathies by both primary care and specialist physicians. We believe that the funds available will be adequate to finance our ongoing operations for at least two years, including the expenditures anticipated for the remainder of 2004, described above.

To date, inflation has not had a material impact on our financial operations or results of operations.

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

As of September 30, 2004, we did not have any off-balance sheet financing arrangements.

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Important Factors That May Affect Future Operating Results

You should carefully consider the following risks and all other information contained in this quarterly report on Form 10-Q and our other public filings before making any investment decisions with respect to our common stock. If any of the following risks occurs, our business, prospects, reputation, results of operations or financial condition could be harmed. In that case, the trading price of our common stock could decline, and you could lose all or part of your investment. This quarterly report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks described below and elsewhere in this quarterly report.

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

Since our inception in 1996, we have incurred losses every quarter. We began commercial sales of our products in May 1999 and we have yet to demonstrate that we can generate sufficient sales of our products to become profitable. The extent of our future operating losses and the timing of profitability are highly uncertain, and we may never achieve or sustain profitability. We have incurred significant net losses since our inception, including net losses of approximately \$8.7 million in 2001, \$4.8 million in 2002, \$3.7 million in 2003 and \$3.4 million for the nine months ended September 30, 2004. At September 30, 2004, we had an accumulated deficit of approximately \$56.6 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability.

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

Widespread adoption of the NC-stat System by the medical community is unlikely to occur if physicians do not receive sufficient reimbursement from third-party payers for performing nerve conduction studies using the NC-stat System. If physicians are unable to obtain adequate reimbursement for procedures performed using the NC-stat System, we may be unable to sell the NC-stat System 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 the NC-stat System. Third-party payers include those governmental programs such as Medicare and Medicaid, workers' compensation programs, private health insurers and other organizations. These third-party payers 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 healthcare for a fixed cost per person, irrespective of the amount of care actually provided. These providers, in an effort to control healthcare 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 Center for Medicare and 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 the NC-stat System. Medicaid reimbursement differs from state to state, and some state Medicaid programs may not reimburse physicians for performing procedures using the NC-stat System 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.

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

We believe that the drawbacks of traditional nerve conduction studies, including those related to the referral process, and the limited treatment options for diabetic peripheral neuropathy, or DPN, have limited the number of nerve conduction studies that are performed. For our future growth, we are relying, in part, on increased use of

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nerve conduction studies. A number of factors could limit the increased use of nerve conduction studies and the NC-stat System, including:

- third-party payers challenging, or the threat of third-party payers challenging, the necessity of increased levels of nerve conduction studies;
- third-party payers reducing or eliminating reimbursement for procedures performed by physicians using the NC-stat System;

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

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

If we are unable to successfully sell the NC-stat System to primary care physicians, our ability to increase our revenues will be limited.

We are focusing our sales and marketing efforts for the NC-stat System on primary care physicians. As these physicians traditionally have not been targeted by companies selling equipment used to perform nerve conduction studies, we may face difficulties in selling our products to them. Particularly, we may be unable to convince these physicians that the NC-stat System provides an effective alternative or useful supplement to existing testing methods. In addition, these physicians may be reluctant to make the capital investment to purchase the NC-stat System and alter their existing practices. If we are unable to successfully sell the NC-stat System to primary care physicians, our ability to increase our revenues will be severely limited.

We are dependent on two single source manufacturers to produce all of our current products, and any change in our relationship with either of these manufacturers could prevent us from delivering products to our customers in a timely manner and may adversely impact our future revenues or costs.

We rely on two third-party manufacturers to manufacture all of our current products. In the event that either of our manufacturers ceases to manufacture sufficient quantities of our products in a timely manner and on terms acceptable to us, we would be forced to locate an alternate manufacturer. Additionally, if either of our manufacturers experiences a failure in its production process, is unable to obtain sufficient quantities of the components necessary to manufacture our products or otherwise fails to meet our quality requirements, we may be forced to delay the manufacture and sale of our products or locate an alternative manufacturer. We may be unable to locate suitable alternative manufacturers for our products, particularly our NC-stat biosensors, for which the manufacturing process is relatively specialized, on terms acceptable to us, or at all. Currently, we rely on a single manufacturer, Polyflex Circuits, Inc., a wholly owned subsidiary of Parlex Corporation, for the manufacture of the NC-stat biosensors, and a single manufacturer, Advanced Electronics, Inc., or AEI, for the manufacture of our NC-stat monitors and docking stations. We order all of our products from Polyflex on a purchase order basis. Because we do not have a supply agreement in place with Polyflex, Polyflex may cease manufacturing our products or increase the price it charges us for our products at any time. We do have a one-year, automatically renewable contract manufacturing agreement with AEI. However, under the agreement, either party may elect not to renew the agreement upon 90 days' prior written notice prior to the end of the current term. Accordingly, AEI could cease manufacturing NC-stat monitors and docking stations for us when the current term of the agreement expires in November 2005. We have not experienced any significant problems in the past with the quality or quantity of products delivered by either AEI or Polyflex. We do occasionally experience transient inventory shortages, typically lasting less than one month, on new products during the initial production ramp-up phase. If any of the changes in our relationships with these manufacturers as described above occurs, our ability to supply our customers will be severely limited until we are able to engage an alternate

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manufacturer or, if applicable, resolve any quality issues with our existing manufacturer. This situation could prevent us from delivering products to our customers in a timely manner, lead to decreased sales or increased costs, or harm our reputation with our customers.

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

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

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

We introduced the NC-stat System to the market in May 1999. We derive all of our revenues from sales of the products that comprise the NC-stat System, and we expect that sales of these products will continue to constitute the substantial majority of our sales for the foreseeable future. Accordingly, our ability to generate revenues is entirely reliant on our ability to market and sell the products that comprise the NC-stat System, particularly the higher-margin disposable biosensors, sales of which accounted for approximately 87.6%, 85.8% and 82.9% of our total revenues for the first nine months of 2004, the year of 2003 and the year of 2002, respectively. Our sales of these products may be negatively impacted by many factors, including:

- changes in reimbursement rates or policies relating to our products by third-party payers;
- the failure of the market to accept our products;
- manufacturing problems;
- claims that our products infringe on patent rights or other intellectual property rights owned by other parties;

- adverse regulatory or legal actions relating to our products;
- competitive pricing and related factors; and
- results of clinical studies relating to our products or our competitors' products.

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

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

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

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

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- the claims of any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other parties may challenge patents, patent claims or patent applications licensed or issued to us; and
- other companies may design around technologies we have patented, licensed or developed.

We also may not be able to protect our patent rights effectively in some foreign countries. For a variety of reasons, we may decide not to file for patent protection. Our patent rights underlying our products may not be adequate, and our competitors or customers may design around our proprietary technologies or independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our patent rights. In addition, the patents licensed or issued to us may not provide a competitive advantage. If any of these events were to occur, our ability to compete in the market would be harmed.

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

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

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

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

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

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

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

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

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

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

We are subject to extensive regulation by the U.S. Food and Drug Administration, which could restrict the sales and marketing of the NC-stat System and could cause us to incur significant costs.

We sell medical devices that are subject to extensive regulation in the United States by the Food and Drug Administration, or FDA, for manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new use of or claim for an existing product, can be marketed in the United States, it must first receive either 510(k) clearance, grant of a *de novo* classification or pre-marketing approval from the FDA, unless an exemption applies. We may be required to obtain a new 510(k) clearance or *de novo* classification or pre-market approval for significant post-market modifications to our products. Each of these processes can be expensive and lengthy. The FDA's process for obtaining 510(k) clearance usually takes from three to 12 months, but it can last longer. The process for obtaining *de novo* classification involves a level of scrutiny similar to the 510(k) clearance process. The process for obtaining pre-market approval is much more costly and uncertain and it generally takes from one to three years, or longer, from the time the application is filed with the FDA.

Medical devices may be marketed only for the indications for which they are approved or cleared. We have obtained 510(k) clearance for the current clinical applications for which we market our products. However, our clearances can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner which in turn would harm our revenue and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices. We also are subject to numerous postmarketing regulatory requirements, including quality system regulations, which relate to the manufacturing of our products, labeling regulations and medical device reporting regulations. Our failure or the failure of either of our contract manufacturers to comply with applicable regulatory requirements could result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- requiring repair, replacement, refunds, recall or seizure of our products;
- imposing operating restrictions, suspension or shutdown of production;

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- refusing our requests for 510(k) clearance or pre-market approval of new products, new intended uses, or modifications to existing products;
- withdrawing 510(k) clearance or pre-market approvals that have already been granted; and
- criminal prosecution.

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

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

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

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

We are subject to the medical device reporting regulations, which require us to report to the FDA if our products cause or contribute to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. The FDA and similar governmental bodies in other countries have the authority to require the recall of our products if we or our contract manufacturers fail to comply with relevant regulations pertaining to manufacturing practices, labeling, advertising or promotional activities, or if new information is obtained concerning the safety or efficacy of our products. A government-mandated or voluntary recall by us could occur as a result of manufacturing defects, labeling deficiencies, packaging defects or other failures to comply with applicable regulations. Any recall would divert management attention and financial resources and harm our reputation with customers. A recall involving the NC-stat System would be particularly harmful to our business and financial results because the products that comprise the NC-stat System are currently our only products.

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

A federal law commonly known as the Medicare/Medicaid anti-kickback law, and several similar state laws, prohibit payments that are intended to induce physicians or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent, or for items or services that were not provided as claimed. Because we may provide some coding and billing information to purchasers of our products, and because we cannot assure that the government will regard any billing errors that may be made as inadvertent, these laws are potentially applicable to us. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance, which can be substantial. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

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

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

The use of the NC-stat System could result in product liability claims that could be expensive, damage our reputation and harm our business.

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

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

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

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

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

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

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

Our success largely depends on the skills, experience and efforts of our officers, including Shai N. Gozani, M.D., Ph.D., our founder and President and Chief Executive Officer; Gary L. Gregory, our Chief Operating Officer; Guy Daniello, our Senior Vice President of Information Technology; Michael Williams, Ph.D., our Senior Vice President of Engineering; Nicholas J. Alessi, Director of Finance and Treasurer; and our other key employees. We maintain a \$5.0 million key person life insurance policies covering any of our other employees. The loss of any of our officers or key employees could weaken our management and technical expertise significantly and harm our business.

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

We are a small company with only 64 employees, and our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining our future performance. We may not be able to meet our future hiring needs or retain existing personnel. We will face challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, as well as independent regional sales agencies and sales representatives, most of whom are geographically dispersed and must be trained in the use and benefits of our products. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

If we do not effectively manage our growth, our business resources may become strained, we may not be able to deliver the NC-stat System in a timely manner and our results of operations may be adversely affected.

We expect to increase our sales force and our total headcount significantly. This growth, as well as any other growth that we may experience in the future, will provide challenges to our organization and may strain our management and operations. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business or we may not be able to attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may become strained, we may not be able to deliver the NC-stat System in a timely manner and our results of operations may be adversely affected.

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

We presently employ 22 regional sales managers who lead more than 50 independent regional sales agencies employing a total of more than 300 sales representatives. We are highly dependent on our regional sales managers to generate our revenues. We currently intend to increase our existing sales force significantly using part of the net proceeds from our initial public offering. Our ability to build and develop a strong sales force will be affected by a number of factors, including:

- our ability to attract, integrate and motivate sales personnel;
- our ability to effectively train our sales force;
- the ability of our sales force to sell an increased number of products;
- the length of time it takes new sales personnel to become productive;
- the competition we face from other companies in hiring and retaining sales personnel;
- our ability to effectively manage a multi-location sales organization;

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- · our ability to enter into agreements with prospective members of our sales force on commercially reasonable terms; and
- our ability to get our independent sales agencies, who may sell products of multiple companies, to commit the necessary resources to
 effectively market and sell our products.

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

Failure to develop products other than the NC-stat System and enhance the NC-stat System could have an adverse effect on our business prospects.

All of our current revenues are derived from selling the NC-stat System. Our future business and financial success will depend, in part, on our ability to continue to introduce new products and upgraded products into the marketplace. Developing new products and upgrades to existing and future products imposes burdens on our research and development department and our management. This process is costly, and we cannot assure you that we will be able to successfully develop new products or enhance the NC-stat System or any future products. In addition, as we develop the market for point-of-service nerve conduction studies, future competitors may develop desirable product features earlier than we do, which could make our competitors' products

less expensive or more effective than our products and could render our products obsolete or unmarketable. If our product development efforts are unsuccessful, we will have incurred significant costs without recognizing the expected benefits and our business prospects may suffer.

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

We currently do, and in the future may need to, compete directly and indirectly with a number of other companies that enjoy significant competitive advantages over us. Currently, in the point-of-service market, we indirectly compete with companies that sell traditional NCS/nEMG equipment. In this market, these companies are indirect competitors because the equipment they sell traditionally has been used by neurologists, who rely upon and seek to obtain referrals from primary care physicians to perform the same types of tests that may be performed by primary care physicians using the NC-stat System. Additionally, in selling the NC-stat System to neurologists, which is not a market we historically have focused on, we compete directly with the companies that sell traditional NCS/nEMG equipment. There are a number of companies that sell traditional NCS/nEMG equipment including the Nicolet Biomedical division of Viasys Healthcare Inc., the Functional Diagnostics division of Medtronic, Inc., Oxford Instruments, Plc., and Cadwell Laboratories, Inc. Additionally, we are aware of one company, Neumed Inc., that markets a nerve conduction study system to the point-of-service market. Of these companies, Viasys Healthcare, Medtronic and Oxford Instruments, in particular, enjoy significant competitive advantages, including:

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

Other than Neumed, we do not know if these companies or others are engaged in research and development efforts to develop products to perform point-of-service nerve conduction studies that would be directly competitive with the NC-stat System. As we develop the market for point-of-service nerve conduction studies, we may be faced with competition from these companies or others that decide and are able to enter this market. Some or all of our future competitors in the point-of-service market may enjoy competitive advantages such as those described above. If we are

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unable to compete effectively against existing and future competitors, our sales will decline and our business will be harmed.

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

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

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

Future clinical studies or other articles regarding our existing products or any competing products may be published that either support a claim, or are perceived to support a claim, that a competitor's product is more accurate or effective than our products or that our products are not as accurate or effective as we claim or previous clinical studies have concluded. Additionally, physician associations or other organizations, such as neurology societies, that may be viewed as authoritative could endorse products or methods that compete with the NC-stat System or otherwise announce positions that are unfavorable to the NC-stat System. Any of these events may negatively affect our sales efforts and result in decreased revenues.

Our future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.

We believe that our current cash and cash equivalents, including the proceeds from our initial public offering, together with our short-term investments and the cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for at least the next 24 months. However, we may seek additional funds from public and private stock offerings, borrowings under credit lines or other sources. Our capital requirements will depend on many factors, including:

- the revenues generated by sales of the NC-stat System and any other products that we develop;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in manufacturing and selling our products;
- the costs of developing new products or technologies and enhancements to existing products;
- the cost of obtaining and maintaining FDA approval or clearance of our products and products in development;

- costs associated with any expansion;
- the costs associated with capital expenditures; and
- the number and timing of any acquisitions or other strategic transactions.

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

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

From time to time we may seek to acquire or invest in businesses, products or technologies, instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

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

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

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

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

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

If we expand, or attempt to expand, into foreign markets, we will be subject to new business risks, including:

• failure to fulfill foreign regulatory requirements to market the NC-stat System or other future products;

- availability of, and changes in, reimbursement within prevailing foreign health care payment systems;
- adapting to the differing business practices and laws in foreign countries;
- difficulties in managing foreign relationships and operations, including any relationships that we establish with foreign distributors or sales or marketing agents;
- limited protection for intellectual property rights in some countries;
- difficulty in collecting accounts receivable and longer collection periods;
- costs of enforcing contractual obligations in foreign jurisdictions;
- recessions in economies outside of the United States;
- political instability and unexpected changes in diplomatic and trade relationships;
- currency exchange rate fluctuations; and
- potentially adverse tax consequences.

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

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

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

- changes in the availability of third-party reimbursement in the United States or other countries;
- the timing of new product announcements and introductions by us or our competitors;
- market acceptance of new or enhanced versions of our products;
- changes in manufacturing costs or other expenses;

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- competitive pricing pressures;
- the gain or loss of significant distribution outlets or customers;
- increased research and development expenses;
- the timing of any future acquisitions; or
- general economic conditions.

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

Our principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

As of July 27, 2004, the date of our initial public offering, our officers, directors and principal stockholders together controlled approximately 71.4% of our outstanding common stock. If some or all of these stockholders act together, they will be able to control our management and affairs in all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. In addition, this significant concentration of share ownership may adversely affect the trading price of our common stock because investors often perceive disadvantages to owning stock in companies with controlling stockholders.

The sale or expected sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales or the expectation of sales of a substantial number of shares of our common stock in the public market could harm the market price of our common stock. As additional shares of our common stock become available for resale in the public market, the supply of our common stock will increase, which could decrease the price. Moreover, the holders of 7,488,758 shares of our common stock, comprised of shares issued upon conversion of our preferred stock, and the holder of a warrant to purchase 100,000 shares of common stock, will have rights, subject to various conditions and limitations, to

require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Also, shares of common stock that we may issue under our existing Amended and Restated 1998 Equity Incentive Plan, our 2004 Stock Option and Incentive Plan and 2004 Employee Stock Purchase Plan may be freely sold, subject to the lock-up agreements entered into in connection with our initial public offering, if applicable. If any of these holders cause a large number of securities to be sold in the public market, the sales could reduce the trading price of our common stock. These sales also could impede our ability to raise future capital.

We will incur increased expenses as a result of recently enacted laws and regulations affecting public companies.

Recently enacted laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted by the Securities and Exchange Commission and by the National Association of Securities Dealers, Inc., will result in increased expenses to us. The new rules could make it more difficult or more costly for us to obtain some types of insurance, including directors' and officers' liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events also could make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as executive officers. We will incur increased expenses in order to comply with these new rules, and we may not be able to accurately predict the timing or amount of these expenses.

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

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

- authorize the issuance of preferred stock which can be created and issued by the board of directors without prior stockholder approval, with rights senior to those of our common stock;
- provide for a classified board of directors, with each director serving a staggered three-year term;
- prohibit our stockholders from filling board vacancies, calling special stockholder meetings, or taking action by written consent;
- provide for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and
- require advance written notice of stockholder proposals and director nominations.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We do not intend to pay cash dividends.

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

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

The statements contained in this quarterly report on Form 10-Q, including under the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other sections of this quarterly report, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, without limitation, statements regarding our or our management's expectations, hopes, beliefs, intentions or strategies regarding the future. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements contained in this quarterly report are based on our current expectations and beliefs concerning future developments and their potential effects on us. There can be no assurance that future developments affecting us will be those that we have anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond our control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations-Important Factors that May Affect Future Operating Results." Should one or more of these risks or uncertainties materialize, or should any of our assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required under applicable secu

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, accrued expenses and long-term obligations. 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 and maintain an average maturity of six months or less. We do not believe that a 10% change in interest rates would have a material impact on the fair value of our investment portfolio or our interest income.

Item 4. Controls and Procedures

(a) Evaluation of disclosure controls and procedures.

Our management carried out an evaluation, with the participation of our Chief Executive Officer and our Director of Finance, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act)) as of September 30, 2004. Based upon that evaluation, our Chief Executive Officer and our Director of Finance concluded that they believe that our disclosure controls and procedures are reasonably effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

(b) Changes in internal controls over financial reporting.

There was no change in our internal control over financial reporting identified in connection with our evaluation of our disclosure controls and procedures that occurred during the period covered by this quarterly report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Part II Other Information

Item 1. Legal Proceedings

None.

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

(a) During the quarterly period ended September 30, 2004, we issued 6,450 shares of our common stock upon the exercise of options for aggregate proceeds of \$14,144.

The securities issued in the foregoing transactions were offered and sold in reliance on exemptions from registration set forth in Section 4(2) of the Securities Act or regulations promulgated thereunder, relating to sales by an issuer not involving any public offering, or an exemption from registration under Rule 701 promulgated under the Securities Act. No underwriters or placement agents were involved in the foregoing issuances and sales.

(b) On July 27, 2004, we completed an initial public offering of 3,000,000 shares of our common stock at a price to the public of \$8.00 per share. There were no selling stockholders in the offering. The offer and sale of all of the shares in the initial public offering were registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-1 (File No. 333-115440), which was declared effective by the Securities and Exchange Commission on July 21, 2004. Punk, Ziegel & Company, L.P. and WR Hambrecht + CO, LLC were the managing underwriters for our initial public offering. As part of the initial public offering, we granted the several underwriters an over-allotment option to purchase up to an additional 450,000 shares of our common stock from us. On August 17, 2004, the underwriters exercised their over-allotment option in full.

The aggregate price of the offering amount registered on our behalf was \$27.6 million. In connection with the offering, we paid approximately \$1.9 million in underwriting discounts and commissions to the underwriters and incurred an estimated \$1.7 million in other offering expenses. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any affiliates of ours. After deducting the underwriting discounts and commissions and offering expenses, we received net proceeds from the offering of approximately \$24.0 million. From July 21, 2004, the effective date of the registration statement, to September 30, 2004 we have used (i) \$3.1 million of the net proceeds to repay in full all outstanding balance under our secured line of credit with Lighthouse Capital Partners and (ii) an estimated \$494,800 of the net proceeds to fund cash spending of our research and development activities. The remainder of the net proceeds have been invested in marketable, investment grade, interest-bearing securities pending their use. Our use of the proceeds from our initial public offering do not represent a material change from the description provided in our prospectus.

Item 3. Defaults Upon Senior Securities

None.

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

Other Information Item 5. 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. 36 **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. November 15, 2004 Date: Shai N. Gozani, M.D., Ph. D. Shai N. Gozani, M.D., Ph. D. Chief Executive Officer and President November 15, 2004 Nicholas J. Alessi Date: Nicholas J. Alessi Director of Finance and Treasurer 37 Exhibit Index Incentive Stock Option Agreement, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan. *10.1 *10.2 Non-Qualified Stock Option Agreement For Company Employees, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan. *10.3 Non-Qualified Stock Option Agreement For Non-Employee Directors, under the NeuroMetrix, Inc. 2004 Stock Option And Incentive Plan. *31.1 Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *31.2 Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *32 Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. * Filed herewith

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INCENTIVE STOCK OPTION AGREEMENT

UNDER THE NEUROMETRIX, INC. 2004 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee: No. of Option Shares: Option Exercise Price per Share: Grant Date: Expiration Date:

Pursuant to the NeuroMetrix, Inc. 2004 Stock Option Incentive Plan (the "Plan") as amended through the date hereof, NeuroMetrix, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value \$0.0001 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan.

Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as otherwise set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to Option Shares (% of the total Option Shares) on additional of the total Option Shares on each , , , and , thereafter until the Stock Option has become exercisable with respect to all of the Option Shares; provided that the total number of Option Shares for which this Stock Option is exercisable will be rounded down to the nearest whole Option Share.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

1. <u>Manner of Exercise</u>.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the

Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that have been beneficially owned by the Optionee for at least six months and are not then subject to any restrictions under any Company plan; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The delivery of certificates representing the Option Shares will be contingent upon the Company's receipt from the Optionee of full payment for the Option Shares, as set forth above and any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the shares attested to.

- (b) Certificates for the shares of Stock purchased upon exercise of this Stock Option shall be issued and delivered to the Optionee upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such issuance and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company shall have issued and delivered the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.
- (c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.
- (d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.

2. <u>Termination of Employment</u> . If the Optionee's employment by the Company or a Subsidiary (as defined in the Plan) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.
(a) <u>Termination Due to Death</u> . If the Optionee's employment terminates by reason of death, any Stock Option held by the Optionee shall become fully exercisable and may thereafter be exercised by the Optionee's legal representative or legatee for a period of 12 months from the date of death or until the Expiration Date, if earlier.
(b) <u>Termination Due to Disability</u> . If the Optionee's employment terminates by reason of disability (as determined by the Administrator), any Stock Option held by the Optionee shall become fully exercisable and may thereafter be exercised by the Optionee for a period of 12 months from the date of termination or until the Expiration Date, if earlier. The death of the Optionee during the 12-month period provided in this Section 3(b) shall extend such period for another 12 months from the date of death or until the Expiration Date, if earlier.
(c) <u>Termination for Cause</u> . If the Optionee's employment terminates for Cause, any Stock Option held by the Optionee shall terminate immediately and be of no further force and effect. For purposes hereof, "Cause" shall mean a vote by the Board resolving that the Optionee shall be dismissed as a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the conviction of or plea of nolo contendere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliberate non-performance (other than by reason of disability) by the Optionee of the Optionee's duties to the Company.
(d) Other Termination. If the Optionee's employment terminates for any reason other than death, disability, or Cause, and unless otherwise determined by the Administrator, any Stock Option held by the Optionee may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any Stock Option that is not exercisable at such time shall terminate immediately and be of no further force or effect.
The Administrator's determination of the reason for termination of the Optionee's employment shall be conclusive and binding on the Optionee and his or her representatives or legatees.
3. <u>Incorporation of Plan</u> . Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.
4. <u>Transferability.</u> This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.
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5. <u>Status of the Stock Option</u> . This Stock Option is intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"), but the Company does not represent or warrant that this Stock Option qualifies as such. The Optionee should consult with his or her own tax advisors regarding the tax effects of this Stock Option and the requirements necessary to obtain favorable income tax treatment under Section 422 of the Code, including, but not limited to, holding period requirements. If the Optionee intends to dispose or does dispose (whether by sale, gift, transfer or otherwise) of any Option Shares within the one-year period beginning on the date after the transfer of such shares to him or her, or within the two-year period beginning on the day after the grant of this Stock Option, he or she will notify the Company within 30 days after such disposition.
6. <u>Tax Withholding</u> . The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Optionee may elect to have the minimum required tax withholding obligation satisfied, in whole or in part, by (i) authorizing the Company to withhold from shares of Stock to be issued, or (ii) transferring to the Company, a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due.
7. <u>Miscellaneous.</u> (a) Notice hereunder shall be given to the Company at its principal place of business, and shall be given to the Optionee at the address set forth below, or in either case at such other address as one party may subsequently furnish to the other party in writing.
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(b) This Stock Option does not confer upon the Optionee any rights with respect to continuance of employment by the Company or any Subsidiary.
Ву:
Title:
The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned.
Dated: Optionee's Signature

NON-QUALIFIED STOCK OPTION AGREEMENT FOR COMPANY EMPLOYEES

UNDER NEUROMETRIX, INC. 2004 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee: No. of Option Shares: Option Exercise Price per Share: Grant Date: Expiration Date:

Pursuant to NeuroMetrix, Inc. 2004 Stock Option and Incentive Plan (the "Plan") as amended through the date hereof, NeuroMetrix, Inc. (the "Company") hereby grants to the Optionee named above an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value \$0.0001 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan.

Exercisability Schedule. No portion of this Stock Option may be exercised until such portion shall have become exercisable. Except as otherwise set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule hereunder, this Stock Option shall be exercisable with respect to Option Shares (% of the total Option Shares) on and an additional of the total Option Shares on each , , and , thereafter until the Stock Option has become exercisable with respect to all of the Option Shares; provided that the total number of Option Shares for which this Stock Option is exercisable will be rounded down to the nearest whole Option Share.

Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

Manner of Exercise.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the

Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that have been beneficially owned by the Optionee for at least six months and are not then subject to any restrictions under any Company plan; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The delivery of certificates representing the Option Shares will be contingent upon the Company's receipt from the Optionee of full payment for the Option Shares, as set forth above and any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

- (b) Certificates for shares of Stock purchased upon exercise of this Stock Option shall be issued and delivered to the Optionee upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such issuance and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company shall have issued and delivered the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.
- (c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.
- (d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration Date hereof.
- 2. <u>Termination of Employment</u>. If the Optionee's employment by the Company or a Subsidiary (as defined in the Plan) is terminated, the period within which to exercise the Stock Option may be subject to earlier termination as set forth below.
- (a) <u>Termination Due to Death</u>. If the Optionee's employment terminates by reason of death, any Stock Option held by the Optionee shall become fully exercisable and may

thereafter be exercised by the (Optionee's legal representat	ive or legatee for a peric	d of 12 months from the o	date of death or until the	Expiration Date, if
earlier.					

- (b) <u>Termination Due to Disability</u>. If the Optionee's employment terminates by reason of disability (as determined by the Administrator), any Stock Option held by the Optionee shall become fully exercisable and may thereafter be exercised by the Optionee for a period of 12 months from the date of termination or until the Expiration Date, if earlier. The death of the Optionee during the 12-month period provided in this Section 3(b) shall extend such period for another 12 months from the date of death or until the Expiration Date, if earlier.
- (c) <u>Termination for Cause</u>. If the Optionee's employment terminates for Cause, any Stock Option held by the Optionee shall terminate immediately and be of no further force and effect. For purposes hereof, "Cause" shall mean a vote by the Board resolving that the Optionee shall be dismissed as a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the conviction of or plea of nolo contendere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliberate non-performance (other than by reason of disability) by the Optionee of the Optionee's duties to the Company.
- (d) Other Termination. If the Optionee's employment terminates for any reason other than death, disability or Cause, and unless otherwise determined by the Administrator, any Stock Option held by the Optionee may be exercised, to the extent exercisable on the date of termination, for a period of three months from the date of termination or until the Expiration Date, if earlier. Any Stock Option that is not exercisable at such time shall terminate immediately and be of no further force or effect.

The Administrator's determination of the reason for termination of the Optionee's employment shall be conclusive and binding on the Optionee and his or her representatives or legatees.

- 3. <u>Incorporation of Plan</u>. Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.
- 4. <u>Transferability.</u> This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner, by operation of law or otherwise, other than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, only by the Optionee, and thereafter, only by the Optionee's legal representative or legatee.
- 5. <u>Tax Withholding</u>. The Optionee shall, not later than the date as of which the exercise of this Stock Option becomes a taxable event for Federal income tax purposes, pay to the Company or make arrangements satisfactory to the Administrator for payment of any Federal, state, and local taxes required by law to be withheld on account of such taxable event. The Optionee may elect to have the minimum required tax withholding obligation satisfied, in

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whole or in part, by (i) authorizing the Company to withhold from shares of Stock to be issued, or (ii) transferring to the Company, a number of shares of Stock with an aggregate Fair Market Value that would satisfy the withholding amount due.

6. Miscellaneous.

- (a) Notice hereunder shall be given to the Company at its principal place of business, and shall be given to the Optionee at the address set forth below, or in either case at such other address as one party may subsequently furnish to the other party in writing.
- (b) This Stock Option does not confer upon the Optionee any rights with respect to continuance of employment by the Company or any Subsidiary.

	By: Title:
The foregoing Agreement is hereby accepted and the terms and conditions thereof hereby agree	ed to by the undersigned.
Dated:	Optionee's Signature
	Optionee's name and address:

NON-QUALIFIED STOCK OPTION AGREEMENT FOR NON-EMPLOYEE DIRECTORS

UNDER NEUROMETRIX, INC. 2004 STOCK OPTION AND INCENTIVE PLAN

Name of Optionee: No. of Option Shares: Option Exercise Price per Share: Grant Date: Expiration Date:

Pursuant to NeuroMetrix, Inc. 2004 Stock Option and Incentive Plan (the "Plan") as amended through the date hereof, NeuroMetrix, Inc. (the "Company") hereby grants to the Optionee named above, who is a Director of the Company but is not an employee of the Company, an option (the "Stock Option") to purchase on or prior to the Expiration Date specified above all or part of the number of shares of Common Stock, par value \$0.0001 per share (the "Stock") of the Company specified above at the Option Exercise Price per Share specified above subject to the terms and conditions set forth herein and in the Plan.

 Exercisability Schedule. No portion of this 	is Stock Option may be exercised until such	portion shall have become	ome exercisable. Except as		
otherwise set forth below, and subject to the discretion of the Administrator (as defined in Section 2 of the Plan) to accelerate the exercisability schedule					
hereunder, this Stock Option shall be exercisable with respe-	ct to Option Shares (% of the total Op	otion Shares) on		
and an additional of the total	Option Shares on each ,	, , and	thereafter until the		
Stock Option has become exercisable with respect to all of the Option Shares; provided that the total number of Option Shares for which this Stock Option is					
exercisable will be rounded down to the nearest whole Option	on Share.				

In the event of (i) the termination of the Optionee's service as a director of the Company because of death, or (ii) a Change of Control of the Company as defined in Section 17 of the Plan, this Stock Option shall become immediately exercisable in full, whether or not exercisable at such time. Once exercisable, this Stock Option shall continue to be exercisable at any time or times prior to the close of business on the Expiration Date, subject to the provisions hereof and of the Plan.

2. <u>Manner of Exercise</u>.

(a) The Optionee may exercise this Stock Option only in the following manner: from time to time on or prior to the Expiration Date of this Stock Option, the Optionee may give written notice to the Administrator of his or her election to purchase some or all of the Option Shares purchasable at the time of such notice. This notice shall specify the number of Option Shares to be purchased.

Payment of the purchase price for the Option Shares may be made by one or more of the following methods: (i) in cash, by certified or bank check or other instrument acceptable to the Administrator; (ii) through the delivery (or attestation to the ownership) of shares of Stock that have been purchased by the Optionee on the open market or that have been beneficially owned by the Optionee for at least six months and are not then subject to restrictions under any Company plan; (iii) by the Optionee delivering to the Company a properly executed exercise notice together with irrevocable instructions to a broker to promptly deliver to the Company cash or a check payable and acceptable to the Company to pay the option purchase price, provided that in the event the Optionee chooses to pay the option purchase price as so provided, the Optionee and the broker shall comply with such procedures and enter into such agreements of indemnity and other agreements as the Administrator shall prescribe as a condition of such payment procedure; or (iv) a combination of (i), (ii) and (iii) above. Payment instruments will be received subject to collection.

The delivery of certificates representing the Option Shares will be contingent upon the Company's receipt from the Optionee of full payment for the Option Shares, as set forth above and any agreement, statement or other evidence that the Company may require to satisfy itself that the issuance of Stock to be purchased pursuant to the exercise of Stock Options under the Plan and any subsequent resale of the shares of Stock will be in compliance with applicable laws and regulations. In the event the Optionee chooses to pay the purchase price by previously-owned shares of Stock through the attestation method, the number of shares of Stock transferred to the Optionee upon the exercise of the Stock Option shall be net of the Shares attested to.

- (b) Certificates for shares of Stock purchased upon exercise of this Stock Option shall be issued and delivered to the Optionee upon compliance to the satisfaction of the Administrator with all requirements under applicable laws or regulations in connection with such issuance and with the requirements hereof and of the Plan. The determination of the Administrator as to such compliance shall be final and binding on the Optionee. The Optionee shall not be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Stock subject to this Stock Option unless and until this Stock Option shall have been exercised pursuant to the terms hereof, the Company shall have issued and delivered the shares to the Optionee, and the Optionee's name shall have been entered as the stockholder of record on the books of the Company. Thereupon, the Optionee shall have full voting, dividend and other ownership rights with respect to such shares of Stock.
- (c) The minimum number of shares with respect to which this Stock Option may be exercised at any one time shall be 100 shares, unless the number of shares with respect to which this Stock Option is being exercised is the total number of shares subject to exercise under this Stock Option at the time.

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(d) Notwithstanding any other provision hereof or of the Plan, no portion of this Stock Option shall be exercisable after the Expiration

3. be subject to early	<u>Termination as Director</u> . If the Optionee ceases to be a Director of the Company, the period within which to exercise earlier termination as set forth below.	e the Stock Option may	
dismissed as a renolo contendere	(a) <u>Termination For Cause</u> . If the Optionee ceases to be a Director for Cause, any Stock Option held by the Optionia and be of no further force and effect. For purposes hereof, "Cause" shall mean a vote by the Board resolving to a result of (i) any material breach by the Optionee of any agreement between the Optionee and the Company; (ii) the concere by the Optionee to a felony or a crime involving moral turpitude; or (iii) any material misconduct or willful and deliby reason of disability) by the Optionee of the Optionee's duties to the Company.	hat the Optionee shall be eviction of or plea of	
Optionee may be	(b) <u>Termination by Reason of Death</u> . If the Optionee ceases to be a Director by reason of death, any Stock Op y be exercised by his or her legal representative or legatee for a period of 12 months from the date of death or until the Ex		
Optionee may be	(c) <u>Other Termination</u> . If the Optionee ceases to be a Director for any reason other than Cause or death, any So be exercised for a period of six months from the date of termination or until the Expiration Date, if earlier.	tock Option held by the	
	<u>Incorporation of Plan</u> . Notwithstanding anything herein to the contrary, this Stock Option shall be subject to and go as of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this A cified in the Plan, unless a different meaning is specified herein.		
	<u>Transferability</u> . This Agreement is personal to the Optionee, is non-assignable and is not transferable in any manner than by will or the laws of descent and distribution. This Stock Option is exercisable, during the Optionee's lifetime, r, only by the Optionee's legal representative or legatee.		
6.	Miscellaneous.		
set forth below, o	(a) Notice hereunder shall be given to the Company at its principal place of business, and shall be given to the w, or in either case at such other address as one party may subsequently furnish to the other party in writing.	Optionee at the address	
	(b) This Stock Option does not confer upon the Optionee any rights with respect to continuance as a Director.		
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(c) Pursuant to Section 15 of the Plan, the Committee may at any time amend or cancel any outstanding portion of this Stock Option, but no such action may be taken which adversely affects the Optionee's rights under this Agreement without the Optionee's consent.			
	By: Title:		
The foregoing A	g Agreement is hereby accepted and the terms and conditions thereof hereby agreed to by the undersigned.		
Dated:	Optionee's Signature		
	Optionee's name and address:		
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CERTIFICATION

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

Date: November 15, 2004

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

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

Chief Executive Officer and President

CERTIFICATION

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

Date: November 15, 2004

/s/ Nicholas J. Alessi

Nicholas J. Alessi

Director of Finance and Treasurer

CERTIFICATION

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

Date: November 15, 2004 /s/ Shai N. Gozani, M.D., Ph. D.

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

Chief Executive Officer and President

/s/ Nicholas J. Alessi

Nicholas J. Alessi

Director of Finance and Treasurer

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