

**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 June 30, 2005

Commission file number 000-50856

**NEUROMETRIX, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**04-3308180**

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

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

**02451**  
(Zip Code)

**(781) 890-9989**

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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

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

Yes  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:

12,174,060 shares of common stock, par value \$0.0001 per share, were outstanding as of August 8, 2005

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**NeuroMetrix, Inc.**  
**Balance Sheets**  
**(Unaudited)**

	<u>June 30,</u> <u>2005</u>	<u>December 31,</u> <u>2004</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,768,020	\$ 1,936,241
Short-term investments	23,986,984	18,574,593
Accounts receivable, net of allowance for doubtful accounts of \$335,000 and \$300,000 at June 30, 2005 and December 31, 2004, respectively	3,723,965	3,126,565
Inventory	2,018,127	1,284,261
Prepaid expenses and other current assets	658,741	672,970
Current portion of deferred costs	172,702	140,719
Total current assets	<u>33,328,539</u>	<u>25,735,349</u>
Restricted cash	1,897,200	1,897,200
Long-term investments	2,834,706	9,497,158
Fixed assets, net	793,516	679,359
Deferred costs	181,682	143,462
Total assets	<u>\$ 39,035,643</u>	<u>\$ 37,952,528</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,493,983	\$ 899,291
Accrued expenses	876,945	593,420
Accrued compensation	1,550,121	1,343,206
Current portion of deferred revenue	546,150	399,468
Total current liabilities	<u>4,467,199</u>	<u>3,235,385</u>
Deferred revenue	640,145	471,734
Other long-term liabilities	160,000	189,091
Total liabilities	<u>5,267,344</u>	<u>3,896,210</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none outstanding	—	—
Common stock, \$0.0001 par value; 50,000,000 shares authorized; 12,169,495 and 12,034,650 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively	1,217	1,203
Additional paid-in capital	92,478,913	92,278,379
Deferred compensation	(597,195)	(745,086)
Accumulated deficit	(58,114,636)	(57,478,178)
Total stockholders' equity	<u>33,768,299</u>	<u>34,056,318</u>
Total liabilities and stockholders' equity	<u>\$ 39,035,643</u>	<u>\$ 37,952,528</u>

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

**NeuroMetrix, Inc.**  
**Statements of Operations**  
**(Unaudited)**

<u>Three Months Ended</u>		<u>Six Months Ended</u>	
<u>June 30, 2005</u>	<u>June 30, 2004</u>	<u>June 30, 2005</u>	<u>June 30, 2004</u>

<b>Revenues:</b>				
Diagnostic device	\$ 960,513	\$ 553,810	\$ 1,772,913	\$ 887,917
Biosensor	7,106,993	3,742,205	13,084,357	6,438,365
Total revenues	8,067,506	4,296,015	14,857,270	7,326,282
<b>Cost of revenues:</b>				
Cost of revenues	2,090,064	1,170,423	3,907,789	1,997,630
Gross margin	5,977,442	3,125,592	10,949,481	5,328,652
<b>Operating expenses:</b>				
Research and development	1,029,070	841,462	1,933,274	1,491,879
Sales and marketing	3,494,499	2,261,939	6,739,150	3,596,549
General and administrative	1,678,480	1,186,412	3,272,520	2,040,952
Total operating expenses	6,202,049	4,289,813	11,944,944	7,129,380
Loss from operations	(224,607)	(1,164,221)	(995,463)	(1,800,728)
Interest income	184,667	13,613	361,047	18,537
Interest expense	(204)	(145,319)	(2,042)	(293,730)
Net loss	(40,144)	(1,295,927)	(636,458)	(2,075,921)
Accretion of redeemable convertible preferred stock	$\frac{3}{4}$	(661,005)	$\frac{3}{4}$	(1,195,427)
Deemed dividend on redeemable convertible preferred stock	$\frac{3}{4}$	$\frac{3}{4}$	$\frac{3}{4}$	(787,885)
Beneficial conversion feature associated with redeemable convertible preferred stock	$\frac{3}{4}$	$\frac{3}{4}$	$\frac{3}{4}$	(7,050,771)
Net loss attributable to common stockholders	\$ (40,144)	\$ (1,956,932)	\$ (636,458)	\$ (11,110,004)
Net loss per common share (basic and diluted)	\$ (0.00)	\$ (1.85)	\$ (0.05)	\$ (10.59)
Weighted average shares used to compute basic and diluted net loss per common share	12,085,448	1,055,993	12,064,393	1,049,492

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

**NeuroMetrix, Inc.**  
**Statements of Cash Flows**  
**(Unaudited)**

	<b>Six Months Ended</b>	
	<b>June 30, 2005</b>	<b>June 30, 2004</b>
<b>Cash flow for operating activities:</b>		
Net loss	\$ (636,458)	\$ (2,075,921)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	131,052	88,272
Compensation expense associated with stock options	147,891	810,279
Accrued payments on long-term debt	$\frac{3}{4}$	55,000
Accretion of debt issuance discount	$\frac{3}{4}$	75,000
Amortization of premium on investments	249,417	—
Changes in operating assets and liabilities:		
Accounts receivable	(597,400)	(917,387)
Inventory	(733,866)	(18,249)
Prepaid expenses and other current assets	14,229	(137,215)
Accounts payable	594,692	321,484
Accrued expenses and compensation	490,440	300,116
Other long-term liabilities	(29,091)	30,909
Deferred revenue and costs	244,890	102,990
Net cash used in operating activities	(124,204)	(1,364,722)
<b>Cash flows for investing activities:</b>		
Purchases of investments	(7,433,535)	—
Maturities of investments	8,434,179	—
Purchases of fixed assets	(245,209)	(248,070)
Net cash provided by (used in) investing activities	755,435	(248,070)
<b>Cash flows from financing activities:</b>		
Proceeds from exercise of stock options	73,285	32,473
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	10,553,484
Proceeds from issuance of common stock under employee stock purchase plan	127,263	$\frac{3}{4}$

Payment of deferred financing costs	¾	(87,657)
Repayments of long-term debt	—	(207,323)
Net cash provided by financing activities	200,548	10,290,977
Net increase in cash and cash equivalents	831,779	8,678,185
Cash and cash equivalents, beginning of period	1,936,241	1,622,516
Cash and cash equivalents, end of period	\$ 2,768,020	\$ 10,300,701
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 2,042	\$ 159,479
Accretion of redeemable convertible preferred stock	\$ —	\$ 1,195,427
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 an 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 and reincorporated in Delaware in May 2001. 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. In connection with the IPO, the Company granted the underwriters a 30-day over-allotment 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 Company’s shares trade on The Nasdaq National Market 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 100,000 shares of common stock. This warrant was exercised in full on June 13, 2005.

The accompanying unaudited balance sheet as of June 30, 2005 and unaudited statements of operations for the three and six month periods ended June 30, 2005 and 2004 and the unaudited statements of cash flows for the six month periods ended June 30, 2005 and 2004 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 statement of the results of operations have been included. Operating results for the six month period ended June 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005 or any other period. These financial statements and notes should be read in conjunction with the financial statements for the year ended December 31, 2004 included in the Company’s Annual Report on Form 10-K (File No. 000-50856). The accompanying balance sheet as of December 31, 2004 has been derived from audited financial statements prepared at that date, but does not include all disclosures required by accounting principles generally accepted in the United States.

### Use of Estimates

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

### Recent Accounting Pronouncements

In March 2005, the Financial Accounting Standards Board (“FASB”) issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*, which is an interpretation of Statement of Financial Accounting Standards (“SFAS”) No. 143, *Accounting for Asset Retirement Obligations*. The interpretation requires a liability for the fair value of a conditional asset retirement obligation be recognized if the fair value of the liability can be reasonably estimated. The interpretation is effective in 2005. The interpretation is not expected to have a material impact on our results of operations or financial position.

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payment* (SFAS 123(R)), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and supersedes Accounting Principles Board (“APB”) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and SFAS 148 *Accounting for Stock-Based Compensation – Transition and Disclosure*. This statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements. This statement establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair value based measurement method in accounting for share-based payment transactions with employees except for equity instruments held by employee share ownership plans. As a result, beginning January 1, 2006, the Company will adopt SFAS 123(R) and begin reflecting the stock compensation expense determined under fair value based methods in the income statement rather than as pro forma disclosure in the notes to the financial statements. The Company is currently reviewing the effect of this statement on its financial statements and expects there to be a material impact on the Company’s results of operations.

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In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets* (SFAS 153), an amendment of APB Opinion No. 29, *Accounting for Nonmonetary Transactions*. SFAS 153 requires that exchanges of nonmonetary assets be measured based on the fair value of the assets exchanged. Further, it expands the exception for nonmonetary exchanges of similar productive assets to nonmonetary assets that do not have commercial substance. The provisions of this Statement are effective for nonmonetary asset exchanges beginning after June 15, 2005. The adoption of the provisions of SFAS 153 is not expected to have a material impact on the Company's financial position or results of operations.

In May 2005, the FASB issued SFAS No. 154 *Accounting for Changes and Error Correction, a Replacement of APB Opinion No. 20 and FASB Statement No. 3* (SFAS 154). SFAS 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes, unless impracticable, retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The provisions of this Statement are effective for accounting changes and corrections of errors made in fiscal periods after December 15, 2005. The adoption of SFAS 154 is not expected to have a material impact on the Company's financial position or results of operations.

## 2. Accounting for Stock-Based Compensation

Employee stock awards granted under the Company's compensation plans are accounted for in accordance with APB 25 and related interpretations. The Company has not adopted the fair value method of accounting for stock-based compensation prescribed by SFAS 123. 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 and the resulting compensation expense is generally recognized over the period of service.

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 123, the Company's net loss attributable to common stockholders and net loss per common share would approximate the pro forma amounts below:

	Three Months Ended		Six Months Ended	
	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
Net loss attributable to common stockholders, as reported	\$ (40,144)	\$ (1,956,932)	\$ (636,458)	\$ (11,110,004)
Add employee stock-based compensation expense included as reported net loss attributable to common stockholders	71,916	765,659	147,891	810,279
Less employee stock-based compensation expense determined under fair value method	(350,630)	(909,862)	(679,663)	(964,003)
Net loss attributable to common stockholders – pro forma	(318,858)	(2,101,135)	(1,168,230)	(11,263,728)
Net loss per common share (basic and diluted):				
As reported	\$ (0.00)	\$ (1.85)	\$ (0.05)	\$ (10.59)
Pro forma	\$ (0.03)	\$ (1.99)	\$ (0.10)	\$ (10.73)

Prior to the July 2004 IPO, the Company established the fair value of common stock by reference to the previously issued redeemable convertible preferred stock and by reference to an expected IPO price. The Company has estimated the fair value of its granted stock options by applying the following weighted average assumptions:

	Three Months Ended		Six months ended	
	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
Risk-free interest rate	3.5%-4.1%	3.9%	3.5%-4.3%	3.1%-3.9%
Expected dividend yield	$\frac{3}{4}$	$\frac{3}{4}$	$\frac{3}{4}$	$\frac{3}{4}$
Expected option term	5 years	5 years	5 years	5 years
Volatility	63.7%	65.0%	60.0%	65.0%
Weighted average fair value of options granted	\$ 7.56	\$ 7.03	\$ 5.51	\$ 7.05

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 has computed volatility based on the actual performance of the stock.

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 effects of applying the fair value method are expected to be material to reported net income or loss in future years.

## 3. Earnings (Loss) Per Common Share

The Company accounts for and discloses net loss per common share in accordance with SFAS No. 128, *Earnings Per Share*. 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).

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 and Six Months Ended	
	June 30, 2005	June 30, 2004
Options outstanding	1,278,780	1,018,396
Warrants outstanding	¾	100,000
Redeemable convertible preferred stock	¾	7,488,758

#### 4. Inventory

Inventory consists of the following:

	June 30, 2005	December 31, 2004
Purchased components	\$ 396,411	\$ 293,263
Finished goods	1,621,716	990,998
Total inventory	\$ 2,018,127	\$ 1,284,261

#### 5. Other Balance Sheet Items

Accrued expenses consist of the following:

	June 30, 2005	December 31, 2004
Professional services	\$ 215,871	\$ 164,701
Other	661,074	428,719
	\$ 876,945	\$ 593,420

#### Product Warranty Costs

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. The Company's accrued warranty liability is included in accrued expenses in the accompanying balance sheets.

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The following is a rollforward of the Company's accrued warranty liability for the three and six month periods ended June 30, 2005 and 2004:

	Three Months Ended		Six Months Ended	
	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
Balance at beginning of period	\$ 64,182	\$ 30,283	\$ 59,876	22,151
Accrual for warranties	79,622	45,570	139,316	81,301
Settlements made	(72,451)	(37,092)	(127,839)	(64,691)
Balance at end of period	\$ 71,353	\$ 38,761	\$ 71,353	\$ 38,761

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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 June 1996. We design, develop and sell proprietary medical devices used to diagnose neuropathies. Our proprietary technology provides physicians with an in-office diagnostic system, the NC-stat System, that 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; (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. 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 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.

From our inception until May 1999, we had devoted substantially all of our efforts to designing and developing the NC-stat System and other potential products, raising capital and recruiting personnel. We believe that one of our strengths is our ability to develop and commercialize innovative products for neurological applications. In May 1999, we shipped our first NC-stat System. At that time we sold one type of biosensor, for the testing of the median motor nerve. In 2000, we introduced an additional biosensor for the testing of the ulnar motor nerve. In 2002, we introduced our second-generation NC-stat System,

as well as two additional biosensors. In 2003, we added to our product line two biosensors with higher functionality that have the ability to test both motor and sensory nerves. In 2004, we introduced two new NC-stat biosensors as well as components for the NC-stat monitor to utilize these new biosensors. The first new biosensor is used to test the ulnar nerve at the elbow and the second to test the sural nerve. In the first six months of 2005, our revenues grew 102.8% from the same period in 2004, generating \$14.9 million in revenues, of which 88.1% was attributable to sales of NC-stat biosensors. Our gross margin percentage in the first six months of 2005 was 73.7%.

We derive our revenues from the sale of NC-stat biosensors, monitors and docking stations directly to end users, which are generally physician practice groups. Our NC-stat biosensors are disposable products that are used once and inactivated after use. The NC-stat monitor is an electronic instrument that is used with the NC-stat biosensors to perform nerve conduction studies for the purpose of diagnosing neuropathies. The NC-stat monitor displays the pertinent results of nerve conduction studies on an LCD screen immediately at the conclusion of each study. The NC-stat docking station is an optional device that is used to transmit to the onCall Information System data generated by the nerve conduction study performed with the NC-stat monitor. The onCall Information System formulates the data it receives for each test into a detailed report that is provided to the customer through facsimile or e-mail.

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. Our revenue recognition policy is to recognize revenue from our monitors and biosensors upon shipment if the fee is fixed and determinable, persuasive evidence of an arrangement exists, collection of the resulting receivable is reasonably assured and product returns are reasonably estimable. Revenues from our docking station are deferred and recognized over the shorter of the estimated customer relationship period or the estimated useful life of the product, currently three years.

Reimbursement from third-party payers is an important element of success for medical products companies. Generally, we believe that the nerve conduction studies performed by our customers with the NC-stat System have been satisfactorily covered by third-party payers. As our presence in the market expands and the use of the NC-stat System increases, we have experienced and are likely to continue to experience an increased focus from third-party payers regarding the reimbursement of nerve conduction studies performed using the NC-stat System and an increased focus from third-party payers regarding the professional requirements for performing nerve conduction studies in general. Widespread adoption of the NC-stat System by the medical community is unlikely to occur if physicians do not receive satisfactory reimbursement from third-party payers for procedures performed with the NC-stat System.

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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 and specialty 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 have increased our sales force to 30 regional sales managers as of June 30, 2005 and plan to more modestly increase our sales force (as compared with the last two quarters during which time we added 8 regional sales managers) and plan to increase our total headcount for the balance of 2005 and participate 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, will provide challenges to our organization and may increase the burden on 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.

In March 2005, we entered into an education and development program agreement with Eli Lilly and Company ("Lilly"). Through this agreement, our Company and Lilly expect to conduct a broad series of up to 84 educational and development programs across the country during 2005 and 2006. The focus of each program is on educating physicians regarding the treatment and diagnosis of diabetic peripheral neuropathy ("DPN"), nerve conduction studies, our NC-stat System and its application in DPN and the benefits to physicians and patients of using the NC-stat System. During the second quarter of 2005, the first series of programs were conducted as originally planned. Lilly has a significant presence in the diabetes market, including drugs targeted at DPN. Lilly has a drug known as Cymbalta approved by the Food and Drug Administration ("FDA") for the treatment of pain associated with DPN and they have a drug known as ruboxistaurin (or Arxxant) that is in a Phase III clinical trial for the treatment of the underlying disease state in patients with DPN. On August 2, 2005, Lilly announced that it completed two Phase III trials to determine the effect of ruboxistaurin on treatment of sensory symptoms associated with DPN. Lilly announced that, in these studies, statistical comparison of the change in sensory symptom scores between the placebo and ruboxistaurin-treated groups did not demonstrate significant differences and did not meet the studies' primary endpoints and, consequently, do not support a new drug application filing. However, Lilly also announced that it was continuing an ongoing, three-year, placebo-controlled trial evaluating ruboxistaurin for the treatment of nerve dysfunction of DPN, scheduled to complete in 2007. For this three-year trial, change in a composite of objective nerve function measures, including nerve conduction studies, is the primary outcome. As a result of these developments, we will be discussing with Lilly our plans with regard to the series of educational and development programs that we were to jointly conduct with Lilly. We cannot assure you that these programs will continue as originally scheduled or at all.

Since our inception in 1996, we have incurred losses every quarter. We incurred net losses of approximately \$8.7 million in 2001, \$4.8 million in 2002, \$3.7 million in 2003, \$4.3 million in 2004 and \$0.6 million in the first six months of 2005. We do not know whether or when we will become profitable. As of June 30, 2005, we had an accumulated deficit of approximately \$58.1 million. We have financed our operations through the public and private placement of equity securities and through debt facilities including a line of credit. As of June 30, 2005, we had received net proceeds of \$43.5 million from the issuance of redeemable convertible preferred stock and \$24.0 million in net proceeds from our initial public offering ("IPO").

Our financial objective is to achieve and sustain profitable growth. Our efforts in 2005 will continue to focus 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, with the goal of increasing our market penetration. During the first six months of 2005 we increased our direct sales force to 30 regional sales managers and we expect to hire four direct sales representatives who will primarily be involved with customer training and assisting regional sales managers. We are also currently evaluating potential additional expansion of the sales force. During the first six months of 2005 we continued efforts on improvements to our biosensors, on the development of new biosensors and on the development of a third generation monitor and docking station. 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 specialist physicians. We believe that the accomplishment of these goals will have a positive impact on our progress toward the objective of achieving profitability.

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## Results of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
<b>Revenues:</b>				
Diagnostic device	11.9%	12.9%	11.9%	12.1%
Biosensor	88.1	87.1	88.1	87.9
Total revenues	100.0	100.0	100.0	100.0
<b>Cost of revenues</b>				
	25.9	27.2	26.3	27.3
<b>Gross margins</b>				
	74.1	72.8	73.7	72.7
<b>Operating expenses:</b>				
Research and development	12.8	19.6	13.0	20.4
Sales and marketing	43.3	52.7	45.4	49.1
General and administrative	20.8	27.6	22.0	27.9
Total operating expenses	76.9	99.9	80.4	97.3
Loss from operations	-2.8	-27.1	-6.7	-24.6
Interest income (expense), net	2.3	-3.1	2.4	-3.7
Net Loss	-0.5%	-30.2%	-4.3%	-28.3%

### Comparison of Three Months Ended June 30, 2005 and June 30, 2004

#### Revenues

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

	12-Month Period Ended June 30,		Change	% Change
	2005	2004		
Customers	2,696	1,924	772	40.1%

	Three Months Ended June 30,		Change	% Change
	2005	2004		
Biosensor units used	173,100	81,500	91,600	112.4

(\$ in thousands)

	2005	2004	Change	% Change
<b>Revenues:</b>				
Diagnostic device	\$ 960.5	\$ 553.8	\$ 406.7	73.4
Biosensor	7,107.0	3,742.2	3,364.8	89.9
Total revenues	\$ 8,067.5	\$ 4,296.0	\$ 3,771.5	87.8%

Diagnostic device revenues were \$960,500 and \$553,800 for the three months ended June 30, 2005 and June 30, 2004, respectively, representing a year-over-year increase of \$406,700, or 73.4%. Of this increase, approximately \$265,100 is attributable to a greater number of units sold, primarily as a result of an increase in the number of regional sales managers and expanded clinical uses for the NC-stat System, an increase in the number of active customer accounts and increased usage per customer account. In addition, approximately \$141,600 of this increase is attributable to an increase in the list price of our NC-stat monitors and docking stations from \$3,500 to \$4,000 effective January 1, 2005, which resulted in a higher average selling price during the three months ended June 30, 2005 as compared to the same period in 2004. Diagnostic device revenues accounted for 11.9% and 12.9% of our total revenues for the three months ended June 30, 2005 and June 30, 2004, respectively.

Biosensor revenues were \$7.1 million and \$3.7 million for the three months ended June 30, 2005 and June 30, 2004, respectively, representing a year-over-year increase of \$3.4 million, or 89.9%. The increase was primarily due to an increased customer base for our biosensors, increased frequency of testing by our customers and the introduction of new biosensors, including the sural biosensor in the fourth quarter of 2004. Biosensor revenues accounted for 88.1% and 87.1% of our total revenues for the three months ended June 30, 2005 and June 30, 2004, respectively.

Our customers used 173,100 biosensor units in the three months ended June 30, 2005, compared to 81,500 units for the same period in 2004, an increase of 91,600 units, or 112.4%. This increase in biosensor usage is primarily the result of the increase in the customer base, increased usage by customers and the introduction of new biosensors, including the sural biosensor in the fourth quarter of 2004. Our customers used approximately 18,000 sural biosensors in the second quarter of 2005. The sural biosensor is an important additional biosensor for our customers' use of the NC-stat System for low back pain and DPN and we believe that its introduction is contributing to the growth in biosensor usage for these clinical indications.

Our total revenues were \$8.1 million and \$4.3 million for the three months ended June 30, 2005 and June 30, 2004, respectively, representing a year-over-year increase of \$3.8 million, or 87.8%. During the 12-month period ending June 30, 2005, a total of 2,696 customers used our NC-stat System compared to 1,924 customers for the same period ending June 30, 2004. This represents a 40.1% year-over-year increase in the number of customers that used our NC-stat System.



We expect revenues to continue to increase in 2005 as a result of the recent expansion of our sales force, which grew from 22 regional sales managers as of December 31, 2004 to 30 regional sales managers at the end of the second quarter of 2005, an increase in the number of active customer accounts and increased usage per customer account. However, 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. In addition, we may experience seasonality in the third quarter of 2005 due to fewer patient visits and fewer physician working days during the summer months.

### Costs and expenses

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

(\$ in thousands)	Three Months Ended June 30,		Change	% Change
	2005	2004		
<b>Cost of revenues:</b>				
Diagnostic device	\$ 259.8	\$ 189.3	\$ 70.5	37.2%
Biosensor	1,830.3	981.1	849.2	86.6
Total costs of revenues	2,090.1	1,170.4	919.7	78.6
<b>Gross margin:</b>				
Diagnostic device	700.7	364.5	336.2	92.2
Biosensor	5,276.7	2,761.1	2,515.6	91.1
Total gross margin	5,977.4	3,125.6	2,851.8	91.2
<b>Gross margin %:</b>				
Diagnostic device	73.0%	65.8%		
Biosensor	74.2	73.8		
Total gross margin %	74.1	72.8		
<b>Operating expenses:</b>				
Research and development (1)	1,029.1	841.5	187.6	22.3
Sales and marketing (1)	3,494.5	2,261.9	1,232.6	54.5
General and administrative (1)	1,678.5	1,186.4	492.1	41.5
Total operating expenses	6,202.0	4,289.8	1,912.2	44.6
Loss from operations	(224.6)	(1,164.2)	939.6	-80.7
Interest income	184.7	13.6	171.1	1,258.1
Interest expense	(0.2)	(145.3)	(145.1)	-99.9
Net loss	(40.1)	(1,295.9)	1,255.8	-96.9
Accretion of dividend on preferred stock	$\frac{3}{4}$	(661.0)	661.0	$\frac{3}{4}$
Net loss available to common stockholders	\$ (40.1)	\$ (1,956.9)	\$ 1,916.8	-98.0

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

Research and development	\$ 19.2	\$ 190.5
Sales and marketing	33.5	253.7
General and administrative	19.3	321.5
Total non-cash stock based compensation	\$ 71.9	\$ 765.7

### Gross Margin

Diagnostic device gross margin percentage was 73.0% and 65.8% for the three months ended June 30, 2005 and June 30, 2004, respectively. The increase in the gross margin percentage in the second quarter of 2005 compared to the same period in 2004 is primarily attributable to an increase in the list price of our NC-stat System from \$3,500 to \$4,000 effective January 1, 2005.

Biosensor gross margin percentage increased to 74.2% for the three months ended June 30, 2005 from 73.8% for the same period in 2004. The small increase in biosensor gross margin percentage is primarily due to manufacturing cost reductions realized for several of our biosensors, offset in part by a change in the mix of biosensors resulting from the introduction of new biosensors in the second half of 2004 which have modestly lower gross margins.

Our overall gross margin percentage was 74.1% for the three months ended June 30, 2005 compared to 72.8% for the same period in 2004. At the beginning of 2005, we raised the list price of our diagnostic devices. The list price increase should continue to result in a higher diagnostic device gross margin percentage in 2005 when compared to 2004. We anticipate our overall gross margin percentage will remain relatively consistent for the remainder of 2005. However, if sales volumes do not increase, if the mix of sales shifts further toward lower margin biosensors, if pricing pressures increase or if the cost of biosensors and diagnostic devices through our third-party manufacturers increases, then gross margin may be negatively impacted in future quarters.

### Research and Development

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

R&D expenses increased \$187,600, or 22.3%, to \$1.0 million for the three months ended June 30, 2005 from \$841,500 for the same period in 2004. As a percentage of revenues, R&D expenses were 12.8% and 19.6% for the three months ended June 30, 2005 and June 30, 2004, respectively. The increase in

expenses was primarily due to an increase of \$129,000 in employee compensation and benefit costs resulting from the hiring of additional employees in our R&D department, an increase of \$112,000 in outside consulting costs and an increase of \$92,700 in clinical development costs. These increases are primarily related to efforts expended on the development of a third generation monitor and docking station and improvements to our existing biosensors and the development of new biosensors. The increases are offset in part by a decrease of \$171,300 in stock-based compensation expense related to employee stock options.

For the remainder of 2005, we expect our spending on R&D will increase due to the hiring of several additional employees to support product development efforts and due to increased clinical study costs. We expect R&D expenses, as a percentage of total revenues, to continue to decrease slightly. This percentage may vary, however, depending primarily on our revenues for the remainder of 2005.

### Sales and Marketing

Sales and marketing expenses increased \$1.2 million, or 54.5%, to \$3.5 million for the three months ended June 30, 2005 from \$2.3 million for the same period in 2004. As a percentage of revenues, sales and marketing expenses were 43.3% and 52.7% for the three months ended June 30, 2005 and June 30, 2004, respectively. The change in expenses was primarily due to an increase of \$1.0 million in employee compensation and benefit costs, including sales commissions paid to our regional sales managers. This increase is due to the expansion of the sales force and higher revenues in the second quarter of 2005 as compared to the second quarter of 2004. Also contributing to the change in expenses was an increase of \$237,700 in sales commissions paid to our independent regional sales agencies, which were related to our higher revenues in the second quarter of 2005, and an increase of \$49,000 in travel expenses due to the expansion of the sales force. The change in expenses was also partially due to an increase of \$123,400 in costs for trade shows, advertising and promotional materials as we have increased our presence at tradeshow and developed new promotional materials. The increases are offset in part by a decrease of \$220,200 in stock-based compensation expense related to employee stock options.

We have increased the number of our regional sales managers to 30 as of the end of the second quarter of 2005 and expect to hire several additional sales and marketing personnel during the remainder of 2005, including four sales representatives who will primarily be involved with customer training and assisting regional sales managers. For 2005, we expect sales and marketing expenses, as a percentage of total revenues, to remain relatively consistent with the level for the second quarter of 2005. This percentage may vary, however, depending primarily on our revenues for the remainder of 2005.

### General and Administrative

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

General and administrative expenses increased \$492,100, or 41.5%, to \$1.7 million for the three months ended June 30, 2005 from \$1.2 million for the same period in 2004. As a percentage of revenues, general and administrative expenses were 20.8% and 27.6% for the three months ended June 30, 2005 and June 30, 2004, respectively. The increase in expenses was primarily due to (a) an increase in employee compensation and benefit costs of \$272,600 due to the expansion of staff and increases in employee compensation; (b) an increase of \$162,400 in our insurance costs, primarily relating to increases in director and officer insurance premiums as a result of the transition to a publicly-traded company; (c) an increase of \$128,300 in professional fees for legal services and for accounting and audit services primarily as a result of the increased regulatory requirements associated with being a publicly-traded company; (d) an increase of \$48,500 in credit card and bank transaction fees related to customer sales and (e) an increase in recruiting costs of \$31,300 associated with new hires. The increases are offset in part by a decrease of \$302,200 in stock-based compensation expense related to employee stock options. We expect our general and administrative expenses to increase during the remainder of 2005 as a result of our expected growth and the additional requirements that we will need to fulfill as a publicly-traded company. These requirements include the provisions of the Sarbanes-Oxley Act of 2002, and the rules promulgated thereunder, regarding internal control over financial reporting which will begin to apply to us as of December 31, 2005. Total general and administrative expenses, as a percentage of total revenues, may increase in the second half of 2005 due to costs incurred in connection with Sarbanes Oxley compliance efforts. This percentage may vary, however, depending primarily on our revenues for the remainder of 2005.

### Interest Income

Interest income was \$184,700 and \$13,600 during the three months ended June 30, 2005 and June 30, 2004, respectively. Interest income was earned from investments in cash equivalents, short-term investments and long-term investments. Interest income increased during the three months ended June 30, 2005 compared to the same period in 2004 because of the investment of the proceeds from the IPO, which was completed in the third quarter of 2004. We expect interest income to be relatively unchanged for the remaining quarters of 2005 compared with the second quarter of 2005.

### Interest Expense

Interest expense was \$200 and \$145,300 during the three months ended June 30, 2005 and June 30, 2004, respectively, representing a decrease of \$145,100. The decrease in interest expense was due to the payment in the third quarter of 2004 of the outstanding balance of \$3.0 million under the line of credit with Lighthouse Capital Partners using a portion of the proceeds from the initial public offering.

## **Comparison of Six Months Ended June 30, 2005 and June 30, 2004**

### **Revenues**

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

	12-Month Period Ended June 30,		Change	% Change
	2005	2004		
Customers	2,696	1,924	772	40.1%
	Six Months Ended June 30,		Change	% Change
	2005	2004		

Biosensor units used	310,700	151,800	158,900	104.7
<b>(\$ in thousands)</b>				
<b>Revenues:</b>				
Diagnostic device	\$ 1,772.9	\$ 887.9	\$ 885.0	99.7
Biosensor	13,084.4	6,438.4	6,646.0	103.2
Total revenues	<u>\$ 14,857.3</u>	<u>\$ 7,326.3</u>	<u>\$ 7,531.0</u>	102.8%

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Diagnostic device revenues were \$1.8 million and \$887,900 for the six months ended June 30, 2005 and June 30, 2004, respectively, representing a year-over-year increase of \$885,000, or 99.7%. Of this increase, approximately \$571,300 is attributable to a greater number of units sold, primarily as a result of an increase in the number of regional sales managers and expanded clinical uses for the NC-stat System. In addition, approximately \$313,700 of this increase is attributable to an increase in the list price of our NC-stat monitors and docking stations from \$3,500 to \$4,000 effective January 1, 2005, which resulted in a higher average selling price during the six months ended June 30, 2005 as compared to the same period in 2004. Diagnostic device revenues accounted for 11.9% and 12.1% of our total revenues for the six months ended June 30, 2005 and June 30, 2004, respectively.

Biosensor revenues were \$13.1 million and \$6.4 million for the six months ended June 30, 2005 and June 30, 2004, respectively, representing a year-over-year increase of \$6.6 million, or 103.2%. The increase was primarily due to an increased customer base for our biosensors, increased frequency of testing by our customers and the introduction of new biosensors, including the sural biosensor in the fourth quarter of 2004. Biosensor revenues accounted for 88.1% and 87.9% of our total revenues for the six months ended June 30, 2005 and June 30, 2004, respectively.

Our customers used 310,700 biosensor units in the six months ended June 30, 2005, compared to 151,800 units for the same period in 2004, an increase of 158,900 units, or 104.7%. This increase in biosensor usage is primarily the result of the increase in the customer base, increased usage by customers and the introduction of new biosensors, including the sural biosensor in the fourth quarter of 2004. Our customers used approximately 28,000 sural biosensors in the first six months of 2005.

Our total revenues were \$14.9 million and \$7.3 million for the six months ended June 30, 2005 and June 30, 2004 respectively, representing a year-over-year increase of \$7.6 million, or 102.8%. During the 12-month period ending June 30, 2005, a total of 2,696 customers used our NC-stat System compared to 1,924 customers for the same period ending June 30, 2004. This represents a 40.1% year-over-year increase in the number of customers that used our NC-stat System.

#### Costs and expenses

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

(\$ in thousands)	Six Months Ended June 30,		Change	% Change
	2005	2004		
<b>Cost of revenues:</b>				
Diagnostic device	\$ 478.9	\$ 322.0	\$ 156.9	48.7%
Biosensor	3,428.9	1,675.6	1,753.3	104.6
Total costs of revenues	<u>3,907.8</u>	<u>1,997.6</u>	<u>1,910.2</u>	95.6
<b>Gross margin:</b>				
Diagnostic device	1,294.0	566.0	728.0	128.6
Biosensor	9,655.5	4,762.7	4,892.8	102.7
Total gross margin	<u>10,949.5</u>	<u>5,328.7</u>	<u>5,620.8</u>	105.5
<b>Gross margin %:</b>				
Diagnostic device	73.0%	63.7%		
Biosensor	73.8	74.0		
Total gross margin %	73.7	72.7		
<b>Operating expenses:</b>				
Research and development (1)	1,933.3	1,491.9	441.4	29.6
Sales and marketing (1)	6,739.1	3,596.5	3,142.6	87.4
General and administrative (1)	3,272.5	2,041.0	1,231.5	60.3
Total operating expenses	<u>11,944.9</u>	<u>7,129.4</u>	<u>4,815.5</u>	67.5
Loss from operations	(995.5)	(1,800.7)	805.2	-44.7
Interest income	361.0	18.5	342.5	1,851.4
Interest expense	(2.0)	(293.7)	291.7	-99.3
Net loss	(636.5)	(2,075.9)	1,439.4	-69.3
Accretion of dividend on preferred stock	¾	(1,195.4)	1,195.4	¾
Deemed dividend on redeemable convertible preferred stock	¾	(787.9)	787.9	¾
Beneficial conversion feature	¾	(7,050.8)	7,050.8	¾
Net loss available to common stockholders	<u>\$ (636.5)</u>	<u>\$ (11,110.0)</u>	<u>\$ 10,473.5</u>	-94.3

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

Research and development	\$	39.0	\$	206.3
Sales and marketing		69.8		271.1
General and administrative		39.1		332.9
Total non-cash stock based compensation	\$	147.9	\$	810.3

### Gross Margin

Diagnostic device gross margin percentage was 73.0% and 63.7% for the six months ended June 30, 2005 and June 30, 2004, respectively. The increase in the gross margin percentage in the first six months of 2005 compared to the same period in 2004 is primarily attributable to an increase in the list price of our NC-stat System from \$3,500 to \$4,000 effective January 1, 2005.

Biosensor gross margin percentage decreased to 73.8% for the six months ended June 30, 2005 from 74.0% for the same period in 2004.

Our overall gross margin percentage was 73.7% for the six months ended June 30, 2005 compared to 72.7% for the same period in 2004.

### Research and Development

R&D expenses increased \$441,400, or 29.6%, to \$1.9 million for the six months ended June 30, 2005 from \$1.5 million for the same period in 2004. As a percentage of revenues, R&D expenses were 13.0% and 20.4% for the six months ended June 30, 2005 and June 30, 2004, respectively. The increase in expenses was primarily due to an increase of \$267,900 in employee compensation and benefit costs resulting from the hiring of additional employees in our R&D department, an increase of \$195,600 in outside consulting costs, an increase of \$78,000 in clinical development costs and an increase of \$49,100 in recruiting costs associated with new hires. These increases are primarily related to efforts expended on the development of a third generation monitor and docking station and on new biosensors and improvements to existing biosensors. These increases were offset in part by a decrease in stock-based compensation expense of \$167,200 related to employee stock options.

### Sales and Marketing

Sales and marketing expenses increased \$3.1 million, or 87.4%, to \$6.7 million for the six months ended June 30, 2005 from \$3.6 million for the same period in 2004. As a percentage of revenues, sales and marketing expenses were 45.4% and 49.1% for the six months ended June 30, 2005 and June 30, 2004, respectively. The change in expenses was primarily due to an increase of \$2.1 million in employee compensation and benefit costs, including sales commissions paid to our regional sales managers. This increase is due to the expansion of the sales force and higher revenues in the first six months of 2005 as compared to the first six months of 2004. Also contributing to the change in expenses was an increase of \$713,300 in sales commissions paid to our independent regional sales agencies, which were related to our higher revenues in the first six months of 2005, and an increase of \$249,700 in travel expenses due to the expansion of the sales force. The change in expenses was also partially due to an increase of \$225,200 in costs for trade shows, advertising and promotional materials as we have increased our presence at tradeshow and developed new promotional materials. These increases were offset in part by a decrease in stock-based compensation expense of \$201,300 related to employee stock options.

### General and Administrative

General and administrative expenses increased \$1.2 million, or 60.3%, to \$3.3 million for the six months ended June 30, 2005 from \$2.0 million for the same period in 2004. As a percentage of revenues, general and administrative expenses were 22.0% and 27.9% for the six months ended June 30, 2005 and June 30, 2004, respectively. The increase in expenses was primarily due to (a) an increase in employee compensation and benefit costs of \$527,000 due to the expansion of staff and salary increases and increases in incentive compensation; (b) an increase of \$304,500 in our insurance costs, primarily relating to increases in director and officer insurance premiums as a result of the transition to a publicly-traded company; (c) an increase of \$269,900 in professional fees for legal services and for accounting and audit services primarily as a result of the increased regulatory requirements associated with being a publicly-traded company; (d) an increase of \$101,400 in franchise taxes and other fees; and (e) an increase in recruiting costs of \$64,700 associated with new hires. These increases were offset in part by a decrease in stock-based compensation expense of \$293,900 related to employee stock options.

### Interest Income

Interest income was \$361,000 and \$18,500 during the six months ended June 30, 2005 and June 30, 2004, respectively. Interest income was earned from investments in cash equivalents, short-term investments and long-term investments. Interest income increased during the six months ended June 30, 2005 compared to the same period in 2004 because of the investment of the proceeds from the IPO, which was completed in the third quarter of 2004, and from the proceeds of the sale of preferred stock in March 2004.

### Interest Expense

Interest expense was \$2,000 and \$293,700 during the six months ended June 30, 2005 and June 30, 2004, respectively, representing a decrease of \$291,700. The decrease in interest expense was due to the payment in the third quarter of 2004 of the outstanding balance of \$3.0 million under the line of credit with Lighthouse Capital Partners using a portion of the proceeds from the initial public offering.

### Deemed Dividend and Beneficial Conversion Feature on Redeemable Convertible Preferred Stock

In the first six 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 pursuant to the anti-dilution protection provisions associated with the Series D redeemable convertible preferred stock. We also recorded a charge of \$7.1 million for a beneficial conversion feature associated with the Series E-1 redeemable convertible preferred stock issued in March 2004. There was no deemed dividend or beneficial conversion charge in the first six months of 2005. All issued and outstanding shares of preferred stock were converted into shares of common stock in connection with the IPO.

## Liquidity and Capital Resources

Our principal source of liquidity is our current cash and cash equivalents, short-term investments and long-term investments. As of June 30, 2005, the weighted average maturity of our short and long term investments was 220 days. Our ability to generate cash from operations is dependent upon our ability to generate revenue from sales of our disposable biosensors and diagnostic devices, as well as our ability to manage our operating costs, capital investments and working capital. A decrease in demand for our products or unanticipated increases in our operating costs would likely have an adverse effect on our liquidity and cash generated from operations. The following sets forth information relating to our liquidity:

(\$ in thousands)	June 30, 2005	December 31, 2004	Change	% Change
Cash and cash equivalents	\$ 2,768	\$ 1,936		
Short-term investments	23,987	18,575		
Long-term investments	2,835	9,497		
Total cash, cash equivalents, short-term investments and long-term investments	\$ 29,590	\$ 30,008	\$ (418)	-1.4%

During the first six months of 2005, our cash and cash equivalents, short-term investments and long-term investments decreased \$418,000 primarily due to the net loss of \$636,500 (offset in part by non-cash charges of \$528,400) and an aggregate increase in accounts receivable and inventories of \$1.3 million and the purchase of \$245,000 in fixed assets, offset by an increase in current liabilities of \$1.1 million, primarily accounts payable and accrued expenses, and \$200,000 in proceeds received from the exercise of stock options and the issuance of common stock under our employee stock purchase plan.

In managing our working capital, two of the financial measurements we monitor are days' sales outstanding, or DSO, and inventory turnover rate, which are presented in the table below for the year ended December 31, 2004 and the three months ended June 30, 2005 and June 30, 2004:

	Year Ended December 31, 2004	Three Months Ended June 30,	
		2005	2004
Days' sales outstanding (days)	50	40	50
Inventory turnover rate (times per year)	4.1	4.8	3.9

Our payment terms extended to our customers generally require payment within 30 days from invoice date. At June 30, 2005, our DSO was at 40 days, a decrease of 10 days as compared to December 31, 2004. This decrease in DSO resulted from increasing revenues and a decrease in the percentage of accounts receivable balances more than 90 days past due. This decrease in the percentage of accounts receivable balances more than 90 days past due was primarily due to more aggressive management of collections and the significant revenue growth in the three months ended June 30, 2005 relative to the more modest increase in our accounts receivable balances during the three months ended June 30, 2005. We continue to focus our efforts on reducing our accounts receivable balances over 90 days past due. Accounts payable are normally paid within 30 to 40 days from receipt of a vendor's invoice.

Our inventory turnover for the three months ended June 30, 2005 was 4.8 times, compared with 4.1 times for the year ended December 31, 2004. The increase in the inventory turnover rate for the three months June 30, 2005 as compared to the year ended December 31, 2004 was primarily due to the effective management of inventory levels of biosensors. We are monitoring our inventories closely, especially as it pertains to the mix of different biosensors sold, and the sales volumes of new biosensors launched in 2004. We expect to increase our inventory levels through the balance of 2005 with a target of maintaining at least three months worth of inventory in our facility in Waltham, MA. This may have the effect of decreasing our inventory turnover rate.

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

	Six Months Ended June 30,	
	2005	2004
	(in thousands)	
Net cash used in operating activities	\$ (124.2)	\$ (1,364.7)
Net cash provided by (used in) investing activities	755.4	(248.1)
Net cash provided by financing activities	200.5	10,291

Cash used in operating activities was approximately \$124,200 in the first six months of 2005 compared with \$1.4 million in the first six months of 2004. The net loss of \$636,500 and the increases of \$597,400 in accounts receivable and \$733,900 in inventories were offset by increases in accounts payable and accrued expenses of \$594,700 and \$490,400, respectively, in the first six months of 2005. The increase in accounts payable was due primarily to an increase in amounts owed to one of the Company's outsourced manufacturers and is also attributable to the growth in the business. The net loss in the first six months of 2004 was \$2.1 million and cash used for operating assets and liabilities in the first six months of 2004 totaled \$0.6 million, including increases in accounts receivable and prepaid expenses.

Cash provided by investing activities was \$755,400 in the first six months of 2005, compared with cash used in investing activities of \$248,100 in the first six months of 2004. In the first six months of 2005, there were net maturities of investments in the amount of approximately \$1.0 million, which was primarily reinvested in cash equivalents. In the first six months of 2005 and 2004 cash was used for the purchase of fixed assets in the amount of \$245,200 and \$248,100, respectively, primarily representing leasehold improvements and tooling equipment for new products in 2005 and tooling and computer equipment in 2004.

Cash provided by financing activities was \$200,500 and \$10.3 million in the first six months of 2005 and 2004, respectively. The cash from financing activities in the first six months of 2004 was generated from the issuance of preferred stock in a private placement with net proceeds of \$10.6 million, offset by payments on long-term debt of \$207,300. Cash provided by financing activities in the first six months of 2005 represents the proceeds from the issuance of shares under our employee stock purchase plan and the exercise of stock options.

In connection with our property 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 \$1,860,000 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, or \$1,897,200. The lease expires in March 2009. The certificate of deposit is renewable in 30-day increments. This amount is classified as restricted cash in the balance sheet.

During the remainder of 2005, we will be continuing to expend funds in connection with our efforts to expand our sales and marketing for the NC-stat System, although more modestly than the expansion in the last several quarters, and continue our ongoing program of making enhancements and improvements to the NC-stat System, including the development of new and/or improved biosensors and the development of a third generation monitor and docking station. In connection with the development efforts on a third generation monitor and docking station, we expect to incur increased capital expenditures over the next two quarters for tooling costs. We also plan to expend funds on the design of a drug delivery system, which is in its early stages of development, for the minimally invasive delivery of therapeutic agents to treat neuropathies by both primary care and specialist physicians. We believe that the combination of funds available from cash and cash equivalents and funds available from our short-term investments and long-term investments will be adequate to finance our ongoing operations for at least twenty four months, including the expenditures described above.

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

#### *Off-Balance Sheet Arrangements*

As of June 30, 2005, we did not have any off-balance sheet financing arrangements.

#### *Recent Accounting Pronouncements*

In March 2005, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations*, which is an interpretation of Statement of Financial Accounting Standards ("SFAS") No. 143, *Accounting for Asset Retirement Obligations*. The interpretation requires a liability for the fair value of a conditional asset retirement obligation be recognized if the fair value of the liability can be reasonably estimated. The interpretation is effective in 2005. The interpretation is not expected to have a material impact on our results of operations or financial position.

In December 2004, the FASB issued SFAS No. 123(R), *Share-Based Payment* (SFAS 123(R)), which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*, and supersedes Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* and SFAS 148 *Accounting for Stock-Based Compensation — Transition and Disclosure*. This statement requires that the cost resulting from all share-based payment transactions be recognized in the financial statements. This statement establishes fair value as the measurement objective in accounting for share-based payment arrangements and requires all entities to apply a fair value based measurement method in accounting for share-based payment transactions with employees except for equity instruments held by employee share ownership plans. As a result, beginning January 1, 2006, the Company will adopt SFAS 123(R) and begin reflecting the stock compensation expense determined under fair value based methods in the income statement rather than as pro forma disclosure in the notes to the financial statements. The Company is currently reviewing the effect of this statement on its financial statements and expects there to be a material impact on the Company's results of operations.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Nonmonetary Assets* (SFAS 153), an amendment of APB Opinion No. 29, *Accounting for Nonmonetary Transactions*. SFAS 153 requires that exchanges of nonmonetary assets be measured based on the fair value of the assets exchanged. Further, it expands the exception for nonmonetary exchanges of similar productive assets to nonmonetary assets that do not have commercial substance. The provisions of this Statement are effective for nonmonetary asset exchanges beginning after June 15, 2005. The adoption of the provisions of SFAS 153 is not expected to have a material impact on the Company's financial position or results of operations.

In May 2005, the FASB issued SFAS 154 *Accounting for Changes and Error Correction, a Replacement of APB Opinion No. 20 and FASB Statement No. 3* (SFAS 154). SFAS 154 provides guidance on the accounting for and reporting of accounting changes and error corrections. It establishes, unless impracticable, retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. SFAS 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. The provisions of this Statement are effective for accounting changes and corrections of errors made in fiscal periods after December 15, 2005. The adoption of SFAS 154 is not expected to have a material impact on the Company's financial position or results of operations.

### **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, \$4.3 million for in 2004 and \$0.6 million for the six months ended June 30, 2005. At June



30, 2005, we had an accumulated deficit of approximately \$58.1 million. It is possible that we will never generate sufficient revenues from product sales to achieve profitability or to sustain profitability if achieved.

**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 or if certain changes are imposed on the professional requirements for performing nerve conduction studies and we may be required to expend substantial resources to address potential reimbursement issues with third-party payers. 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. Additionally, we may be required to expend substantial resources to address potential reimbursement issues with 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 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;

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- 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.

**We may not be able to accurately predict the size of the market for our NC-stat System.**

We may not be able to accurately predict the size of the market for products used to diagnose neuropathies, such as our NC-stat System. Neuropathies traditionally have been diagnosed by an NCS/nEMG procedure, performed by a neurologist or physician in a related specialty. We estimate that there are approximately two million traditional NCS/nEMG procedures performed each year in the United States; however, we anticipate that the advantages and increased availability of the NC-stat System will significantly increase the number of nerve conduction studies performed. Based on our analysis of current data, we estimate that the potential market size for the NC-stat System in the diabetes, low back pain and carpal tunnel syndrome markets in the aggregate could be as great as 9.5 million annual patient tests. This represents a more than four-fold increase in the size of the market for nerve conduction studies and is based upon a number of assumptions and estimates, which themselves may not be accurate. For example, we have assumed that all initial office visits for low back pain may represent an opportunity for use of the NC-stat System, and we have estimated that an annual testing rate of 33% for all individuals diagnosed with diabetes represents the potential addressable market in diabetes. Market size is difficult to predict, and we cannot assure you that our assumptions or estimates will prove to be correct. The industry and market data on which we have based our assumptions and estimates of future market size, which is described in our annual report on Form 10-K for the year ended December 31, 2004, may be inaccurate or incomplete, and we have not independently verified those data. If our estimate of the size of the market for our NC-stat System is incorrect, our potential revenue growth may be limited.

**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 are currently negotiating an agreement with Polyflex but there are no assurances that we will enter into such an agreement on favorable terms or at all. 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' 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 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 disposable biosensors, sales of which accounted for approximately 88.1% of our total revenues for the first six months of 2005 and 87.6% and 85.8% of our total revenues in 2004 and 2003, 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;
- 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 twelve 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 post-marketing regulatory requirements, including quality system regulations, which relate to the manufacturing of our products, labeling regulations and medical device reporting regulations. Our failure or either contract manufacturer's failure 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;
- 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.

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**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.

**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; W. Bradford Smith, Chief Financial Officer; and our other key employees. We maintain a \$5.0 million key person life insurance policy on Dr. Gozani, for which the Company is the beneficiary, but do not maintain 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 85 employees as of June 30, 2005, 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 have recently significantly increased our sales force and our total headcount. 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 and maintain our independent sales agent network, our revenues may decline, our future revenue growth may be limited and our expenses may increase.**

As of June 30, 2005, we employ 30 regional sales managers and utilize a network of over 450 independent sales agents. We are highly dependent on our regional sales managers and independent sales agents to generate our revenues. We have recently significantly increased our sales force and expect to further increase our sales force during 2005, although more modestly than the recent growth in the sales force. 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;
- 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., 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 and Medtronic, 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 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 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 together with our short-term and long-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 12 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.

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;
- 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.**

Based on most recent information, our officers, directors and principal stockholders together controlled a significant portion 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 shares of our common stock, comprised of shares issued upon conversion of our preferred stock 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. Immediately following our initial public offering, these stockholders held 7,488,758 shares of our common stock that had these registration rights. 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. 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.**

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 acquirers 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 our stockholders sole source of potential gain for the foreseeable future.

### **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 securities laws.

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

We do not use derivative financial instruments in our investment portfolio and have no foreign exchange contracts. Our financial instruments consist of cash, cash equivalents, short-term investments, accounts receivable, accounts payable, 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 long-term investments with a maturity of eighteen months or less and maintain an average maturity of twelve 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 Chief Financial Officer, 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 June 30, 2005. Based upon that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are 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 controls over 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 control 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.

## **Part II Other Information**

### **Item 1. Legal Proceedings**

None.

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

On July 21, 2004, the Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-115440), relating to the initial public offering of our common stock. We expect to continue to use the net proceeds from the initial public offering for general corporate purposes, including to expand our selling and marketing and services organizations, develop new distribution channels, expand our research and development efforts, improve our operational and financial systems and for other working capital purposes. We may also use a portion of the net proceeds to acquire or invest in complementary businesses, products or technologies. We have no specific understandings, commitments or agreements with respect to any such acquisition or investment. Except as set forth below, we have not allocated any portion of the net proceeds for any specific purpose. 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 June 30, 2005 we have used (i) \$3.1 million of the net proceeds to repay in full the outstanding balance under our secured line of credit with Lighthouse Capital Partners, (ii) an estimated \$2,707,100 of the net proceeds to fund cash spending of our research and development activities, (iii) an estimated \$3,144,200 of the net proceeds to fund the expansion of our sales and marketing efforts and (iv) an estimated \$287,000 for the purchase of capital equipment. 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 does not represent a material change from the description provided in our prospectus.

On June 13, 2005, we issued 63,707 shares of our common stock to Lighthouse Capital Partners IV, L.P. upon the conversion in full of a warrant to purchase up to 100,000 shares of our common stock at an exercise price of \$6.00 per share. The securities issued in the foregoing transaction 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, and Section 3(a)(9) of the Securities Act relating to exchanges of securities. No underwriters or placement agents were involved in the foregoing issuance.

## Item 3. Defaults Upon Senior Securities

None.

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

At the Annual Meeting of Stockholders held on May 18, 2005, our stockholders voted as follows:

(a) To elect one member of our Board of Directors to serve as a Class I Director until the 2008 Annual Meeting of Stockholders.

<u>Nominee</u>	<u>Vote "For"</u>	<u>Vote Withheld</u>
William J. Laverack, Jr.	11,691,932	110,700

There were no broker non-votes or abstentions with respect to this matter. The terms in office of David E. Goodman, M.D., Charles R. LaMantia and W. Mark Lortz continued after the annual meeting.

(b) To ratify the selection of PricewaterhouseCoopers LLP to serve as the Company's independent auditors for the year ending December 31, 2005.

<u>Vote "For"</u>	<u>Vote "Against"</u>	<u>Abstentions</u>	<u>Broker Non-Votes</u>
11,801,032	100	1,500	—

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## Item 5. Other Information

None.

## Item 6. Exhibits

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

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## SIGNATURES

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

NEUROMETRIX, INC.

Date: August 11, 2005

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

Date: August 11, 2005

/s/ W. Bradford Smith  
W. Bradford Smith  
Chief Financial Officer

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Exhibit Index

- \*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

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\* Filed herewith

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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 officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2005

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

**CERTIFICATION**

I, W. Bradford Smith, certify that:

1. I have reviewed this quarterly report on Form 10-Q of NeuroMetrix, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2005

/s/ W. Bradford Smith  
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W. Bradford Smith  
Chief Financial Officer

## 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: August 11, 2005

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

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

Chief Executive Officer and President

/s/ W. Bradford Smith

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W. Bradford Smith

Chief Financial Officer

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.